Review Criteria for Restricted Drugs
Prior Authorization Medications

1. **Benefits: For MPD**, see footer for note. This document/ criterion applies to the Commercial, Triple Tier, Self-Funded and Qualified Health Plans formularies. **For Dual Choice:** this document applies to Back Office Only medication requests.
2. Medical Benefited is reviewed by QRM; Pharmacy Benefited is reviewed by Pharmacy Consult Service. If a drug is not listed in the initial table, it does not require QRM review and does not need a referral. Read notes for guidance.
3. ****Certain Medications require an IR Consultative Panel Review: For initial requests, do not create a referral. QRM Reviewers will communicate directly with the National Emerging Therapeutics Strategy Program to initiate review - Emerging-Therapeutics-Strategy-Program@kp.org.**
4. Criteria apply to both BRAND and GENERIC formulations of the drug listed unless otherwise noted
5. **How to navigate this document: To locate criteria throughout the document, CTRL+click on the drug name in the Brand Name Column. Press (Ctrl + Home) to return to the top of the document. Press (Alt + Left Arrow) to go back to the prior view.**

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
Abecma® (Back Office ONLY)	Idecabtagene vicleucel	Medicare Part B			Medical-Benefited
Adakveo® (Back Office ONLY)	Crizanlizumab-tmca	Medicare Part B			Medical-Benefited
Adalimumab Products					
Abrilada™	Adalimumab- afzb	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited ****NOTE:** Amjevita (Adalimumab-atto) –No referral required.
Cyltezo®	Adalimumab-adbm		MPD: NF** Send to PCS		
Hadlima™	Adalimumab-bwwd		MPD: NF** Send to PCS		
Hulio®	Adalimumab-fkjp		MPD: NF** Send to PCS		
Humira/Humira Citrate Free®	Adalimumab		MPD: NF** Send to PCS	J0135	
Hyrimoz®	Adalimumab-adaz		MPD: NF** Send to PCS		
Idacio®	Adalimumab-aacf		MPD: NF** Send to PCS		
Simlandi®	Adalimumab-ryvk		MPD: NF** Send to PCS		
Unbranded adalimumab-aacf	Adalimumab-aacf		MPD: NF** Send to PCS		
Unbranded adalimumab-adaz	Adalimumab-adaz		MPD: NF** Send to PCS		
Unbranded adalimumab-adbm	Adalimumab-adbm		MPD: NF** Send to PCS		
Unbranded adalimumab-bwwd	Adalimumab-bwwd		MPD: NF** Send to PCS		
Unbranded adalimumab-fkjp	Adalimumab-fkjp		MPD: NF** Send to PCS		
Unbranded adalimumab-ryvk	Adalimumab-ryvk		MPD: NF** Send to PCS		
Yuflyma	Adalimumab-aaty		MPD: NF** Send to PCS		

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Adbry™	Tralokinumab-ldrm	Medicare Part D	MPD: F		Pharmacy-Benefited
Adempas®	Riociguat	Medicare Part D	MPD: F		Pharmacy-Benefited
Adstiladrin® (Back Office ONLY)	Nadofaragene firadenovec	Medicare Part B			Medical-Benefited **(Requires IR Consultative Panel Review)**
Afrezza®	Insulin (Oral Inhalation)	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
§Agamree®	Vamorolone	Medicare Part D	MPD: F		Pharmacy-Benefited
Akeega™	Niraparib-Abiraterone	Medicare Part D	MPD: F		Pharmacy-Benefited
Alhemo®	Concizumab-mtci	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Alkindi® Sprinkle	Hydrocortisone	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
§Altuviiio™	Antihemophilic Factor - Recombinant [Fc-VWF-XTEN Fusion Protein-ehtl]	Medicare Part B			Medical-Benefited
Alunbrig®	Brigatinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Alyftrek™	Vanzacaftor, Tezacaftor, and Deutivacaftor	Medicare Part D	MPD: F		Pharmacy-Benefited
Ampyra™	Dalfampridine	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Amtagvi™ (Back Office ONLY)	Lifileucel	Medicare Part B			Medical-Benefited
Amyloid Beta-directed Antibodies:					
Kisunla™ (Back Office ONLY)	Donanemab-azbt	Medicare Part B			Medical-Benefited **(Requires IR Consultative Panel Review)**
Leqembi/ Leqembi Iqlik (IV- Back Office ONLY)	Lecanemab-irmb	Medicare Part B (IV formulation)/ Medicare Part D (SQ formulation)	MPD: NF** Send to PCS		Medical-Benefited **(Requires IR Consultative Panel Review)**
Andembry	Garadacimab-gxii	Medicare Part D	MPD: F		Pharmacy-Benefited
Anktiva® (Back office ONLY)	Nogapendekin alfa inbakicept-pmln	Medicare Part B			Medical-Benefited
§Anzupgo®	Delgocitinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Apretude (Back office ONLY)	Cabotegravir	Medicare Part B			Medical-Benefited

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Agneursa™	Levacetylleucine	Medicare Part D	MPD: F		Pharmacy-Benefited
§Aqvesme™	Mitapivat	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Arcalyst™	Rilonacept powder for solution	Medicare Part D	MPD: F	J3490	Pharmacy-Benefited
Arikayce®	Amikacin liposome inhalation suspension	Medicare Part D	MPD: F		Pharmacy-Benefited
Aubagio®	Teriflunomide ****NOTE: Create referral only if request for brand name**	Medicare Part D	MPD: F (generic); MPD: NF** Send to PCS (brand name only is NF)		Pharmacy-Benefited
Augtyro™	Repotrecitinib	Medicare Part D	MPD: F		Pharmacy-Benefited
§Auvelity	Dextromethorphan/Bupropion	Medicare Part D	MPD: F		Pharmacy-Benefited
Avastin® Intravenous (Back office ONLY)	Bevacizumab	Medicare Part B			Medical-Benefited
§Avlayah	Tividenofusp alfa-eknm	Medicare Part B			Medical-Benefited
Avmapki-Fakzynja	Avutometinib-defactinib	Medicare Part D	MPD: F		Pharmacy-Benefited
§Awiqli	Insulin icodec-abae	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Ayvakit®	Avapritinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Bafiertam®	Monomethyl fumarate	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
§Balversa	Erdafitinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Benlysta (IV formulation-Back Office ONLY)	Belimumab	Medicare Part B or D	MPD: F (when dispensed at pharmacy)		**Medical Benefited**: IV formulation; **Pharmacy Benefited:** Other Formulations
Berinert®	Human C1 Inhibitor	Medicare Part B or D	MPD: F (when dispensed at pharmacy)		**Medical Benefited**: IV formulation; **Pharmacy Benefited:** Other Formulations
Besremi®	Ropeginterferon alfa-2b	Medicare Part B or D	MPD: F (when dispensed at pharmacy)		Pharmacy-Benefited

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Bimzelx®	Bimekizumab	Medicare Part D	MPD: F		Pharmacy-Benefited
§Bizengri®(Back office Only)	Zenocutuzumab	Medicare Part B			Medical-Benefited
Blenrep (Back office Only)	Belantamab mafodotin	Medicare Part B			Medical-Benefited
Bosulif®	Bosutinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Blujepa®	Gepotidacin Mesylate	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Botulinum Toxin: (Back Office)					
Botox® (P) (Back Office Only)	Botulinum Toxins Type A	Medicare Part B		J0585 (type A)	Medical-Benefited ****NOTE:** Botox and Daxxify are floor stock for Neurology and Ophthalmology. QRM review is not required for migraine, blepharospasm, or hemifacial spasm indications. Patients should be referred to Neurology for migraine indications or Ophthalmology for blepharospasm or hemifacial spasm indications.
	Botulinum Toxins Type B			J0587 (type B)	
Daxxify®(N) (Back Office Only)	DaxibotulinumtoxinA	Medicare Part B			
Dysport™ (N) (Back Office Only)	Botulinum Toxins Type A	Medicare Part B		J0586	
Myobloc® (N) (Back Office Only)	Botulinum Toxins Type B	Medicare Part B			
Xeomin® (N) (Back Office Only)	Botulinum Toxins Type A	Medicare Part B			
Braftovi®	Encorafenib	Medicare Part D	MPD: F		Pharmacy-Benefited
Brexafemme®	Ibrexafungerp	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Brinsupri	Brensocatib	Medicare Part D	MPD: F		Pharmacy-Benefited
§Briumvi™ (Back Office Only)	Ublituximab-xiiy	Medicare Part B			Medical-Benefited
Bronchitol®	Mannitol inhalation powder	Medicare Part B or D	MPD: F (when dispensed at pharmacy)		Pharmacy-Benefited
Bylvay™	Odevixibat	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited

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§Bysanti	Milsaperidone	Medicare Part D	MPD: F		Pharmacy-Benefited
Cabenuva (Back Office ONLY)	Cabotegravir and rilpivirine	Medicare Part B			Medical-Benefited
Cablivi®	Caplacizumab-yhdp	Medicare Part B or D	MPD: F (when dispensed at pharmacy)		**Medical Benefited**: IV administration; **Pharmacy Benefited:** SQ Administration
Cerdelga™	Eliglustat	Medicare Part D	MPD: F		Pharmacy-Benefited
Calcitonin gene-related peptide (CGRP Inhibitors):					
Aimovig™ (N)	Erenumab-aooe	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Emgality® (N)	Galcanezumab-gnlm	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Vyepti™ (N) (Back Office ONLY)	Eptinezumab-jjmr	Medicare Part B		J3032	Medical-Benefited
Calquence®	Acalabrutinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Camzyos™	Mavacamten	Medicare Part D	MPD: NF** Send to PCS		Medical-Benefited **(Requires IR Consultative Panel Review)**
CAR-T Therapy: (Back Office ONLY)					
Aucatzyl® Breyanzi® Carvykti® Kymriah® Yescarta®	Obecabtagene autoleucel Lisocabtagene maraleucel Ciltacabtagene autoleucel Tisagenlecleucel Axicabtagene ciloleucel	Medicare Part B			Medical-Benefited
Cayston®	Aztreonam	Medicare Part D	MPD: F		Pharmacy-Benefited
CeQur Simplicity™	Insulin patch	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Ctexli	Chenodiol	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Cholbam®	Cholic acid	Medicare Part D	MPD: F		Pharmacy-Benefited
Cibinqo™	Abrocitinib	Medicare Part D	MPD: F (100mg)/ MPD: NF** Send to PCS (50mg and 200mg)		Pharmacy-Benefited
Cimzia®	Certolizumab pegol	Medicare Part D	MPD: NF** Send to PCS	J0717	Pharmacy-Benefited
Cinqair® (Back Office ONLY)	Reslizumab	Medicare Part B			Medical-Benefited

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Cobenfy™	Xanomeline and Trospium	Medicare Part D	MPD: F		Pharmacy-Benefited
Columvi	Glofitamab-gxbm	Medicare Part B			Medical-Benefited
Cometriq®	Cabozantinib **NOTE: Do not create referral for Cabometyx	Medicare Part D	MPD: F		Pharmacy-Benefited
Contrave®	Naltrexone and Bupropion	Not covered under Medicare Part D			Pharmacy-Benefited
Copaxone®	Glatiramer acetate	Medicare Part D	MPD: NF** Send to PCS	J1595	Pharmacy-Benefited
Copiktra®	Duvelisib	Medicare Part D	MPD: F		Pharmacy-Benefited
Corticotropin Gel					
Acthar® (IV Administration Back Office ONLY)	Repository corticotropin	Medicare Part D	MPD: NF** Send to PCS	J0800	**Medical Benefited**: IV administration; **Pharmacy Benefited:** SQ Administration
Cortrophin™	Repository corticotropin	Medicare Part D	MPD: F		Pharmacy-Benefited
Cosentyx® (IV Formulation Back Office ONLY)	Secukinumab	Medicare Part B or D	MPD: F (when dispensed at pharmacy)		**Medical Benefited**: IV administration; **Pharmacy Benefited:** SQ Administration
Crenessity™	Crinecerfont	Medicare Part D	MPD: F		Pharmacy-Benefited
Cresemba® (IV Formulation Back Office ONLY)	Isavuconazonium sulfate	Medicare Part B or D	MPD: F (when dispensed at pharmacy)		**Medical Benefited**: IV formulation; **Pharmacy Benefited:** Other Formulations
Crysvita® (Back Office ONLY)	Burosumab-twza	Medicare Part B			Medical-Benefited
§Cuvrior	Trientine	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Danyelza™(Back Office Only)	Naxitamab-gqgk	Medicare Part B			Medical-Benefited
Daraprim®	Pyrimethamine	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Darzalex Faspro™ (Back Office ONLY)	Daratumumab and hyaluronidase-fihj	Medicare Part B			Medical-Benefited

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Datroway	Datopotamab Deruxtecan	Medicare Part D	MPD: F		Medical-Benefited
Daurismo™	Glasdegib	Medicare Part D	MPD: F		Pharmacy-Benefited
Dawnzera™	Donidalorsen	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Daybue™ Daybue Stix	Trofinetide	Medicare Part D	MPD: F (Daybue)/ MPD: NF** Send to PCS (Daybue Stix)		Pharmacy-Benefited
Demser	Metyrosine	Medicare Part D	MPD: F		Pharmacy-Benefited
Denosumab 60 mg Products (Back Office Only)					
Stoboclo® (P) §Bildyos® §Bosaya §Enoby Jubbonti® Ospomyv™ §Osvyrti Prolia®	Denosumab-bmwo Denosumab-nxxp Denosumab-kyqq Denosumab-qbde Denosumab-bddz Denosumab-dssb Denosumab-desu Denosumab	Medicare Part B		J3590	Medical-Benefited
Denosumab 120 mg Products (Back Office Only)					
Osenvelt® (P) §Aukelso §Bilprevda® Bomyntra® §Jubereq Wyost® Xbryk™ Xgeva® §Xtrenbo	Denosumab-bwmo Denosumab-kyqq Denosumab-nxxp Denosumab-bnht Denosumab-desu Denosumab-bbdz Denosumab-dssb Denosumab Denosumab-qbde	Medicare Part B			Medical-Benefited
Desoxyn®	Methamphetamine	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Diacomit®	Stiripentol	Medicare Part D	MPD: F		Pharmacy-Benefited
Dipeptidyl peptidase 4 (DPP-IV) inhibitors*:					
Zituvio™	**Sitagliptin (P)**	Medicare Part D	MPD: NF** Send to PCS (brand)/ MPD: F (generic)	Pharmacy-Benefited	
Zituvimet	**Sitagliptin and metformin (P)**	Medicare Part D	MPD: NF** Send to PCS		
Glyxambi™	Linagliptin and Empagliflozin	Medicare Part D	MPD: NF** Send to PCS		
Januvia™	Sitagliptin	Medicare Part D	MPD: F		

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Janumet™/Janumet™ XR	Sitagliptin and metformin	Medicare Part D	MPD: NF** Send to PCS		
Jentadueto™	Linagliptin and metformin	Medicare Part D	MPD: NF** Send to PCS		
Jentadueto® XR	Linagliptin and metformin	Medicare Part D	MPD: NF** Send to PCS		
Kazano™	Alogliptin and metformin	Medicare Part D	MPD: NF** Send to PCS		
Kombiglyze™ XR	Saxagliptin and metformin ER	Medicare Part D	MPD: NF** Send to PCS		
Nesina™	Alogliptin	Medicare Part D	MPD: NF** Send to PCS		
Onglyza™	Saxagliptin	Medicare Part D	MPD: NF** Send to PCS		
Oseni™	Alogliptin and pioglitazone	Medicare Part D	MPD: NF** Send to PCS		
Qtern®	Saxagliptin and dapagliflozin	Medicare Part D	MPD: NF** Send to PCS		
Steglujan™	Sitagliptin and ertugliflozin	Medicare Part D	MPD: NF** Send to PCS		
Tradjenta	Linagliptin	Medicare Part D	MPD: NF** Send to PCS		
Trijardy® XR	Empagliflozin, linagliptin, and metformin	Medicare Part D	MPD: NF** Send to PCS		
Zituvimet XR	Sitagliptin and metformin	Medicare Part D	MPD: NF** Send to PCS		
Dojolvi®	Triheptanoin	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Doptelet	Avatrombopag	Medicare Part D	MPD: F		Pharmacy-Benefited
Dupixent®	Dupilumab	Medicare Part D	MPD: F		Pharmacy-Benefited
Duvyzat™	Givinostat	Medicare Part D	MPD: F		Pharmacy-Benefited
Ebglyss™	Lebrikizumab-lbkz	Medicare Part D	MPD: F		Pharmacy-Benefited
Eculizumab Products (Back Office Only)					
Epysqli (P) Bkemv® Soliris®	Eculizumab-aagh Eculizumab-aeeb Eculizumab	Medicare Part B			Medical-Benefited
Egrifta SV §Egrifta WR™	Tesamorelin	Medicare Part D	MPD: F		Pharmacy-Benefited
Ekterly	Sebetralstat	Medicare Part D	MPD: F		Pharmacy-Benefited
Elevidys™ (Back Office ONLY)	Delandistrogene Moxeparvovec	Medicare Part B			Medical-Benefited

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Elfabrio® (Back Office ONLY)	Pegunigalsidase alfa	Medicare Part B			Medical-Benefited
Elmiron®	Pentosan polysulfate sodium	Medicare Part D	MPD: F		Pharmacy-Benefited
Eloctate® (Back Office ONLY)	Antihemophilic Factor (Recombinant)	Medicare Part B		J7205	Medical-Benefited
Elrexfio (Back Office Only)	Elranatamab-bcmm	Medicare Part B		J1323	Medical-Benefited
Emflaza®	Deflazacort	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Empaveli™	Pegcetacoplan	Medicare Part B or D	MPD: NF** Send to PCS		Pharmacy-Benefited
Emsam®	Selegiline	Medicare Part D	MPD: F		Pharmacy-Benefited
Enbrel®	Etanercept	Medicare Part D	MPD: F	J1438	Pharmacy-Benefited
Encelto	Revakinagene taroretcel	Medicare Part B			Medical-Benefited
Endari™	L-Glutamine	Medicare Part D	MPD: F		Pharmacy-Benefited
Endothelin Receptor Antagonists for IgA Nephropathy					
Filspari	Sparsentan	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Vanrafia	Atrasentan	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Ensacove	Ensartinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Enspryng™	Satralizumab-mwge	Medicare Part B or D	MPD: NF** Send to PCS		Pharmacy-Benefited
Enstilar®	Calcipotriene and betamethasone dipropionate	Medicare Part D	MPD: F		Pharmacy-Benefited
Entyvio® (IV Formulation Back Office ONLY)	Vedolizumab	Medicare Part B or D	MPD: F (Pen formulation)	J3380	**Medical Benefited**: IV formulation; **Pharmacy Benefited:** Other Formulations
Enzyme replacement therapy: (Back Office ONLY)					
Elelyso®(P) Cerezyme® (N) Vpriv® (N)	Taliglucerase alfa Imiglucerase Velaglucerase alfa	Medicare Part B			Medical-Benefited
§Eohilia™	Budesonide	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Epclusa®	Sofosbuvir and velpatasvir	Medicare Part D	MPD: F		Pharmacy-Benefited

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Epidiolex®	Cannabidiol	Medicare Part D	MPD: F		Pharmacy-Benefited
Epkinly®	Epcoritamab-bysp	Medicare Part D	MPD: F		Pharmacy-Benefited
Erivedge®	Vismodegib	Medicare Part D	MPD: F		Pharmacy-Benefited
Erleada®	Apalutamide	Medicare Part D	MPD: F		Pharmacy-Benefited
Eucrisa®	Crisaborole	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Evenity® (Back office only)	Romosozumab-aqqg	Medicare Part B			Medical-Benefited
Evkeeza®	Evinacumab	Medicare Part B			Medical-Benefited
Evrysdi™	Risdiplam	Medicare Part D	MPD: F		Medical-Benefited **(Requires IR Consultative Panel Review)**
§Exdensur	Depemokimab-ulaa	Medicare Part B			Medical-Benefited
Exon Skipping Therapies (Back Office ONLY)					
Amondys 45™ Exondys 51® Viltepso® Vyondys 53	Casimersen Eteplirsen Viltolarsen Golodirsen	Medicare Part B			Medical-Benefited
Exxua	Gepirone	Medicare Part D	MPD: F		Pharmacy-Benefited
Fabhalta®	Iptacopan	Medicare Part D	MPD: F		Pharmacy-Benefited
Fabrazyme® (Back Office ONLY)	Agalsidase beta	Medicare Part B			Medical-Benefited
Fasenra®	Benralizumab	Medicare Part B or D	MPD: F (30 mg/ml Syringe & 30mg/ml Pen Only)	J0517	Pharmacy-Benefited
Ferriprox®	Deferiprone	Medicare Part D	MPD: F (generic 500 mg and 1000 mg tablets) MPD: NF** Send to PCS (Brand)		Pharmacy-Benefited ****NOTE:** The generic 1000mg is F (no referral needed). The 500mg tablet, solution & Ferriprox Twice A Day 1000mg need a referral.
§Filspari (FSGS Indication)	Sparsentan	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited

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Filsuvez®	Birch triterpenes	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Fintepla®	Fenfluramine	Medicare Part D	MPD: F		Pharmacy-Benefited
Firazyr® (N)	Icatibant	Medicare Part D	MPD: F (generic) MPD: NF** Send to PCS (brand)		Pharmacy-Benefited
Firdapse®	Amifampridine phosphate	Medicare Part D	MPD: F		Pharmacy-Benefited
Fotivda®	Tivozanib	Medicare Part D	MPD: F		Pharmacy-Benefited
Fruzaqla	Fruquintinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Galafold™	Migalastat	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Gattex® (N)	Teduglutide	Medicare Part D	MPD: F		Pharmacy-Benefited
§Gazyva (Back Office ONLY)	Obinutuzmab	Medicare Part B			Medical-Benefited
Gilenya™ (N)	Fingolimod	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Gilotrif®	Afatinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Givlaari™ (Back Office ONLY)	Givosiran	Medicare Part B			Medical-Benefited
Gleevec®	Imatinib mesylate	Medicare Part D	MPD: F (generic) MPD: NF** Send to PCS (brand)		Pharmacy-Benefited
Glimepiride 3 mg	Glimepiride 3mg only	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
GLP-1 Receptor Agonists* (Cardiovascular Indication):					
Wegovy™ (Oral and subcutaneous formulations)	Semaglutide	Medicare Part D	MPD: F (auto-injector) MPD: NF** Send to PCS (tablets and **HD** auto-injector)		Pharmacy-Benefited
Ozempic (Subcutaneous formulation)			MPD: F		
GLP-1 Receptor Agonists* (Metabolic Dysfunction-Associated Steatohepatitis (MASH), formerly termed Nonalcoholic Steatohepatitis (NASH)):					
Wegovy™ (Oral and subcutaneous formulations)	Semaglutide	Medicare Part D	MPD: F (auto-injector) MPD: NF** Send to PCS		Pharmacy-Benefited

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
			(tablets and **HD** auto-injector)		
Ozempic (Subcutaneous formulation)			MPD: F		
GLP-1 Receptor Agonists* (Weight Loss Treatments):					
Wegovy™ (Oral and subcutaneous formulations) Foundayo Saxenda® Ozempic (subcutaneous formulation)	Semaglutide Orforglipron Liraglutide Semaglutide	Not covered under Medicare Part D			Pharmacy-Benefited
GLP-1 Receptor Agonists* (Diabetes Indication):					
Ozempic® (P)	Semaglutide	Medicare Part D	MPD: F (SQ formulation) MPD: NF** Send to PCS (oral tablets)		Pharmacy-Benefited
Rybelsus® (P)	Semaglutide	Medicare Part D	MPD: NF** Send to PCS		
Soliqua® (N)	Insulin glargine/lixisenatide	Medicare Part D	MPD: NF** Send to PCS		
Trulicity® (N)	Dulaglutide	Medicare Part D	MPD: NF** Send to PCS		
Victoza®	**Liraglutide (P)**	Medicare Part D	MPD: F (generic)/ MPD: NF** Send to PCS (brand)		
Xultophy® (N)	Insulin degludec/liraglutide	Medicare Part D	MPD: NF** Send to PCS		
Gomekli™	Mirdametinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Growth Hormones:					
Omnitrope® (P)	Somatropin (growth hormone) injectable	Medicare Part D	MPD: F (generic)/ MPD: NF** Send to PCS (brand)	J2941	Pharmacy-Benefited
Genotropin® (N)		Medicare Part D	MPD: NF** Send to PCS		
Humatrope® (N)		Medicare Part D	MPD: F (6 mg cartridge only)		
Norditropin® (N)		Medicare Part D	MPD: F (5, 10,15 mg pens only)		
Nutropin AQ (N)		Medicare Part D	MPD: NF** Send to PCS		

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
Serostim® (N)		Medicare Part D	MPD: NF** Send to PCS		
Ngenla™	Somatrogon-ghla	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Sogroya®	Somapacitan-beco	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Skytrofa®	Lonapegsomatropin	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Harvoni®	Ledipasvir and sofosbuvir	Medicare Part D	MPD: F		Pharmacy-Benefited
§Hemgenix®	Etranacogene dezaparvovec-drlb	Medicare Part B			Medical-Benefited **(Requires IR Consultative Panel Review)**
Hemlibra®	Emicizumab-kxwh	Medicare Part B or D	MPD: NF** Send to PCS		Pharmacy-Benefited **HOG will ask for back office. This is pharmacy benefit only.
§Hepcludex	Bulevirtide-gmod	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Hereditary Transthyretin-Mediated Amyloidosis – Polyneuropathy (hATTR-PN) Therapies					
Amvuttra™ (P) (Back Office ONLY)	Vutrisiran	Medicare Part B			Medical-Benefited
Onpattro™ (Back Office ONLY)	Patisiran	Medicare Part B			Medical-Benefited
Wainua™	Eplontersen	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
§Hernexeos®	Zongertinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Hetlioz®	Tasimelteon	Medicare Part D	F (generic)/ MPD: NF** Send to PCS (brand)		Pharmacy-Benefited
Human C1 Esterase Inhibitors:					
Haegarda®(P)	Human C1 esterase inhibitor	Medicare Part B or D	MPD: F (when dispensed at pharmacy)		Pharmacy-Benefited
Cinryze®		Medicare Part B or D	MPD: F (when dispensed at pharmacy)		
Hyaluronic Acid Derivatives (viscosupplements): (Back Office ONLY)					
Durolane® (P)	Hyaluronic acid injections	Medicare Part B			Medical-Benefited
Supartz® (2nd Line)				J7321	
Gelsyn-3™ (3rd Line)					
Euflexxa® (N)				J7323	
Gel-One® (N)					

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
Hyalgan® (N)					
Hymovis (N)					
Hymovis-One (N)					
Orthovisc® (N)					
Synvisc® (N)				J7325	
Synvisc-One® (N)					
Synojoynt (N)					
Visco-3 (N)					
Triluron (N)					
Trivisc (N)					
Hyftor	Sirolimus	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
§Hympavzi	Marstacimab-hncq	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
§Ibrance	Palbociclib	Medicare Part D	MPD: F		Pharmacy-Benefited
Ibsrela®	Tenapanor	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Ibtrozi	Taletrectinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Iclusig®	Ponatinib	Medicare Part D	MPD: F		Pharmacy-Benefited
§Icotyde	Icotrokinra	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Idhifa	Enasidenib	Medicare Part D	MPD: F		Pharmacy-Benefited
§Idvynso	Doravirine and Islatravir	Medicare Part D	MPD: F		Pharmacy-Benefited
Ilaris® (Back office Only)	Canakinumab	Medicare Part B			Medical-Benefited
Ilumya™ (Back office Only)	Tidrakizumab	Medicare Part B		J3245	Medical Benefited
Imbruvica®	Ibrutinib	Medicare Part D	MPD: F / MPD: NF** Send to PCS (560 mg only)		Pharmacy-Benefited
Imcivree™	Setmelanotide	This drug is not covered under Medicare Part D**			Pharmacy-Benefited

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
Imdelltra™ (Back office Only)	Tarlatamab-dlle	Medicare Part B			Medical-Benefited
§Imlygic® (Back office only)	Talimogene laherparepvec	Medicare Part B			Medical-Benefited
Immune Globulin Intravenous (IVIG): (Back Office)					
Alyglo™	Immune globulin, human-stwk	Medicare Part B			Medical-Benefited ****NOTE: Gammagard Liquid IV** (no referral needed).
Asceniv	Immune globulin, human-slra				
Bivigam	Immune globulin, human				
Gammagard S/D	Immune globulin, human				
Gammaked	Immune globulin, human				
Gammaplex	Immune globulin, human				
Octagam	Immune globulin, human				
Privigen	Immune globulin, human				
Panzyga	Immune globulin, human-ifas				
§Qivigy	Immune globulin, human-kthm				
Yimmugo	Immune globulin, human-dira				
Immune Globulin Subcutaneous: (Initial Dose - Back Office)					
Cutaquig®	Immune globulin	Medicare Part B or D	MPD: NF** Send to PCS		**Medical Benefited**: Administered Back Office; **Pharmacy Benefited:** Dispensed at Pharmacy
Cuvitru®		Medicare Part B or D	MPD: NF** Send to PCS		
Hizentra®		Medicare Part B or D	MPD: NF** Send to PCS		
Hyqvia®		Medicare Part B or D	MPD: F (when dispensed at pharmacy)		
Xembify®		Medicare Part B or D	MPD: NF** Send to PCS		
Impavido®	Miltefosine	Medicare Part D	MPD: F		Pharmacy-Benefited
Inbrija®	Levodopa (oral inhalation)	Medicare Part D	MPD: F		Pharmacy-Benefited
Infliximab (Back Office ONLY): ****Note:** Inflectra (Infliximab-DYYB infusion) –No referral required.					
Avsola®	Infliximab-axxq	Medicare Part B			Medical-Benefited
Infliximab (unbranded)	Infliximab	Medicare Part B			
Renflexis	Infliximab-abda	Medicare Part B			
Remicade (branded)	Infliximab	Medicare Part B		J1745	
§Zymfentra	Infliximab-DYYB auto-injector& pre-filled syringe	Medicare Part D	MPD: F		Pharmacy-Benefited
Ingrezza®	Valbenazine	Medicare Part D	MPD: F / MPD: NF** Send to PCS (capsule sprinkle formulation only)		Pharmacy-Benefited

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
Inluriyo	Imlunestrant	Medicare Part D	MPD: F		Pharmacy-Benefited
Inlyta®	Axitinib	Medicare Part D	MPD: F		Pharmacy-Benefited
InPen™	Smart Insulin Pen	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
§Inqovi	Decitabine and cedazuridine	Medicare Part D	MPD: F		Pharmacy-Benefited
Inrebic®	Fedratinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Insulin Human:					
Novolin® 70/30 Novolin® N Novolin® R	Insulin isophane and regular Insulin isophane Insulin regular	Medicare Part D	MPD: F (Novolin R FlexPen); MPD: NF** Send to PCS: All others		Pharmacy-Benefited
Interferons:					
Avonex® Betaseron® Plegridy® **Rebif®**	Interferon beta-1a Interferon beta-1b Peginterferon beta-1a Interferon beta-1a	Medicare Part D	MPD: F	J1826	Pharmacy-Benefited
			MPD: F		
			MPD: NF** Send to PCS		
			MPD: F / MPD: NF** Send to PCS (22 and 44 mcg syringes)		
Iqirvo®	Elafibranor	Medicare Part D	MPD: F		Pharmacy-Benefited
Isturisa®	Osilodrostat	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Itovebi™	Inavolisib	Medicare Part D	MPD: F		Pharmacy-Benefited
Jadenu® (N) Exjade® (N)	Deferasirox **NOTE: Create referral only if request for brand name	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Jascayd	Nerandomilast	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Jaypirca™	Pirtobrutinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Jelmyto® (Back Office ONLY)	Mitomycin	Medicare Part B			Medical-Benefited
Joenja®	Leniolisib	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Journavx™	Suzetrigine	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
Jublia®	Efinaconazole	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Juxtapid™	Lomitapide	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Jynarque®	Tolvaptan	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Kalbitor® (Back Office ONLY)	Ecallantide	Medicare Part B			Medical-Benefited
Kalydeco™	Ivacaftor	Medicare Part D	MPD: F		Pharmacy-Benefited
Kebilidi (Back office Only)	Eladocagene exuparvovec	Medicare Part B			Medical-Benefited **(Requires IR Consultative Panel Review)**
Kerendia®	Finerenone	Medicare Part D	MPD: F		Pharmacy-Benefited
Kerydin®	Tavaborole	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Kesimpta®	Ofatumumab	Medicare Part D	MPD: F		Pharmacy-Benefited
Keveyis®	Dichlorphenamide	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Kevzara®	Sarilumab	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
§Khindivi®	Hydrocortisone	Medicare Part D	MPD: F		Pharmacy-Benefited
Kimmtrak® (Back Office ONLY)	Tebentafusp-tebn	Medicare Part B			Medical-Benefited
Korlym™	Mifepristone	Medicare Part D	MPD: F		Pharmacy-Benefited
Komzifti	Ziftomenib	Medicare Part D	MPD: F		Pharmacy-Benefited
Koselugo™	Selumetinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Krazati®	Adagrasib	Medicare Part D	MPD: F		Pharmacy-Benefited
Krystexxa® (Back Office ONLY)	Pegloticase	Medicare Part B			Medical-Benefited
Kuvan™	Sapropterin	Medicare Part D	MPD: NF** Send to PCS	J3490	Pharmacy-Benefited
§Kygevvi	Doxecitine and doxribtimine	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Lamzede® (Back Office ONLY)	Velmanase alfa-tycv	Medicare Part B			Medical-Benefited
Lantidra™ (Back Office ONLY)	Donislecel	Medicare Part B			Medical-Benefited
Lazcluze™	Lazertinib	Medicare Part D	MPD: F		Pharmacy-Benefited

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
Lemtrada® (Back Office ONLY)	Alemtuzumab	Medicare Part B			Medical-Benefited
Lenacapavir					
Sunlenca® Yeztugo®	Lenacapavir	Medicare Part B (injection) or D (tabs)	MPD: F (Sunlenca); MPD: NF** Send to PCS (Yeztugo)	J1961	**Medical Benefited**: SQ injection; **Pharmacy Benefited:** tablet
§Lenmeldy™ (Back Office ONLY)	Atidarsagene autotemcel	Medicare Part B			Medical-Benefited **(Requires IR Consultative Panel Review)**
Leqvio (Back Office ONLY)	Inclisiran	Medicare Part B			Medical-Benefited
Lerochol	Lerodalcibep-liga	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Leuprolide Products:					
Fensolvi® (Back Office ONLY)	Leuprolide acetate	Medicare Part B			Medical-Benefited
Lupron Depot-Ped® (Back Office ONLY)	Leuprolide acetate	Medicare Part B			Medical-Benefited
§Lifyorli	Relacorilant	Medicare Part D	MPD: F		Pharmacy-Benefited
§Lipfendra	Enlicitide	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Litfulo™	Ritlecitinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Livdelzi®	Seladelpar	Medicare Part D	MPD: F		Pharmacy-Benefited
Livmarli™	Maralixibat	Medicare Part D	MPD: F (Tabs); MPD: NF** Send to PCS (Solution)		Pharmacy-Benefited
Livtencity™	Maribavir	Medicare Part D	MPD: F		Pharmacy-Benefited
§Loargys	Pegzilarginase-nbln	Medicare Part B			Medical-Benefited
Lodoco®	Colchicine	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Loqtorzi™(Back Office ONLY)	Toripalimab-tpzi	Medicare Part B			Medical-Benefited
Lorbrena®	Lorlatinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Lumakras™	Sotarasib	Medicare Part D	MPD: F		Pharmacy-Benefited
§Lumryz™	Sodium Oxybate	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
Lunsumio (Back Office ONLY) Lunsumio Velo (Back Office ONLY)	Mosunetuzumab-axgb	Medicare Part B			Medical-Benefited
Lupkynis™	Voclosporin	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Luxturna (Back Office ONLY)	Voretigene neparvovec-rzyl	Medicare Part B			Medical-Benefited **(Requires IR Consultative Panel Review)**
§Lynavoy	Linerixibat	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Lynkuet®	Elinzanetant	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Lynozyfic (Back office Only)	Linvoseltamab-gcpt	Medicare Part B			Medical-Benefited
Lytgobi®	Futibatinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Mavenclad®	Cladribine	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Mavyret™	Glaceprevir and pibrentasvir	Medicare Part D	MPD: F		Pharmacy-Benefited
Mayzent®	Siponimod	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Mektovi®	Binimetinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Metformin ER Formulations:					
Fortamet® (P) (generic)	Metformin ER Tablet **Extended Release 24 Hour ONLY**	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Glumetza®		Medicare Part D	MPD: NF** Send to PCS		
Miplyffa™	Arimoclomol	Medicare Part D	MPD: F		Pharmacy-Benefited
Mirvaso® Gel	Brimonidine	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
§Modeyso™	Dordaviprone	Medicare Part D	MPD: F		Pharmacy-Benefited
Monjuvi® (Back Office ONLY)	Tafasitamab-cxix	Medicare Part B			Medical-Benefited
Mulpleta®	Lusutrombopag	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Myalept®	Metreleptin	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Mycapssa®	Octreotide acetate	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Myfembree®	Relugolix, estradiol, and norethindrone acetate	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
§Myqorzo	Aficamten	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
Mytesi®	Crofelemer	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Neffy®	Epinephrine	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Nemluvio®	Nemolizumab	Medicare Part D	MPD: F		Pharmacy-Benefited
Nerlynx®	Neratinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Neupogen®	Filgrastim ****NOTE: Create referral only if request for brand name Neupogen**	Medicare Part B or Medicare Part D	MPD: F (Granix, Zarxio, Nivestym); MPD: NF** (Neupogen) Send to PCS if obtaining via pharmacy benefit		**Medical Benefited:** Administered Back Office **Pharmacy-Benefited:** Dispensed at Pharmacy
Nexletol ®	Bempedoic acid	Medicare Part D	MPD: F		Pharmacy-Benefited
Nexlizet™	Bempedoic acid and ezetimibe	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Niktimvo™ (Back Office ONLY)	Axatilimab-csfr	Medicare Part B			Medical-Benefited
Nitrofurantoin	Nitrofurantoin (oral suspension)	Medicare Part D	MPD: F		Pharmacy-Benefited
Northera®	Droxidopa ****NOTE: Create referral only if request for brand name**	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Noxafil®	Posaconazole	Medicare Part D	MPD: F (generic); MPD: NF** Send to PCS (brand)		Pharmacy-Benefited
Nubeqa™	Darolutamide	Medicare Part D	MPD: F		Pharmacy-Benefited
Nucala® (*Vial Formulation - Back Office Only)	Mepolizumab	Medicare Part B *(SQ solution/vial formulation only)*	MPD: F *(pre-filled syringe and autoinjector formulations only)*	J2182	**Medical Benefited**: SQ solution/ vial; **Pharmacy Benefited:** Pre-filled syringe and autoinjector
Nuedexta®	Dextromethorphan/Quinidine	Medicare Part D	MPD: F		Pharmacy-Benefited
Nulibry® (Back office only)	Fosdenopterin	Medicare Part B			Medical-Benefited
Nuplazid®	Pimavanserin	Medicare Part D	MPD: F		Pharmacy-Benefited

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
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Nurtec ODT™	Rimegepant	Medicare Part D	MPD: F		Pharmacy-Benefited
§Ocrevus™ (Back Office ONLY) §Ocrevus Zunovo™ (Back Office ONLY)	Ocrelizumab	Medicare Part B		J2350	Medical-Benefited
Odomzo®	Sonidegib	Medicare Part D	MPD: F		Pharmacy-Benefited
Ogsiveo	Nirogacestat	Medicare Part D	MPD: F		Pharmacy-Benefited
Ojemda™	Tovorafenib	Medicare Part D	MPD: F		Pharmacy-Benefited
Ohtuvayre™	Ensifentrine	Medicare Part D	MPD: F		Pharmacy-Benefited
Ojjaara™	Momelotnib dihydrochloride	Medicare Part D	MPD: F		Pharmacy-Benefited
Olumiant®	Baricitinib	Medicare Part D	MPD: F (1MG & 2MG) MPD: NF** Send to PCS (4MG)		Pharmacy-Benefited
Omnipod 5 System and Pods	System and Pods	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited (If requesting kit and pods separate referrals are needed)
Omnipod™ DASH Intro Kit and Pods	Intro Kit and Pods	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited (If requesting kit and pods separate referrals are needed)
Omvoh™ (IV- Back Office Only)	Mirikizumab	Medicare Part B or D	MPD: NF** Send to PCS		**Medical Benefited**: IV formulation; **Pharmacy Benefited:** Other Formulations
Onexton	Clindamycin/Benzoyl peroxide	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Onureg®	Azacitidine	Medicare Part D	MPD: F		Pharmacy-Benefited
Opdualag™ (Back Office ONLY)	Nivolumab and relatlimab-rmbw	Medicare Part B			Medical-Benefited
§Opfolda™	Miglustat	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
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§Opsynvi®	Macitentan and tadalafil	Medicare Part D	MPD: F		Pharmacy-Benefited
Opzelura™	Ruxolitinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Orfadin®	Nitisinone	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Orgovyx™	Relugolix	Medicare Part D	MPD: F		Pharmacy-Benefited
Oriahnn™	Elagolix, estradiol, and norethindrone acetate; elagolix	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Orilissa®	Elagolix	Medicare Part D	MPD: F		Pharmacy-Benefited
Orkambi®	Lumacaftor and ivacaftor	Medicare Part D	MPD: F		Pharmacy-Benefited
§Orladeyo™	Berotralstat	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Orlynvah™	Sulopenem etzadroxil-probenecid	Medicare Part D	MPD: F		Pharmacy-Benefited
Orserdu™	Elacestrant	Medicare Part D	MPD: F		Pharmacy-Benefited
Ortikos®	Budesonide	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
§Otarmeni	Lunsotogene parvec-cwha	Medicare Part B			Medical-Benefited
Otezla®	Apremilast	Medicare Part D	MPD: F / MPD: NF** Send to PCS (Extended-Release Formulations only)		Pharmacy-Benefited
Oxervate™	Cenegermin-bkbj	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Oxlumo® (Back Office ONLY)	Lumasiran	Medicare Part B			Medical-Benefited
Padcev™ (Back Office ONLY)	Enfortumab vedotin-ejfv	Medicare Part B			Medical-Benefited
Palforzia® (Initial Dose Escalation - Back Office ONLY)	Peanut allergen powder-dnfp	Medicare Part B or D	MPD: F (when dispensed at pharmacy)		**Medical Benefited**: Initial Dose Escalation Kit; **Pharmacy Benefited:** Continuing Therapy
Palsonify	Paltusotine	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Palynziq™	Pegvaliase-pqpz	Medicare Part D	MPD: F		Pharmacy-Benefited

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
Panretin®	Alitretinoin	Medicare Part D	MPD: F		Pharmacy-Benefited
Papzimeos (Back office Only)	Zopapogene imadenovec	Medicare Part B			Medical-Benefited
Parathyroid Hormone Analogs:					
Forteo® (P)	Teriparatide	Medicare Part D	MPD: F	J3110	Pharmacy-Benefited
Tymlos®	Abaloparatide	Medicare Part D	MPD: NF** Send to PCS		
PCSK-9 Inhibitors:					
Repatha®(P)	Evolocumab	Medicare Part D	MPD: F		Pharmacy-Benefited
Praluent®	Alirocumab	Medicare Part D	MPD: NF** Send to PCS		
Pegfilgrastim Products:					
Fulphila® (P)	Pegfilgrastim-jmdb	Medicare Part D	MPD: F		Pharmacy-Benefited
Fylnetra®	Pegfilgrastim-pbbk	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Neulasta® and Neulasta Onpro®	Pegfilgrastim	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Nyvepria™	Pegfilgrastim-apgf	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Stimufend®	Pegfilgrastim-fpgk	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Udenyca®	Pegfilgrastim-cbqv	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Ziextenzo™	Pegfilgrastim-bmez	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Pemazyre®	Pemigatinib	Medicare Part D	MPD: F		Pharmacy-Benefited
§Pemgarda	Pemivibart	Medicare Part D	MPD: NF** Send to PCS		Medical-Benefited
§Phesgo® (Back Office ONLY)	Pertuzumab, trastuzumab, and hyaluronidase	Medicare Part B			Medical-Benefited
§Phyrago	Dasatinib	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
PiaSky®	Crovalimab-akkz	Medicare Part D	MPD: NF** Send to PCS		Medical-Benefited
Piqray®	Alpelisib	Medicare Part D	MPD: F		Pharmacy-Benefited
Pombiliti (Back Office ONLY)	Cipaglucosidase alfa-atga	Medicare Part B			Medical-Benefited
Ponvory™	Ponesimod	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Prevymis™	Letermovir	Medicare Part B or D	MPD: F (when dispensed at pharmacy)		**Medical Benefited**: IV formulation; **Pharmacy Benefited:**

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§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
					Other Formulations
Procysbi™	Cysteamine delayed release	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Provenge® (Back Office ONLY)	Sipuleucel-T	Medicare Part B		Q2043	Medical-Benefited
Pyrukynd	Mitapivat	Medicare Part D	MPD: F		Pharmacy-Benefited
Qalsody™ (Back Office ONLY)	Tofersen	Medicare Part B			Medical-Benefited
Qbrexza®	Glycopyrronium	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Qinlock®	Ripretinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Qulipta™	Atogepant	Medicare Part D	MPD: F		Pharmacy-Benefited
Radicava ORS®	Edaravone	Medicare Part D	MPD: F		Pharmacy-Benefited
Ravicti®	Glycerol phenylbutyrate	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Reblozyl® (Back office ONLY)	Luspatercept-aamt	Medicare Part B			Medical-Benefited
Rebyota™ (Back office ONLY)	Fecal Microbiota, Live-jslm	Medicare Part B			Medical-Benefited
Redemplo	Plozasiran	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Relistor®	Methylnaltrexone	Medicare Part D	MPD: F		Pharmacy-Benefited
RET Inhibitors:					
Gavreto™	Pralsetinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Retevmo®	Selpercatinib	Medicare Part D	MPD: F		
Revlimid®	Lenalidomide ****NOTE: Create referral only if request for brand name**	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Revuforj®	Revumenib	Medicare Part D	MPD: F		Pharmacy-Benefited
Rezdiffra™	Resmetirom	Medicare Part D	MPD: F		Pharmacy-Benefited
Rezlidhia®	Olutasidenib	Medicare Part D	MPD: F		Pharmacy-Benefited
Rezurock™	Belumosudil	Medicare Part D	MPD: F		Pharmacy-Benefited
Rezzayo™ (Back Office ONLY)	Rezafungin	Medicare Part B			Medical-Benefited
Rhapsido	Remibrutinib	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Rhopressa®	Netarsudil	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited

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Rinvoq™	Upadacitinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Rituxan® (Back Office ONLY)	Rituximab	Medicare Part B		J9312	Medical-Benefited
Rivfloza®	Nedosiran	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Rocklatan®	Netarsudil + Latanoprost	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Rolvedon™	Eflapegrastim	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Romvimza™	Vimseltinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Rozlytrek®	Entrectinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Rubraca®	Rucaparib	Medicare Part D	MPD: F		Pharmacy-Benefited
Ruconest®	C1 inhibitor (recombinant)	Medicare Part B or D	MPD: NF** Send to PCS		Pharmacy-Benefited
Rukobia	Fostemsavir	Medicare Part D	MPD: F		Pharmacy-Benefited
Rybrevant Faspro (Back Office ONLY)	Amivantamab and Hyaluronidase	Medicare Part B			Medical-Benefited
Rydapt®	Midostaurin	Medicare Part D	MPD: F		Pharmacy-Benefited
Ryoncil (Back office Only)	Remestemcel-L	Medicare Part B			Medical-Benefited
Rystiggo®	Rozanolixizumab	Medicare Part B			Medical-Benefited
Ryzneuta™ (Back Office ONLY)	Efbemalenograstim alfa	Medicare Part B			Medical-Benefited
Sajazir®	Icatibant	Medicare Part B or D	MPD: F (when dispensed at pharmacy)		Pharmacy-Benefited
§Saphnelo	Anifrolumab	Medicare Part B			**Medical Benefited:** Administered Back Office **Pharmacy-Benefited:** Dispensed at Pharmacy
Scemblix®	Asciminib	Medicare Part D	MPD: F		Pharmacy-Benefited
Sephience™	Sepiapterin	Medicare Part D	MPD: F		Pharmacy-Benefited
Sickle Cell Disease (SCD) Gene Therapies (Back Office Only)					
Casgevy™	Exagamglogene autotemcel, exa-cel)	Medicare Part B			Medical-Benefited

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					(Requires IR Consultative Panel Review)
Lyfgenia®	Lovotibeglogene autotemcel, lovo-cel	Medicare Part B			Medical-Benefited **(Requires IR Consultative Panel Review)**
Siklos®	Hydroxyurea	Medicare Part D	MPD: F		Pharmacy Benefited
Siliq™	Brodalumab	Medicare Part D	MPD: F		Pharmacy-Benefited
Simponi®	Golimumab	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Simponi Aria® (Back Office ONLY)		Medicare Part B			Medical-Benefited
Skyclarys	Omaveloxolone	Medicare Part D	MPD: F		Medical-Benefited **(Requires IR Consultative Panel Review)**
Skyrizi®	Risankizumab	Medicare Part B or D	MPD: F (when dispensed at pharmacy)		**Medical Benefited**: IV formulation; **Pharmacy Benefited:** SQ formulations
Skysona®(Back Office Only)	Elivaldogene autotemcel	Medicare Part B			Medical-Benefited **(Requires IR Consultative Panel Review)**
Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors*:					
Dapagliflozin (P)	Dapagliflozin	Medicare Part D	MPD: F		Pharmacy-Benefited
Brenzavvy™	Bexagliflozin	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Farxiga™	Dapagliflozin	Medicare Part D	MPD: F		
Inpefa™	Sotagliflozin	Medicare Part D	MPD: NF** Send to PCS		
Invokana™	Canagliflozin	Medicare Part D	MPD: NF** Send to PCS		
Jardiance®	Empagliflozin	Medicare Part D	MPD: NF** Send to PCS		
Steglatro™	Ertugliflozin	Medicare Part D	MPD: NF** Send to PCS		
Synjardy™	Empagliflozin and metformin	Medicare Part D	MPD: NF** Send to PCS		
Glyxambi™	Empagliflozin and linagliptin	Medicare Part D	MPD: NF** Send to PCS		
Invokamet™	Canagliflozin and metformin	Medicare Part D	MPD: NF** Send to PCS		

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§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
Invokamet XR	Canagliflozin and metformin	Medicare Part D	MPD: NF** Send to PCS		
Xigduo XR™	Dapagliflozin and metformin	Medicare Part D	MPD: NF** Send to PCS		
Segluromet™	Ertugliflozin and metformin	Medicare Part D	MPD: NF** Send to PCS		
§Sofdra™	Sofpironium	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Sohonos™	Palovarotene	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Somatuline® Depot (Back Office ONLY)	Lanreotide	Medicare Part B			Pharmacy-Benefited
Somavert®	Pegvisomant	Medicare Part D	MPD: F		Pharmacy-Benefited
Soolantra®	Ivermectin	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Sotyktu	Deucravacitinib	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Sovaldi®	Sofosbuvir	Medicare Part D	MPD: F		Pharmacy-Benefited
Spevigo® (Vials: Back Office ONLY)	Spesolimab-sbzo	Medicare Part B (vials)/Medicare Part D (syringes)	MPD: F (syringes)		**Medical Benefited**: IV formulation; **Pharmacy Benefited:** Other Formulations
Spinraza™ (Back Office ONLY)	Nusinersen	Medicare Part B			Medical-Benefited **(Requires IR Consultative Panel Review)**
Spravato (Back Office Only)	Esketamine	Medicare Part B		J3490	Medical-Benefited
Sprycel®	Dasatinib	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Stimulants:					
Adderall XR®	Dextroamphetamine and Amphetamine ****NOTE: Create referral only if request for brand name**	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Concerta®	Methylphenidate ****NOTE: Create referral only if request for brand name**	Medicare Part D	MPD: NF** Send to PCS		
Jornay PM®	Methylphenidate ****NOTE: Create referral only if request for brand name**	Medicare Part D	MPD: NF** Send to PCS		
Mydayis™	Dextroamphetamine and Amphetamine	Medicare Part D	MPD: NF** Send to PCS		

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	**NOTE: Create referral only if request for brand name				
Quillichew ER®	Methylphenidate **NOTE: Create referral only if request for brand name	Medicare Part D	MPD: NF** Send to PCS		
Strensiq®	Asfotase alfa	Medicare Part D	MPD: F		Pharmacy-Benefited
Stivarga®	Regorafenib	Medicare Part D	MPD: F		Pharmacy-Benefited
Sucraid®	Sacrosidase	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Sunosi™	Solriamfetol	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Supprelin® LA (Back Office Only)	Histrelin implant	Medicare Part B		J9226	Medical Benefited
Symdeko	Tezafactor and ivacaftor	Medicare Part D	MPD: F		Pharmacy-Benefited
Synarel®	Nafarelin acetate	Medicare Part D	MPD: F		Pharmacy-Benefited
Syprine®	Trientine	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Tabrecta™	Capmatinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Tafinlar® plus Mekinist®	Dabrafenib plus Trametinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Takhzyro™	Lanadelumab-flyo	Medicare Part D	MPD: F		Pharmacy-Benefited
Taltz®	Ixekizumab	Medicare Part D	MPD: F		Pharmacy-Benefited
Talzenna®	Talazoparib	Medicare Part D	MPD: F		Pharmacy-Benefited
Targretin gel	Bexarotene	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Tarpeyo	Budesonide	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Tascenso ODT™	Fingolimod	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Tasigna®	Nilotinib	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Tavalisse	Fostamatinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Tavneos™	Avacopan	Medicare Part D	MPD: F		Pharmacy-Benefited
Tecfidera™	Dimethyl fumarate **NOTE: Create referral only if request for brand name	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Tecvayli™	Teclistamab-cqyv	Medicare Part B			Medical-Benefited

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§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
§Tempo Personalized Diabetes Management Platform		Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Tepezza™ (Back Office ONLY)	Teprotumumab-trbw	Medicare Part B		J3241	Medical-Benefited **(Requires IR Consultative Panel Review)**
Tepmetko®	Tepotinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Testosterone:					
Aveed®	Testosterone undecanoate	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Jatenzo®	Testosterone undecanoate	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Kyzatrex™	Testosterone undecanoate	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Tlando™	Testosterone undecanoate	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Tezspire™	Tezepelumab-ekko	Medicare Part B or D	MPD: F (when dispensed at pharmacy)		Pharmacy-Benefited
Tibsovo®	Ivosidenib	Medicare Part D	MPD: F		Pharmacy-Benefited
Tirzepatide Products (Diabetes Indication)					
Zepbound KwikPen Mounjaro	Tirzepatide	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Tivdak (Back Office ONLY)	Tisotumab vedotin-tftv	Medicare Part B			Medical-Benefited
Trastuzumab Products (Back Office Only)					
Herceptin® Herzuma® Kanjinti® Ogivri® Ontruzant® Trazimera®	Trastuzumab Trastuzumab-pkrb Trastuzumab-anns Trastuzumab-dkst Trastuzumab-dttb Trastuzumab-qyyp	Medicare Part B			Medical-Benefited
Tremfya®	Guselkumab	Medicare Part D	MPD: F	J1628	Pharmacy-Benefited
Tresprostinil Products					
Tyvaso® Inhalation Solution Tyvaso® DPI Institutional or Maintenance Kit Tyvaso ® DPI Titration Kit	Treprostinil	Medicare Part D	MPD: NF** Send to PCS / MPD: F: Starter/Refill Kit 0.6 mg/ml; DPI Titration Kit 16		Pharmacy-Benefited ****NOTE:** Remodulin (brand and

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
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			mcg&32 mcg&48 mcg; DPI Maintenance Kits 16 mcg, 32 mcg, 48 mcg, and 64 mcg		generic) do **NOT** require QRM referral/ review**
Yutrepia™	Treprostinil	Medicare Part D	MPD: F		Pharmacy-Benefited
Trikafta®	Elexacaftor, Tezacaftor, Ivacaftor, Ivacaftor	Medicare Part D	MPD: F		Pharmacy-Benefited
§Trodelvy (Back Office ONLY)	Sacituzumab govitecan-hziy	Medicare Part B			Medical-Benefited
§Truqap™	Capivasertib	Medicare Part D	MPD: F		Pharmacy-Benefited
§Trutakna	Atacicept-vymj	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
§Tryngolza™	Olezarsen	Medicare Part D	MPD: F		Pharmacy-Benefited
§Tryvio™	Aprocitentan	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
TTR Stabilizers/Silencers					
Vyndamax (P)	Tafamidis	Medicare Part D	MPD: F		Pharmacy-Benefited
Attruby™	Acoramidis	Medicare Part D	MPD: F		Pharmacy-Benefited
Amvuttra® (Back Office ONLY)	Vutrisiran	Medicare Part B			Medical Benefited
Tukysa®	Tucatinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Turalio®	Pexidartinib	Medicare Part D	MPD: F		Pharmacy-Benefited
§Twiist Insulin Pump	N/A	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Tysabri® (Back Office ONLY)	Natalizumab IV solution	Medicare Part B		J2323	Medical-Benefited
Tzield™ (Back Office ONLY)	Teplizumab-mzwv	Medicare Part B			Medical-Benefited **(Requires IR Consultative Panel Review)**
Ubrelvy™	Ubrogepant	Medicare Part D	MPD: F		Pharmacy-Benefited
Uceris®	Budesonide extended release	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Ultomiris® (Back Office ONLY)	Ravulizumab-cwvz	Medicare Part B			Medical-Benefited
Uplizna™ (Back Office ONLY)	Inebilizumab-cdon	Medicare Part B			Medical-Benefited

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§Uptravi	Selexipag	Medicare Part D	MPD: F		Pharmacy-Benefited
Ustekinumab Products					
Imuldosa™	Ustekinumab-srlf	Medicare Part D	MPD: NF** Send to PCS		**Medical Benefited**: IV formulation; **Pharmacy Benefited:** Other Formulations ****NOTE:** Yesintek (Ustekinumab-kfce) –No referral required.
Otulfi™	Ustekinumab-aauz	Medicare Part D	MPD: NF** Send to PCS		
Pyzchiva® (IV formulation- Back office ONLY)	Ustekinumab-ttwe	Medicare Part D or B	MPD: NF** Send to PCS		
Selarsdi™	Ustekinumab-aekn	Medicare Part D	MPD: NF** Send to PCS		
§Starjemza	Ustekinumab-hmny	Medicare Part D or B	MPD: NF** Send to PCS		
Stelara® (IV formulation- Back office ONLY)	Ustekinumab	Medicare Part D or B	MPD: F	J3357	
Steqeyma (IV formulation- Back office ONLY)	Ustekinumab-stba	Medicare Part D or B	MPD: NF** Send to PCS		
Wezlana™	Ustekinumab-auub	Medicare Part D or B	MPD: NF** Send to PCS		
Vafseo®	Vadadustat	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Vanflyta®	Quizartinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Vascepa ®	Icosapent ethyl	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Velsipity™	Etrasimod Arginine	Medicare Part D	MPD: F		Pharmacy-Benefited
Vemlidy®	Tenofovir alafenamide	Medicare Part D	MPD: F		Pharmacy-Benefited
Veopoz (Back Office ONLY)	Pozelimab	Medicare Part B			Medical-Benefited
Vezah™	Fezolinetant	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Verquvo®	Vericiguat	Medicare Part D	MPD: F (10 mg only)/ MPD: NF** Send to PCS		Pharmacy-Benefited
Verzenio®	Abemaciclib	Medicare Part D	MPD: F		Pharmacy-Benefited
Viberzi®	Eluxadoline	Medicare Part D	MPD: F		Pharmacy-Benefited
Vigabatrin Products					
Sabril®	Vigabatrin	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Vigabatrin Powder (P)	Vigabatrin	Medicare Part D	MPD: F		Pharmacy-Benefited

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Vigabatrin Tablets	Vigabatrin	Medicare Part D	MPD: F		Pharmacy-Benefited
Vigadrone®	Vigabatrin	Medicare Part D	MPD: F (only 500 mg tabs)/ MPD: NF** Send to PCS (500 mg pack)		Pharmacy-Benefited
Vigafyde™	Vigabatrin	Medicare Part D	MPD: F		Pharmacy-Benefited
Vijoice®	Alpelisib	Medicare Part D	MPD: F		Pharmacy-Benefited
Vitrakvi®	Larotrectinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Vivjoa™	Oteseconazole	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Vizimpro®	Dacomitinib	Medicare Part D	MPD: F		Pharmacy-Benefited
VMAT2 Inhibitors:					
Xenazine®	Tetrabenazine	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Austedo®/ Austedo® XR	Deutetrabenazine	Medicare Part D	MPD: F		Pharmacy-Benefited
Vocabria	Cabotegravir	Medicare Part D	MPD: F		Medical Benefited
Vonjo™	Pacritinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Voquezna®	Vonoprazan	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Voquezna® Dual Pak®	Vonoprazan, amoxicillin	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Voquezna® Triple Pak®	Vonoprazan, amoxicillin, and clarithromycin	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Voranigo®	Vorasidenib	Medicare Part D	MPD: F		Pharmacy-Benefited
Vosevi®	Sofosbuvir, velpatasvir, and voxilaprevir	Medicare Part D	MPD: F		Pharmacy-Benefited
Vowst™	Fecal, microbiospore, live-brpk	Medicare Part D	MPD: F		Pharmacy-Benefited
Voxzogo™	Vosoritide	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
§Voydeya™	Danicopan	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Voyxact	Sibeprenlimab-szsi	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Vtama®	Tapinarof	Medicare Part D	MPD: F		Pharmacy-Benefited

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
Vumerity	Diroximel fumarate	Medicare Part D	MPD: F		Pharmacy-Benefited
Vyalev™	Foscarbidopa/foslevodopa	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Vyjuvek™	Beremagene geperpavec	Medicare Part B or D	MPD: NF** Send to PCS		Medical-Benefited **(Requires IR Consultative Panel Review)**
§Vykat™ XR	Diazoxide choline	Medicare Part D	MPD: F		Pharmacy-Benefited
§Vyvgart (Back Office Only) §Vyvygart Hytrulo	Efgartigimod alfa Efgartigimod alfa and hyaluronidase	Medicare Part B Medicare Part D (prefilled syringe)	MPD: F		Medical-Benefited Pharmacy-Benefited (prefilled syringe)
Vyzulta	Latanoprostene bunod	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Wakix®	Pitolisant	Medicare Part D	MPD: F		Pharmacy-Benefited
Waskyra (Back office Only)	Etuvetidigene autotemcel	Medicare Part B			Medical-Benefited **(Requires IR Consultative Panel Review)**
Wayrilz	Rilzabrutinib	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Welireg	Belzutifan	Medicare Part D	MPD: F		Pharmacy-Benefited
Winrevair™	Sotatercept-csrk	Medicare Part D	MPD: F		Pharmacy-Benefited
Xalkori®	Crizotinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Xdemvy®	Lotilaner	Medicare Part D	MPD: F		Pharmacy-Benefited
Xenpozyme™ (Back Office Only)	Olipudase alfa-rpcp	Medicare Part B			Medical-Benefited
Xermelo®	Telotristat	Medicare Part D	MPD: F		Pharmacy-Benefited
Xhance®	Fluticasone	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Xiaflex™ (Back Office Only)	Collagenase clostridium histolyticum injection	Medicare Part B		J0775	Medical-Benefited

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
Xolair®	Omalizumab injectable	Medicare Part B or D	MPD: F (when dispensed at pharmacy)	J2357	**Medical Benefited:** Administered Back Office **Pharmacy-Benefited:** Dispensed at Pharmacy
Xolremdi™	Mavorixafor	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Xospata®	Gilteritinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Xphozah®	Tenapanor	Medicare Part D	MPD: F		Pharmacy-Benefited
Xpovio®	Selinexor	Medicare Part D	MPD: F		Pharmacy-Benefited
§Xromi®	Hydroxyurea	Medicare Part D	MPD: F		Pharmacy-Benefited
Xtandi®	Enzalutamide	Medicare Part D	MPD: F		Pharmacy-Benefited
Xyrem®	Sodium oxybate	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Xywav™	Oxybate salts (calcium, magnesium, potassium, and sodium)	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
§Yartemlea (Back Office ONLY)	Narsoplimab-wuug	Medicare Part B			Medical-Benefited
Yorvipath®	Palopegteriparatide	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
§Yuviwel	Navepegritide	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Zavesca®	Miglustat	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Zavzpret™	Zavegepant	Medicare Part D	MPD: F		Pharmacy-Benefited
Zejula®	Niraparib	Medicare Part D	MPD: F / MPD: NF** Send to PCS (100 mg tabs)		Pharmacy-Benefited
Zepatier®	Elbasvir and grazoprevir	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Zepbound™ (Weight Loss Indication)	Tirzepatide	Not covered under Medicare Part D For weight loss ONLY for Part D, Do not send to PCS.			Pharmacy-Benefited

Brand Name and/or Therapeutic Class	Generic Name	Medicare Status	MPD F or NF** (See Footer)	J-Code	Notes
§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee					
Zeposia®	Ozanimod	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Zilbrysq®	Zilucoplan	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Zokinvy	Lonafarnib	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Zolgensma® (Back Office ONLY)	Onasemnogene abeparvovec-xioi	Medicare Part B			Medical-Benefited **(Requires IR Consultative Panel Review)**
Zolinza®	Vorinostat	Medicare Part D	MPD: F		Pharmacy-Benefited
Zoryve™	Roflumilast	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Zurzuvae™	Zuranolone	Medicare Part D	MPD: F		Pharmacy-Benefited
Zusduri (Back Office ONLY)	Mitomycin	Medicare Part B			Medical-Benefited
§Zycubo	Copper histidinate	Medicare Part D	MPD: NF** Send to PCS		Pharmacy-Benefited
Zydelig®	Idelalisib	Medicare Part D	MPD: F		Pharmacy-Benefited
Zykadia®	Ceritinib	Medicare Part D	MPD: F		Pharmacy-Benefited
Zynteglo®(Back Office Only)	Betibeglogene autotemcel	Medicare Part B			Medical-Benefited **(Requires IR Consultative Panel Review)**

§ Criteria per Policy Number GA.PHM.407- temporary PA criteria until full drug reviewed by P&T committee

Drug	Prior Authorization Criteria

CAR-T Therapy
 	
Abecma
(Idecabtagene vicleucel)
	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.**
	
	Candidates for Abecma should meet ALL of the following criteria:
	
	• **MUST verify member's benefit information. If member's coverage is through Target, CLOSE the request.** Member must go through Aradigm for this therapy.
	• Diagnosis of relapsed or refractory multiple myeloma (RRMM)
	• Prescribed by an Oncologist
	• Age ≥ 18 years
	• Progression on, or intolerant to ≥3 prior lines of therapy with at least one from each of the following three drug classes, with or without prior transplant:
	  ○ Immunomodulatory agents (lenalidomide, pomalidomide)
	  ○ Proteasome inhibitors (carfilzomib, bortezomib, ixazomib)
	  ○ Anti-CD38 monoclonal antibodies (isatuximab, daratumumab)
	• Absolute neutrophil count ≥500/µL
	• Absolute lymphocyte count >100/µL
	• Platelet count ≥50,000/µL
	• Adequate organ function defined as (patients with borderline organ function may still be eligible based on center of excellence standards):
	  ○ Left Ventricular Ejection Fraction ≥45%
	  ○ Creatinine clearance ≥40 mL/min
	  ○ Alanine aminotransferase (ALT) ≤5 times the upper limit of normal (ULN) for age
	  ○ Total bilirubin <2 mg/dl
	  ○ Baseline oxygen saturation > 91% on room air
	
	Reasons for Non-coverage:
	• Autoimmune disease with or without use of chronic immunosuppressants
	• Central nervous system (CNS) involvement with myeloma or clinically relevant CNS pathology (e.g., seizure disorder)
	• Plasma cell leukemia
	• Solitary plasmacytomas
	• Pregnancy
	• Known infection with HIV (detectable viral load)
	• Hepatitis B (HBsAG positive and detectable viral load)
	• Hepatitis C virus (anti-HCV positive and detectable viral load)
	• Presence of fungal, bacterial, viral, or other infection that is uncontrolled or requiring intravenous antimicrobials for management.
	  ○ Simple urinary tract infection and uncomplicated bacterial pharyngitis are permitted if responding to active treatment.
	• Detectable cerebrospinal fluid malignant cells or brain metastases or with a history of CNS lymphoma, cerebrospinal fluid malignant cells, or brain metastases
	
	Initial Approval: ONE TIME DOSE ONLY. At this time, CAR-T therapy is intended as a one-time (single infusion) treatment. Repeat treatment of any CAR-T therapy is considered investigational and is not recommended outside of enrollment in a clinical trial.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** **Continued Approval:** Not applicable. CAR-T is intended as a one-time (single infusion) treatment **Dosage and administration:** • KP members will be referred to institutions that are certified to administer CAR-T therapies. • Abecma is only available through restricted programs under a Risk Evaluation and Mitigation Strategy (REMS)
Adakveo (Crizanlizumab-tmca)	**Candidates for treatment with Adakveo should meet ALL the following criteria:** • Prescribed by a Hematology-Oncology Specialist • Age ≥ 16 years • Patient diagnosed with sickle cell anemia or sickle beta thalassemia (documented by hemoglobin electrophoresis) • Patient currently taking maximum tolerated dose of hydroxyurea (35 mg/kg or dose limited by absolute neutrophil count (ANC) ≤1,000/uL or platelets ≤100,000/uL) for at least 3 months, unless history of intolerance or patient declines use due to potential adverse effects • Documentation of prior trial of L-glutamine for at least 3 to 6 months before considering crizanlizumab-tmca • Documentation of two or more sickle cell pain crises within prior 12 months requiring intervention (hospitalizations, emergency department or urgent care visits) • Patient using appropriate contraception if of childbearing potential • Baseline CBC, PT/INR, ALT, bilirubin, GFR, and pregnancy test if of childbearing potential. Reasons for Non-coverage: • ALT ≥3x upper limit of normal (ULN) or direct bilirubin ≥2 mg/dL • GFR ≤45 mL/min/1.73 m2 • Concomitant use of voxelotor (Oxbryta) Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: 6 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage or criteria for discontinuation below. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Criteria for discontinuation:

Drug	Prior Authorization Criteria
	• No clinically meaningful reduction in frequency of VOEs (vaso-occlusive event) after 6 to 12 months of treatment • Intolerance to medication • Non-adherence to medication or follow-up labs and assessments • Patient is receiving treatment with voxelotor <u>Dosing and Administration:</u> Administer 5 mg/kg by intravenous infusion over 30 minutes on Week 0, Week 2, and every 4 weeks thereafter. Per product labeling, crizanlizumab-tmca should be prepared and administered by a healthcare professional.

Adalimumab Products*
 	
Preferred Formulary: Amjevita (Adalimumab-atto) – No PA required
 	
<u>QRM Adalimumab Products</u>: PA Required
 	
<u>Preferred QRM</u>: Hadlima (Adalimumab-bwwd)
 	
<u>Non-Preferred QRM:</u> Abrilada (Adalimumab-afzb)
 	
Unbranded Adalimumab-fkjp
 	
Simlandi (Adalimumab-ryvk)
 	
Unbranded Adalimumab-ryvk
 	
Unbranded Adalimumab-adaz
 	
Unbranded Adalimumab-adbm
	Candidates for treatment with branded Humira or a QRM adalimumab product should meet ALL the following criteria PLUS the individual disease state criteria that follows:
	• Patient has a negative interferon-gamma release assay test for TB Infection within the past 24 months or is positive for latent TB and has completed treatment in the past or is currently on treatment.
	• Medication is not being used in combination with another biologic or advanced small molecule (e.g., tofacitinib, upadacitinib, apremilast) for the same indication
	• Documented inadequate response, intolerance, and/or contraindication after at least a 3-month trial of **ALL** of the following medications, in the following order: Amejvita, then Hadlima. If the request is for Hadlima, proceed to approval.
	  ○ Inadequate response defined as documented new or worsening symptoms or significant disease flare not characteristic of previous disease course confirmed by objective findings and physical assessment.
	• If the request is for a non-preferred QRM adalimumab product, then also follow disease-specific criteria below:
	
	<u>Criteria for rheumatoid arthritis, psoriatic arthritis, and spondyloarthritis:</u>
	• Prescribed by a Rheumatologist or Dermatologist
	• History of inadequate response or intolerance to **TWO** of the following after at least a 3-month trial: tofacitinib, infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade), etanercept (Enbrel)
	
	<u>Criteria for juvenile idiopathic arthritis:</u>
	• Prescribed by a Pediatric Rheumatologist or Rheumatologist
	• Age ≥ 2 years
	• History of inadequate response or intolerance to each of the following therapies after at least a 3-month trial:
	  ○ Conventional synthetic DMARD (e.g., methotrexate, leflunomide, OR sulfasalazine)
	  ○ Etanercept (Enbrel)
	  ○ Tofacitinib (required only for polyarticular JIA patients weighing ≥ 40 kg)
	
	<u>Criteria for Hidradenitis Suppurativa:</u>
	• Prescribed by a Dermatologist

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
Unbranded Adalimumab-bwwd Cyltezo (Adalimumab-adbm) Hulio (Adalimumab-fkjp) Yuflyma (Adalimumab-aaty) Hyrimoz (Adalimumab-adaz) Idacio (Adalimumab-aacf) Unbranded Adalimumab-aacf Humira (Adalimumab) *** all products available with citrate free formulations**	• Documented diagnosis of moderate-to-severe Hidradenitis Suppurative • Age ≥ 12 years • Documented trial, intolerance or contraindication to the following therapies: ○ Topical clindamycin 1% solution/lotion/gel (minimum of 12 weeks) ○ Intralesional corticosteroids (minimum of 4 weeks) ○ Oral antibiotics (e.g., doxycycline, tetracycline, clindamycin +/- rifampin, erythromycin) (minimum of 10 weeks) **OR** ○ Infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade) (minimum of 2 infusions) **Criteria for plaque psoriasis:** • Prescribed by a Dermatologist • Documented diagnosis of moderate-to-severe plaque psoriasis • Documented failure or clinically significant adverse effects to at least one of the following therapies (of at least a 3-month trial), unless contraindicated or clinical reason to avoid treatment: ○ Methotrexate ○ Cyclosporine ○ Acitretin ○ Infliximab product (Infliximab-dyyb/Inflectra [preferred]) • Inadequate response (of at least a 3-month trial), intolerance and/or contraindication to each of the following: ○ Ustekinumab product (Yesintek [preferred], Stelara) ○ Cosentyx (secukinumab) **Criteria for uveitis:** • Prescribed by an Ophthalmologist or Rheumatologist • Documented diagnosis of non-infectious chronic intermediate uveitis, anterior or posterior uveitis, or panuveitis **Adult criteria for moderate to severe Crohn's disease or ulcerative colitis:** • Prescribed by a Gastroenterologist • Negative test for hepatitis B within the past 24 months • A documented inadequate response (after at least a 3-month trial), intolerance and/or contraindication to **ALL** of the following: ○ Infliximab product (e.g., Infliximab-dyyb/Inflectra [preferred], Remicade) ○ Ustekinumab product (e.g., Yesintek [preferred], Stelara) ○ Entyvio (vedolizumab) – a trial is not required for CD, if documentation of small bowel, perianal or fistulizing / penetrating disease ○ Tofacitinib (for UC only, preferred JAK inhibitor) OR Rinvoq (upadacitinib) (for CD and UC) ○ Cimzia (for CD only and patient is in remission) ○ Velsipity (etrasimod)

Drug	Prior Authorization Criteria
	○ Simponi (golimumab) ○ Patient must try/fail all of the agents listed above unless provider documents rationale why additional anti-TNF agent is inappropriate (i.e., primary or secondary non-response despite therapeutic drug level +/- presence of anti-drug antibodies or adverse effect requiring a different mechanism of action, member temporarily located outside of our KP network and cannot receive infusions) **Pediatric criteria for Crohn's disease or ulcerative colitis:** **FDA pediatric approval for Crohn's dx only but data supports use in UC* • Prescribed by a Gastroenterologist • Age < 18 years • Negative test for hepatitis B within the past 24 months • Documented inadequate response with or loss of response, intolerance or contraindication to **ALL** of the following: ○ Infliximab product (Inflectra preferred) ▪ Clinician should optimize dose, 5-10 mg/kg and consider dose interval change (q4 weeks), with an adequate therapeutic trial of at least 2 infusions ○ Ustekinumab product (Yesintek preferred) ○ Entyvio (vedolizumab) – a trial is not required for CD, if documentation of small bowel, perianal or fistulizing / penetrating disease Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Subcutaneous formulation:** Approve for member to fill subcutaneous formulation via the outpatient pharmacy benefit only Continued Approval: 12 months. Confirm patient meets all above coverage criteria AND documented clinically significant benefit from the medication during specialist follow-up in the last 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Subcutaneous formulation:** Approve for member to fill subcutaneous formulation via the outpatient pharmacy benefit only
Adbry (Tralokinumab-ldrm)	**Candidates for treatment with Adbry should meet ALL the following criteria:** Diagnosis of Atopic Dermatitis: • Prescribed by a dermatologist • Age ≥ 12 years • If patient has been treated with a biologic drug or oral JAK inhibitor for atopic dermatitis in the past 6 months, proceed to initial approval. For all other patients, confirm additional criteria below are met: • Documented diagnosis of moderate-to-severe atopic dermatitis (such as BSA ≥ 10%, involvement of high-impact areas [e.g., face, hands, feet, genitals, skin folds], or documented major impact on quality of life)

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
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Inadequate response, intolerance or contraindication to ONE of the following:

Topical calcineurin inhibitor [e.g., tacrolimus (Protopic) (preferred) or pimecrolimus (Elidel)]
Medium to very high potency topical corticosteroid [listed from lower to higher potency in each category]

<table>
<tr><th>Medium Potency</th><th>High and Very High Potency</th></tr>
<tr><td>Triamcinolone acet 0.025% O, C</td><td>Fluocinonide 0.05% O, C, G</td></tr>
<tr><td>Triamcinolone acet 0.1% O,C</td><td>Fluocinonide-emollient 0.05% C</td></tr>
<tr><td>Betamethasone val 0.1% C</td><td>Desoximetasone 0.25% C</td></tr>
<tr><td>Mometasone 0.1% O, C</td><td>Betameth diprop aug 0.05% C</td></tr>
<tr><td>Triamcinolone acet 0.5% C</td><td>Betamethasone diprop aug 0.05% O, G</td></tr>
<tr><td>Betamethasone diprop 0.05% C</td><td>Clobetasol 0.05% O, C</td></tr>
</table>
O = oint, C = cream, G = gel, L = lotion

Documented inadequate response, intolerance, or contraindication to phototherapy; or documentation supporting an exception to the phototherapy requirement, including:

<u>Pediatric</u> patients who are developmentally unable to independently stand in light unit or unable to reliably attend frequent in-office treatments
Involvement of sensitive areas (e.g., hands, feet, face, body folds, genitals)
History of photosensitivity disorder (e.g., Lupus, Dermatomyositis, Porphyria, Xeroderma pigmentosum)
History of melanoma or abnormal moles or multiple non-melanoma skin cancers
NOTE: Light box trial required unless member has a High Deductible Health Plan

Documented inadequate response or intolerance to at least ONE of the following (or documented contraindications to all): mycophenolate, cyclosporine, azathioprine, or methotrexate.
NOT used in combination with another biologic medication [e.g., dupilumab (Dupixent), omalizumab (Xolair), lebrikizumab-lbkz (Ebglyss), nemolizumab-ilto (Nemluvio)] or Janus Kinase inhibitor [e.g., upadacitinib (Rinvoq), baricitinib (Olumiant)] for the same condition.

<u>Initial Approval</u>: 6 months

Approve for member to fill via the outpatient pharmacy benefit only
Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)

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</table>

Drug	Prior Authorization Criteria

	Continued Approval: 12 months. Continue approval if the following criteria are met:
	
	For new members who were initiated on Adbry outside of KPGA:
	• Patient is confirmed to be clinically stable on it by a Specialist in the last 6 months.
	• For adult patients weighing <100kg with clear or almost clear skin after at least 16 weeks of Adbry:
	  ○ Prescribed dose of 300mg SC every 4 weeks unless there is a special circumstance documented (e.g. resistant disease, flare with previously attempted dose extension).
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	For existing members who have previously met the full criteria above:
	• Documented adequate response and tolerance of medication during specialist follow up in the last 12 months.
	• For adult patients weighing <100kg with clear or almost clear skin after at least 16 weeks of Adbry:
	  ○ Prescribed dose of 300mg SC every 4 weeks unless there is a special circumstance documented (e.g. resistant disease, flare with previously attempted dose extension).
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**

Adempas
(Riociguat)
	Candidates for treatment with Adempas (riociguat) should meet ALL the following criteria:
	
	Criteria for diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH):
	• Age ≥ 18 years
	• Prescribed by a pulmonologist or cardiologist
	• Diagnosis of World Health Organization (WHO) Group 4 CTEPH
	• Patient is not a candidate for surgery (i.e., pulmonary endarterectomy) OR patient has persistent CTEPH despite surgery
	
	Criteria for diagnosis of pulmonary arterial hypertension (PAH):
	• Age ≥ 18 years
	• Prescribed by a pulmonologist or cardiologist
	• Diagnosis of PAH WHO Group 1 confirmed by right heart catheterization
	• Patient has New York Heart Association Functional Class II to IV symptoms
	• Documented failure, intolerance to contraindication to **ONE** of the following regimens:
	  ○ Ambrisentan (generic Letairis) AND a PDE5 inhibitors (e.g., tadalafil or sildenafil*)
	  ○ Bosentan (generic Tracleer) AND a PDE5 inhibitors (e.g., tadalafil or sildenafil*)
	  ○ Macitentan (Opsumit) AND a PDE5 inhibitors (e.g., tadalafil or sildenafil*)
	
	Initial Approval: 12 months

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Continued Approval: 12 months, if documentation of positive clinical response to therapy by specialist in the past 12 months *Note: For PAH, PDE5 inhibitors should be dosed as follows: tadalafil 20mg two tablets daily or sildenafil 20mg one tablet three times daily

Adstiladrin (Nadofaragene firadenovec-vncg)	**Candidates for Adstiladrin should meet ALL of the following criteria:**
	
	**Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).*
	
	• Prescribed by Urologists or any qualified prescribing physician (in consultation with a tumor board recommended)
	• Age ≥ 18 years
	• Confirmed biopsy pathology of either carcinoma in situ (CIS) with or without Ta/T1 papillary tumors
	• Non-responsive to Bacillus Calmette-Guérin (BCG) defined as having an adequate induction treatment with BCG, (e.g., received at least two previous courses of BCG within a 12-month period, defined as at least five of six induction BCG instillations and at least two out of three instillations of maintenance BCG, or at least two of six instillations of a second induction course, where maintenance BCG is not given)
	• High-grade BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) which includes patients who have:
	  ○ Recurrence despite adequate BCG treatment and have a persistent high-grade
	  ○ Recurrence within 12 months after BCG was initiated
	  ○ Relapse with high-grade CIS within 12 months of last intravesical BCG treatment despite an initial complete response to BCG
	  ○ Relapse with high-grade Ta/T1 NMIBC within six months of last intravesical BCG treatment
	• All visible papillary tumors are resected and those with persistent T1 disease on transurethral resection of bladder tumor (TURBT) should undergo an additional re-transurethral resection of bladder tumor within approximately four to six weeks prior to beginning treatment
	• Life expectancy >2 years
	• No concomitant upper tract urothelial carcinoma or urothelial carcinoma within the prostatic urethra
	• Patient using appropriate contraception if of childbearing potential
	
	Reasons for Non-coverage:
	• Immunocompromised or on immunocompromising medications, including systemic steroids
	• Current or previous evidence of muscle invasive (muscularis propria) or metastatic disease or with any variant histology
	• Current systemic therapy for any cancer
	• Prior treatment with adenovirus-based drugs

Drug	Prior Authorization Criteria
	• Suspected hypersensitivity to interferon-alfa 2b • Suspicion of urinary tract infection or bacterial cystitis • Pregnant or lactating • Intravesical therapy within eight weeks prior to initiating therapy Initial Approval: 3 months Continued Approval: 12 months. Documented clinical response to therapy and none of the following below • Recurrence of high-grade disease based on results of the first assessment at three months after initiating treatment or on any subsequent assessment • Cannot hold instillation for one hour • Patients cannot tolerate intravesical dosing • Intolerance to medication • Non-adherence to medication administration, follow-up labs, or assessments • Pregnancy Dosing and Administration: • Intravesical instillation only, and not for intravenous use, topical use, or oral administration • Recommended dose is 75 mL at a concentration of 3 x 1011 viral particles (vp)/mL instilled into the bladder via a urinary catheter, once every three months
Afrezza (Inhaled Insulin)	**Candidates for treatment with Afrezza should meet ALL the following criteria:** • Prescribed by Endocrinology • Age ≥ 18 years • Documented Forced Expiratory Volume in 1 second (FEV1) within the last 60 days of ≥ 70% • Documented diagnosis of type 1 diabetes mellitus and used in combination with a basal insulin AND inadequate response, intolerance, or contraindication to Kirsty or equivalent insulin aspart AND Humalog or equivalent insulin lispro AND Apidra (insulin glulisine) vial or pen **OR** • Documented diagnosis of type 2 diabetes mellitus and inadequate response, intolerance, or contraindication to Humulin R AND Kirsty or equivalent insulin aspart, AND Humalog or equivalent insulin lispro AND Apidra (insulin glulisine) vial or pen Reasons for Non-coverage: • Patient smokes or quit smoking within previous 6 months • Hypersensitivity to regular human insulin or any of the inhaled insulin excipients • Patient has active lung cancer • Patient has chronic respiratory disease (e.g., asthma, COPD) • For the treatment of diabetic ketoacidosis

Drug	Prior Authorization Criteria
	Initial Approval: 12 months Continued Approval: 24 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continued approval will be based on clinical documentation of ALL the following • Repeat pulmonary function tests confirms patient has NOT experienced a decline of 20% or more in FEV_1 • Documented Hemoglobin A1c is stable or has decreased • Patient does not smoke Dosing: • 4-24 units inhalation dose per meal (based on individual patient insulin requirements)
Agamree (Vamorolone)	**Candidates for treatment with Agamree should meet ALL the following criteria:** • Documented diagnosis of Duchenne muscular dystrophy (DMD) • Prescribed by a pediatric or adult neurologist with neuromuscular expertise • Age ≥ 2 years • Patient has tried prednisone or prednisolone for at least 12 months and experienced a significant adverse effect such as persistent mood or behavioral change or weight gain that is negatively impacting a comorbid condition like diabetes • Documented trial and failure of deflazacort (Emflaza) Reasons for Noncoverage: • No prior history of prednisone use • Patient is in stage 1 of the disease (the pre-symptomatic phase) Initial Approval Period: 6 months Continued Approval Period: 12 months. Confirm patient meets all above coverage criteria without reasons for noncoverage or criteria for discontinuation. In addition, the following must be met: • Documented adherence to follow-up assessments (i.e., weight, BMI, blood pressure, HbA1c, and ophthalmology evaluation [every 12 months]) Criteria for Discontinuation: • Non-adherence to follow-up assessments • Intolerance due to adverse effects • Development of cataract or optic nerve atrophy
Akeega (Niraparib-Abiraterone)	**Candidates for Akeega should meet ALL of the following criteria**: • Prescribed by Hematology/Oncology • Age ≥ 18 years • Documented diagnosis of metastatic castration-resistant prostate cancer (mCRPC)

Drug	Prior Authorization Criteria

(NOTE: separate prescriptions required for ingredients in combination product)	• The patient's cancer has a deleterious or suspected deleterious BRCA mutation
	• Akeega will be used in combination with an oral corticosteroid (e.g., prednisone, prednisolone, methylprednisolone)
	• Not used in combination with enzalutamide, abiraterone, apalutamide, darolutamide, docetaxel, cabazitaxel
	• Patient must meet ONE of the following:
	  ○ The patient had a bilateral orchiectomy
	  ○ The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
	  ○ The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])
	• Separate prescriptions are required for ingredients in combination product:
	  ○ Zejula 200 mg: Take 1 capsule by mouth daily PLUS
	  ○ Abiraterone 250 mg: Take 4 capsules by mouth daily
	
	<u>Reasons for Non-Coverage:</u>
	• Pregnancy or lactation
	• Co-administration with strong CYP3A4 inducers (i.e., rifampin, carbamazepine, St. John's Wort, long-acting barbiturates)
	• Moderate or severe hepatic impairment
	• History or current diagnosis of myelodysplastic syndrome (MDS)/acute myeloid leukemia (AML)
	
	<u>Initial Approval</u>: 12 months
	• ONLY approve for separate prescriptions: Zejula PLUS abiraterone
	
	<u>Continued Approval:</u> 12 months. For continued approval for treatment with Akeega, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread
	• ONLY approve for separate prescriptions: Zejula PLUS abiraterone

Alhemo (Concizumab-mtci)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Candidates for treatment with Alhemo (concizumab-mtci) should meet ALL the following criteria:
	
	• Prescribed by a hematologist
	• Age ≥ 12 years
	• Documentation of **one** of the following:
	  ○ Diagnosis of hemophilia A (congenital factor VIII deficiency)
	  ○ Diagnosis of hemophilia B (congenital factor IX deficiency)
	• Alhemo will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
	• If diagnosed with hemophilia A: patient has tried and failed, unable to tolerate, or has contraindication to at least 1 of the following therapies:
	  ○ Advate

Drug	Prior Authorization Criteria
	○ Kogenate FS ○ Xyntha ○ Elocate ○ Jivi ○ Espercot • If diagnosed with hemophilia B: patient has tried and failed, unable to tolerate, or has contraindication to at least 1 of the following therapies: ○ BeneFix ○ Ixinity ○ Rixubis ○ Alprolix ○ Rebinyn ○ Idelvion Reasons for Non-coverage: • Concurrent use with non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh]) or Hympavzi (marstacimab-hncq) • Pregnancy Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval:12 months. Patient continues to meet all criteria above and has shown clinical benefit compared to baseline with Alhemo therapy with documentation of improvement in bleeding rates. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
Alkindi Sprinkle (Hydrocortisone)	**Candidates for treatment with Alkindi should meet ALL the following criteria:** • Patient is <6 years of age • Prescribed by, or in consultation with, a pediatric endocrinologist • Patient has a diagnosis of adrenocortical insufficiency • Each individual dose must be less than 5 mg AND • Patient must have documented inability to crush hydrocortisone tablets and mix with soft foods. Initial approval: 12 months Continued approval: 12 months. Member must continue to meet criteria listed above and ALL the following: • Member remains ineligible to transition to generic hydrocortisone tablets or crush tablets and mix in soft foods.

Drug	Prior Authorization Criteria
	• Member has exhibited improvement or stability of disease symptoms (e.g., improved cortisol levels over baseline, improvement in symptoms such as hypotension, hyponatremia). *Alkindi Sprinkles available only via Anovo® Specialty Pharmacy. Call AnovoRx at 1-833-343-2500 or fax prescription form available at Alkindi Sprinkle Patient Referral Form.

Altuviiio (Antihemophilic Factor -Recombinant [Fc-VWF-XTEN Fusion Protein-ehtl])	**Candidates for treatment with Altuviiio must meet ALL the following criteria:**
	
	• Prescribed by a hematologist
	• Diagnosis of severe congenital FVIII deficiency (hemophilia A) with documentation of <1% endogenous Factor VIII activity
	• Used as treatment of ONE of the following
	  ○ Routine prophylaxis to reduce the frequency of bleeding episodes
	  ○ On-demand treatment and control of bleeding
	  ○ Perioperative management of bleeding
	• Tried and failed or unable to tolerate TWO of the following Standard Half-Life Recombinant Factor VIII products:
	  ○ Advate
	  ○ Kogenate FS
	  ○ Xyntha
	• Tried and failed or unable to tolerate TWO of the following Extended Half-Life Recombinant Factor VIII products:
	  ○ Eloctate
	  ○ Jivi (if patient is 12 years or older)
	  ○ Esperoct
	• Tried and failed or unable to tolerate Hemlibra (emicizumab)
	
	Initial Approval: 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	Continued Approval: 12 months. Patient must meet all criteria above.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	Dosing and Administration:
	• Each Altuviiio vial label states FVIII activity in international units (IU or unit).
	• For routine prophylaxis: 50 IU/kg once weekly.
	• For on-demand treatment and control of bleeding episodes, and perioperative management: Single dose of 50 IU/kg; additional doses of 30 or 50 IU/kg every 2 to 3 days may be considered.
	• To achieve a specific target FVIII activity level, use the following formula: Dosage (IU) = Body Weight (kg) × Desired FVIII Increase (IU/dL or % normal) × 0.5 (IU/kg per IU/dL).

Drug	Prior Authorization Criteria

Alunbrig
(Brigatinib)
	Candidates for treatment with brigatinib (Alunbrig) must meet ALL the following criteria:
	
	• Prescribed by a hematologist or oncologist
	• Patient is ≥18 years of age
	• Patient has anaplastic lymphoma kinase (ALK)-positive disease
	• Patient has one of the following:
	  ○ Advanced, recurrent, or metastatic non-small cell lung cancer that has progressed on or patient is intolerant to alectinib (Alecensa)
	  ○ Advanced, recurrent, or metastatic inflammatory myofibroblastic tumor
	  ○ Inoperable myofibroblastic tumor
	  ○ Relapsed or refractory Erdheim-Chester Disease
	
	Initial Approval: 12 months with quantity limited to 30 tablets per 30 days.
	
	Continued Approval: 12 months with quantity limited to 30 tablets per 30 days. For continued approval for treatment with Alunbrig, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread
	
	For new members who were initiated on Alunbrig outside of KPGA: Patient should meet ALL the following criteria:
	• Prescribed by hematology/oncology
	• Patient is ≥18 years of age
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread
	• Quantity limit of 30 tablets per 30 days.

Alyftrek
(Vanzacaftor, Tezacaftor, and Deutivacaftor)
	Candidates for treatment with Alyftrek (vanzacaftor, tezacaftor, and deutivacaftor) should meet ALL of the following criteria:
	
	• Prescribed by adult or pediatric pulmonology (or other designated specialist) with expertise in providing cystic fibrosis (CF) care
	• Confirmed diagnosis of CF
	• Age 6 years or older
	• Documentation of at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on clinical and/or in vitro data (see table 1).
	• Documentation of **ONE** of the following:
	  ○ Inadequate response (after at least a 3-month trial), intolerance or contraindication to Trikafta (elexacaftor/ivacaftor/tezacaftor)
	  ○ A CFTR gene mutation that is responsive to Alyftrek but is not responsive to Trikafta
	• Do not approve in any of the following cases:

Drug	Prior Authorization Criteria
	○ If ALT or AST is > 5X the upper limit of normal (ULN) **OR** the ALT or AST is > 3X ULN concomitantly with a bilirubin that is > 2X ULN ○ Prior solid organ or hematological transplantation, unless approved by transplant center ○ Dual therapy with another CFTR potentiator [i.e., Kalydeco (ivacaftor), Orkambi (ivacaftor/lumacaftor), Symdeko (ivacaftor/tezacaftor), Trikafta (elexacaftor/tezacaftor,ivacaftor)] ○ Severe hepatic impairment (Child-Pugh Class C) ○ Concomitant use with strong CYP3A inducers (e.g. rifampin, St. John's Wort, phenobarbital, carbamazepine, phenytoin) Table 1: List of CFTR Gene Variants Responsive to Alyftrek **Note: Refer to the Alyftrek Prescribing Information for additional FDA-approved CFTR gene variants that may not be listed below.* **Based on Clinical Data*** *A455E* | *G551D*† | *L1077P*† | *R352Q* | *S1251N* | *S945L* | *W1098C*† *D1152H* | *G85E*† | *L206W* | *R75Q* | *S549N* | *V562I* | *W1282R* *F508del*† | *H1054D* | *M1101K*† | *S1159F* | *S549R* | *V754M* | *Y563N*† *G1244E* | *I336K* | *R1066H*

Drug	Prior Authorization Criteria

Based on in vitro Data‡						
1140-1151dup	*D443Y*	*G1265V*	*I1398S*	*M150R*	*R1283M*	*S977F*
1461insGAT	*D443Y;G576A;R668C§*	*G126D*	*I148L*	*M152L*	*R1283S*	*S977F;R1438W§*
1507_1515del9	*D513G*	*G1298V*	*I148N*	*M152V*	*R1438W*	*T1036N*
2055del9	*D529G*	*G1349D*	*I148T*	*M265R*	*R170H*	*T1053I*
2183A→G	*D565G*	*G149R*	*I148T;H609R§*	*M348K*	*R248K*	*T1057R*
2851A/G	*D567N*	*G149R;G576A;R668C§*	*I175V*	*M394L*	*R258G*	*T1086A*
293A→G	*D572N*	*G178E*	*I331N*	*M469V*	*R297Q*	*T1086I*
3007del6	*D579G*	*G178R*	*I336L*	*M498I*	*R31C*	*T1246I*
3131del15	*D58H*	*G194R*	*I444S*	*M952I*	*R31L*	*T1299I*
3132T→G	*D58V*	*G194V*	*I497S*	*M952T*	*R334L*	*T1299K*
3141del9	*D614G*	*G213E*	*I502T*	*M961L*	*R334Q*	*T164P*
3143del9	*D651H*	*G213E;R668C§*	*I506L*	*N1088D*	*R347H*	*T338I*
314del9	*D651N*	*G213V*	*I506T*	*N1195T*	*R347L*	*T351I*
3195del6	*D806G*	*G226R*	*I506V*	*N1303I*	*R347P*	*T351S*
3199del6	*D836Y*	*G239R*	*I506V;D1168G§*	*N1303K‡*	*R352W*	*T351S;R851L§*
3331del6	*D924N*	*G253R*	*I521S*	*N186K*	*R516G*	*T388M*
3410T→C	*D979A*	*G27E*	*I530N*	*N187K*	*R516S*	*T465I*
3523A→G	*D979V*	*G27R*	*I556V*	*N396Y*	*R553Q*	*T465N*
3601A→C	*D985H*	*G314E*	*I586V*	*N418S*	*R555G*	*T501A*
3761T→G	*D985Y*	*G314R*	*I601F*	*N900K*	*R560S*	*T582S*
3791C/T	*D993A*	*G424S*	*I601T*	*P1013H*	*R560T*	*T604I*
3850G→A	*D993G*	*G437D*	*I618N*	*P1013L*	*R600S*	*T908N*
3978G→C	*D993Y*	*G451V*	*I618T*	*P1021L*	*R668C*	*T990I*
4193T→G	*E1104K*	*G461R*	*I807M*	*P1021T*	*R709Q*	*V1008D*
546insCTA	*E1104V*	*G461V*	*I86M*	*P111L*	*R74Q*	*V1010D*
548insTAC	*E1126K*	*G463V*	*I980K*	*P1372T*	*R74Q;R297Q§*	*V1153E*
A1006E	*E116K*	*G480C*	*K1060T*	*P140S*	*R74Q;V201M;D1270N§*	*V11I*
A1025D	*E116Q*	*G480D*	*K162E*	*P205S*	*R74W*	*V1240G*
A1067P	*E1221V*	*G480S*	*K464E*	*P439S*	*R74W;D1270N§*	*V1293G*
A1067T	*E1228K*	*G500D*	*K464N*	*P499A*	*R74W;R1070W;D1270N§*	*V1293I*
A1067V	*E1409K*	*G545R*	*K522E*	*P574H*	*R74W;S945L§*	*V1415F*
A107G	*E1433K*	*G551A*	*K522Q*	*P5L*	*R74W;V201M§*	*V201M*
A1081V	*E193K*	*G551R*	*K951E*	*P67L*	*R74W;V201M;D1270N§*	*V232A*
A1087P	*E217G*	*G551S*	*L1011S*	*P750L*	*R74W;V201M;L997F§*	*V232D*
A120T	*E264V*	*G576A*	*L102R*	*P798S*	*R751L*	*V317A*
A1319E	*E282D*	*G576A;R668C§*	*L102R;F1016S§*	*P988R*	*R75L*	*V322M*
A1374D	*E292K*	*G576A;S1359Y§*	*L1065P*	*P99L*	*R75Q;L1065P§*	*V392G*
A141D	*E384K*	*G622D*	*L1065R*	*Q1012P*	*R75Q;N1088D§*	*V456A*
A1466S	*E403D*	*G622V*	*L1227S*	*Q1100P*	*R75Q;S549N§*	*V456F*

Initial approval: 12 months

- **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**

Continued approval for new and existing members: 12 months. Confirm patient meets all above coverage criteria and is confirmed to be clinically stable by a pulmonologist in the past 12 months. Additionally, patient must have documentation of at least ONE of the following:

- Improved, maintained or a less than expected decline in pulmonary health as demonstrated by reduced pulmonary exacerbations
- Improved or maintained nutritional health as demonstrated by an increase or less than expected decline in BMI

Drug	Prior Authorization Criteria
	• Prescriber attests to patient having a clinically meaningful response to therapy • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**

Intravenous Immune Globulin Products (IVIG):
 	
Preferred: Gammagard Liquid [Immune globulin (Human) IV] – (no PA required)
 	
Secondary preferred: Gamunex-C 10% [Immune globulin (human), IV] – (no PA required)
 	
Non-preferred IVIg Products (listed in alphabetical order, not in order of preference):
Alyglo [Immune globulin (human)-stwk, IV]
 	
Asceniv [Immune globulin (human)-slra]
 	
Bivigam [Immune globulin (human), IV]
 	
Gammagard S/D [Immune globulin (human), IV]
 	
Gammaked [Immune globulin (human), IV]
 	
Gammaplex [Immune globulin (human), IV]
 	
Octagam [Immune globulin (human), IV]
	Gammagard Liquid [immune globulin (human), IV] is KPs preferred IVIG and is available to patients without prior authorization. A documented trial and failure of Gammagard and Gamunex-C is required prior to approval for any non-preferred IVIG products.
	
	Candidates for treatment with non-preferred IVIG must meet ALL the following criteria:
	
	• IVIG is being prescribed for ONE of the following:
	  ○ Primary immunodeficiency (including but not limited to congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies) in patients 17 years and older
	  ○ Idiopathic thrombocytopenic purpura (ITP)
	  ○ Chronic inflammatory demyelinating polyneuropathy (CIDP)
	  ○ Multifocal motor neuropathy
	  ○ Kawasaki syndrome
	  ○ B-cell chronic lymphocytic leukemia (CLL)
	  ○ Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections or pediatric acute onset neuropsychiatric syndrome (PANDAS)
	  ○ Prophylaxis of bacterial infections in pediatric HIV infection
	  ○ Prophylaxis of bacterial infections in bone marrow transplant (BMT)/hematopoietic stem cell transplant (HSCT) recipients
	  ○ Dermatomyositis
	  ○ Polymyositis
	  ○ Myasthenia Gravis
	  ○ Guillain-Barre syndrome
	  ○ Lambert-Eaton myasthenic syndrome
	  ○ Fetal/neonatal alloiummune thrombocytopenia
	  ○ Parovarius B19-induced pure red cell aplasia
	  ○ Stiff-person syndrome
	  ○ Management of immune checkpoint inhibitor-related nervous system adverse events
	• Documented trial and failure or contraindication to preferred Gammagard Liquid 10%, KP's preferred IVIG product, AND Gamunex-C 10%
	
	<u>Initial Approval</u>: 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	• **Approve for administration ONLY in KPGA infusion center, absent director level approval**
	
	<u>Continued Approval</u>: 12 months. Confirm patient meets all above criteria. In addition, continue approval if patient has documented clinical benefit.

Drug	Prior Authorization Criteria
Privigen [Immune globulin (human), IV] **Panzyga** [Immune globulin (human)-ifas, IV] **Qivigy** [Immune globulin (human)-kthm, IV] **Yimmugo** [Immune globulin (human)-dira, IV]	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for administration ONLY in KPGA infusion center, absent director level approval**

Ampyra (Dalfampridine)	**Candidates for treatment with Ampyra should meet ALL the following criteria:**
	
	Ampyra extended-release tablets should be reserved for treatment intended to improve walking capacity in ambulatory patients with multiple sclerosis (MS). **Ampyra is symptomatic treatment only and is not disease-modifying.**
	
	• Must be prescribed by a neurologist
	• Patient has a confirmed diagnosis of MS.
	• Patient is ambulatory with a baseline 25-foot walk between 5 to 45 seconds
	  ○ Documentation of baseline timed 25-foot walk must be submitted by the prescribing physician.
	• Should be used for improvement of speed of ambulation.
	• Physical therapy should be considered and appropriately used before exposing patients to Ampyra
	• Patient must have normal renal function (CrCl > 50 ml/min).
	• Patient does not have a history of seizures
	• For brand name Ampyra, must have a documented allergy/intolerance to the components of generic dalfampridine and a trial of the authorized generic dalfampridine by Mylan if available.
	
	<u>Reasons for Non-coverage:</u>
	Ampyra should NOT be used in patients with any of the following:
	• History of seizures
	• Moderate or severe renal impairment
	  ○ Moderate renal impairment is defined as creatinine clearance (CrCl) of 30 to 50 mL/min; severe impairment is defined as CrCl of less than 30 mL/min.
	• Non-Ambulatory patients
	  ○ Ampyra clinical trials included only ambulatory patients. Therefore, efficacy and safety have not been tested in non-ambulatory patients.
	• Patients taking any other form of fampridine, such as compounded fampridine (4-aminopyridine or 4-AP) products.

Drug	Prior Authorization Criteria
	Initial approval period: 2 months • Patient should be evaluated for response 30-60 days after starting the medication • Patient should be instructed that continuation of the drug depends upon being evaluated for response. • Patients should be advised that the reason for this evaluation is to avoid any unnecessary exposure to the drug and its possible risk. Continued approval: Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, approval will be based on if a response is obtained during the first 2 months that the patient is on the medication, medical records documenting this response, including the walking time for the 25-foot walking test after taking Ampyra along with a new prior authorization request should be submitted prior to continued approval being granted. Continued approval period is 12 months. Response Assessment: A response should become evident within two weeks. Patients should be given a trial of Ampyra lasting from 30 to 60 days and then evaluated for response to determine whether to continue the drug. One objective indicator should be used, along with any subjective indicators, to assess response. • A useful objective assessment is the Timed 25-Foot Walk (T25FW) test. This was the test used in clinical trials qualifying Ampyra for approval. o A baseline should be established at one or more visit after any possible physical therapy and before initiation of Ampyra. o Response to Ampyra can then be evaluated with repeat T25FW tests (or equivalent) after 30 to 60 days of drug. • A subjective assessment should include meaningful improvements in functional parameters or activities of daily living. • Response to Ampyra should be evident within two months. o Continuation of Ampyra in patients who do not have a significant response – a majority of patients in clinical trials – may expose these patients to the risk of seizures without sufficient benefit to justify the risk. o Modest improvements in walking speed or function must be considered against the risk of seizures. o
Amtagvi (Lifileucel)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM OR AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** **Candidates for treatment with Lifileucel must meet ALL the following criteria:** • Age ≥ 18 years • Prescribed by an Oncologist • Patient is diagnosed with unresectable or metastatic melanoma (Stage IIIC or Stage IV) who have progressed following ≥1 prior systemic therapy including a PD-1/PD-L1 blocking antibody [i.e., pembrolizumab (Keytruda), nivolumab (Opdivo)] o **AND** If patient has a documented BRAF V600 mutation, then patient was previously treated with a BRAF inhibitor [i.e., dabrafenib (Tafinlar), encorafenib

Drug	Prior Authorization Criteria

	(Braftovi), vemurafenib (Zelboraf)] with or without a MEK inhibitor [i.e., binimetinib (Mektovi), cobimetinib (Cotellic), trametinib (Mekinst)]
	• Patient must have at least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5 cm in diameter post-resection to generate tumor-infiltrating lymphocyte (TIL) therapy
	• Documented baseline hematologic parameters listed below:
	  ○ Absolute neutrophil count (ANC) ≥ 1000/mm^3
	  ○ Hemoglobin (Hb) ≥ 9.0 g/dL
	  ○ Platelet ≥ 100,000/mm^3
	
	Reasons for Non-coverage:
	• Pregnant or breastfeeding
	• Diagnosed with melanoma of uveal/ocular origin
	• Uncontrolled brain metastases
	• Currently on chronic systemic steroid therapy
	• Patients who have any form of primary immunodeficiency (such as severe combined immunodeficiency disease [SCID] and acquired immunodeficiency syndrome [AIDS])
	• Documented left ventricular ejection fraction (LVEF) < 45% or New York Heart Association (NYHA) functional classification > Class 1
	• Documented forced expiratory volume in 1 second (FEV1) of ≤ 60%
	• Organ allograft or prior cell transfer
	
	Approval: ONE-TIME APPROVAL ONLY
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM OR AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	Dosage and Administration:
	• **Must be administered at an authorized treatment center and may require a level of agreement for administration.**
	  ○ Winship Cancer Institute of Emory University and Northside Hospital are the only authorized treatment centers in GA as of August 2025. Please visit the Amtagvi website to see if additional authorized treatment centers have been added.
	  ○ Additional information concerning administration can be found here: https://www.amtagvi.com/support-and-resources/authorized-treatment-center/

Amyloid Beta-directed Antibodies: **Leqembi/ Leqembi Iqlik** (Lecanemab) **Kisunla**	**Candidates for treatment with Leqembi or Kisunla must meet ALL the following criteria:** **Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).* • Patient is 50-90 years old • Prescribed by a Neurologist or Geriatrician* • BMI >17 and <35

Drug	Prior Authorization Criteria

(Donanemab-azbt)
 	
Note: Leqembi Iqlik is ONLY approved for use after a patient completes 18 months of Leqembi IV therapy
	• Diagnosis of early dementia or mild cognitive impairment (MCI) due to Alzheimer's disease (AD)
	• MRI within 1 year with no evidence of vascular disease or cerebral amyloid angiopathy (see reasons for non-coverage)
	• Baseline cognitive testing within 1 year indicating mild dementia as demonstrated by ONE of the following:
	  ○ Mini-Mental State Examination (MMSE) score ≥ 22 OR
	  ○ Saint Louis University Mental Status (SLUMS) score ≥ 17 OR
	  ○ Montreal Cognitive Assessment (MoCA) score ≥ 17
	• Documentation of ONE of the following:
	  ○ Positive amyloid-beta and p-tau via spinal tap OR
	  ○ Positive amyloid-beta on amyloid positron emission tomography (PET) scan
	• Patient is on AD medications including cholinesterase inhibitors (donepezil, rivastigmine, and galantamine) or N-methyl-D-aspartate antagonists (memantine) for at least 30 days
	• Documentation of ApoE genotyping to assess risk for Amyloid Related Imaging Abnormalities (ARIA) AND patient is not apolipoprotein E E4 (Apo E4) homozygous
	• For **Leqembi-Iqlik**: patient must complete 18 months of Leqembi IV AND have documented poor vein access OR transportation difficulties
	
	*For Medicare Part D coverage, prescriber must be enrolled and participate in a CMS-approved registry
	
	<u>Reasons for Non-Coverage:</u>
	• MRI scan does not show any of the following:
	  ○ Four or more microbleeds
	  ○ Any signs of prior brain hemorrhage 1 cm or more
	  ○ Superficial siderosis
	  ○ Brain tumor other than small meningiomas
	  ○ Signs of prior strokes (i.e., cortical encephalomalacia)
	  ○ Moderate or severe microvascular disease
	  ○ For a full list of exclusions please see IR Practice Recommendations: IR Practice Recommendation Exclusions
	• Stroke, transient ischemic attacks (TIA) or seizure within 1 year prior
	• Clinically significant psychiatric illness within prior six months
	• Any immunological disease which is not adequately controlled, or systemic treatment with immunosuppressants, immunoglobulins, or monoclonal antibodies
	• Any other medical conditions (e.g., cardiac, respiratory, gastrointestinal, renal disease) which is not adequately controlled
	• Malignant neoplasms within three years (except those who have had at least three years of documented uninterrupted remission)
	• Bleeding disorder or platelet abnormalities that are not under adequate control (including a platelet count <50,000 OR INR>1.5)

Drug	Prior Authorization Criteria

	• Thyroid stimulating hormone level above normal range or low serum vitamin B12 level
	• Life expectancy of less than one year
	
	Initial Approval: 6 months.
	
	• Approve IV formulations for administration in KP infusion center only
	
	Continued Approval: 12 months. Confirm patient meets all above coverage criteria and does not meet any criteria for discontinuation listed below.
	• Patient must have repeat cognitive testing within the past 6 months demonstrating mild cognitive impairment as indicated by ONE of the following:
	  ○ Mini-Mental State Examination (MMSE) score ≥ 22 OR
	  ○ Saint Louis University Mental Status (SLUMS) score ≥ 17 OR
	  ○ Montreal Cognitive Assessment (MoCA) score ≥ 17
	• If patient has completed 18 months of Leqembi IV therapy, approve for maintenance dose regimen of IV infusion every 4 weeks
	• For **Leqembi-Iqlik**: if patient has completed 18 months of Leqembi IV AND has documented poor vein access OR transportation difficulties, approve for member to fill Leqembi Iqlik via the outpatient pharmacy benefit only.
	
	For new members who were initiated on Leqembi / Leqembi Iqlik (lecanemab) or Kisunla (donanemab) outside of KPGA:
	• Confirm patient meets all above coverage criteria and doses not meet any criteria for discontinuation listed below.
	
	Criteria for discontinuation:
	• DONANEMAB ONLY: Discontinue after 18-24 months of treatment
	• LECANEMAB ONLY: consider discontinuation after 18-24 months of treatment. If continuing after 18 months of treatment, transition to maintenance dosing of every 4-week IV infusion.
	• Progression to moderate dementia as indicated by ONE of the following:
	  ○ Mini-Mental State Examination (MMSE) score < 22 OR
	  ○ Saint Louis University Mental Status (SLUMS) score < 17 OR
	  ○ Montreal Cognitive Assessment (MoCA) score < 17
	• Patient misses more than two consecutive doses or more than two doses in a six-month period
	• Lack of response to therapy based on physician evaluation of cognition and functional assessments
	• For radiographically moderate or severe ARIA-E or ARIA-H, moderate or severe clinical symptoms of ARIA-E, or symptomatic clinical symptoms of ARIA-H
	• In patients who develop intracerebral hemorrhage greater than 1 cm in diameter

Andembry (Garadacimab-gxii)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**

Drug	Prior Authorization Criteria

	Candidates for treatment with Andembry (garadacimab-gxii) should meet ALL of the following criteria:
	
	• Prescribed by an allergist or immunologist
	• Age ≥ 12 years
	• Diagnosed with hereditary angioedema (HAE) confirmed by ONE of the following:
	  ○ C1 esterase inhibitor (C1-INH) antigenic level below the lower limit of normal; OR
	  ○ C1-INH functional level below the lower limit of normal; OR
	  ○ Normal C1-INH levels and ONE of the following:
	  ▪ Confirmed presence of variant(s) in the F12, ANGPT1, PLG, KNG1, MYOF, and HS3ST6 gene(s)
	  ▪ Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema
	  ▪ Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de novo mutation(s) (i.e., no family history; HAE-unknown)
	• Andembry will be used for prophylaxis against HAE attacks
	• Documentation that other causes of angioedema have been ruled out (e.g., angiotensin-converting enzyme [ACE] inhibitor-induced angioedema, angioedema related to an estrogen-containing drug)
	• Documented trial of or contraindication to ONE of the following agents: Cinryze (C1 esterase inhibitor), Haegarda (C1 esterase inhibitor), Takhzyro (lanadelumab-flyo), or Orladeyo (berotralstat)
	
	<u>Reasons for non-coverage:</u>
	
	• Concurrent use with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], Orladeyo [berotralstat], Dawnzera [donidalorsen]
	• Moderate or severe hepatic impairment (NCI-ODWG Criteria: total bilirubin >1.5 x ULN regardless of AST level)
	
	<u>Initial Approval:</u> 1 month (quantity limit of #2.4mL per 30 days)
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	<u>Continued Approval</u>: 11 months (quantity limit of #1.2mL per 30 days). Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, must have improvement in HAE attacks (reductions in attack frequency or attack severity) compared to baseline.
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**

Drug	Prior Authorization Criteria

Anktiva
(Nogapendekin alfa inbakicept-pmln)
	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	Candidates for treatment with Anktiva (nogapendekin alfa inbakicept-pmln) must meet ALL the following criteria:
	
	• Patient is ≥18 years of age
	• Prescribed by Urologist or Oncologist
	• Documented diagnosis of Bacillus Calmette-Guérin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.
	  ○ Unresponsive defined as persistent/recurrent disease following adequate BCG therapy
	  ▪ Adequate BCG is defined as the administration of ≥5 of 6 doses of an initial induction course plus either of ≥2 of 3 doses of maintenance therapy or ≥2 of 6 doses of a second induction course
	• Patient is ineligible for cystectomy
	• Anktiva will be used in combination with BCG
	• Documented trial, intolerance or contraindication to Adstiladrin AND Keytruda
	
	Reasons for Non-coverage:
	• Pregnancy
	
	Initial Approval: 6 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	Continued Approval: 12 months. Continued approval for treatment with Anktiva (nogapendekin alfa inbakicept-pmln) should meet ALL of the criteria above in addition to the criteria below:
	• Patient has an ongoing compete response defined as ONE of the following (a or b):
	  ○ Patient has negative cystoscopy and meets ONE of the following [(i) or (ii)]:
	  ▪ Negative urine cytology; OR
	  ▪ Malignant urine cytology if cancer found in the upper tract or prostatic urethra and random bladder biopsies are negative; OR
	  ○ Patient has positive cystoscopy with biopsy-proven benign or low-grade Ta non-muscle invasive bladder cancer and negative urine cytology
	• Patient has not received greater than 37 months of therapy (24 doses as maintenance therapy)
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	Dosing and Administration:
	• For intravesical use only

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>
Induction: Intravesical: 400 mcg once a week (in combination with Bacillus Calmette-Guérin [BCG]) for 6 weeks. A second induction course may be administered if complete response is not achieved at month 3
Maintenance: Intravesical: 400 mcg once a week (in combination with BCG) for 3 weeks at months 4, 7, 10, 13, and 19 (for a total of 15 maintenance doses); for patients with an ongoing complete response at month 25 and beyond, maintenance dosing may be administered once weekly for 3 weeks at months 25, 31, and 37 (for a total of 9 additional maintenance doses). The recommended duration of treatment is until disease persistence after second induction, until disease recurrence or progression or unacceptable toxicity, or for a maximum of 37 months
</td></tr>
<tr><td>Anzupgo
(Delgocitinib)</td><td>
Candidates for treatment with Anzupgo (delgocitinib) should meet ALL of the following criteria:

Diagnosed with moderate to severe chronic hand eczema
Prescribed by a dermatologist
Age ≥ 18 years
Documented modified Investigator’s Global Assessment for Chronic Hand Eczema (IGA-CHE) score of 3 or 4
Documented inadequate response, intolerance, or contraindication ALL of the following:

Medium to very high potency topical corticosteroid for a minimum of 2 weeks:

<table>
<tr><th>Medium Potency</th><th>High and Very High Potency</th></tr>
<tr><td>Triamcinolone acet 0.1%, 0.025% O, C</td><td>Betameth diprop aug 0.05% C</td></tr>
<tr><td>Betamethasone val 0.1% C</td><td>Fluocinonide 0.05% O, C, G</td></tr>
<tr><td>Mometasone 0.1% O, C</td><td>Fluocinonoide-emollient 0.05% C</td></tr>
<tr><td>Triamcinolone acet 0.5% C</td><td>Desoximetasone 0.25% C</td></tr>
<tr><td>Betamethasone diprop 0.05% C</td><td>Betamethasone diprop aug 0.05% O, G</td></tr>
<tr><td>Betamethasone val 0.1% L</td><td>Clobetasol 0.05% O, C</td></tr>
</table>
O = oint, C = cream, G = gel, L = lotion

Topical calcineurin inhibitors [Pimecrolimus (Elidel) or tacrolimus (Protopic)] for a minimum of 2 weeks

Documented trial of or contraindication to <u>TWO</u> of the following topical agents:

PDE-4 Inhibitors: [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)]
AhR agonist: Vtama (tapinarof)
JAK inhibitor: Opzelura (ruxolitinib)

<u>Reasons for Non-coverage:</u>

Concurrent use with non-steroidal topicals (examples below)

calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

</td></tr>
</table>

Drug	Prior Authorization Criteria
	○ PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)] ○ JAK inhibitors [e.g., Opzelura (ruxolitinib)] ○ AhR agonists [e.g., Vtama (tapinarof)] • Concurrent use with systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm]) • Concurrent use with other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib]) • Concurrent use with potent immunosuppressants (e.g., azathioprine, cyclosporine) Initial Approval: 4 months (with quantity limited to 60g per 30 days) Continued Approval: 12 months if the patient has a clinically significant benefit from the medication documented by the prescriber specialist.
Apretude (Cabotegravir)	**Candidates for treatment with (cabotegravir) Apretude® should meet all the following criteria:** • Prescribed by an Infectious Disease or HIV Specialist • Age ≥ 12 years • Weight ≥ 35 kg • Prescribed for pre-exposure prophylaxis (PrEP) of HIV • One of the following criteria must be met: ▪ Patient is a cisgender female who has trial, intolerance, or contraindication to emtricitabine/tenofovir disoproxil fumarate (generic Truvada). Cisgender females do not need a trial of Descovy due to a lack of FDA indication in this population. Contraindications to generic Truvada are: ○ DEXA scan showing T-Score < -2.0 ○ eGFR < 60 on at least 2 back to back labs. ○ Unable to take any oral medications documented by inability to swallow or digest or absorb oral medications (e.g., ongoing throat radiation therapy, gastrointestinal surgeries impacting absorption/digestion or oral meds) ○ Patient has a documented diagnosis of current substance use disorder, current psychosis, currently homeless, or currently another specific condition that would interfere with reliably taking oral medications. ▪ Patient has a history of allergy or intolerance to Emtricitabine/tenofovir disoproxil fumarate (generic Truvada) AND Descovy (emtricitabine/tenofovir alafenamide) OR ▪ Patient has a contraindication to generic Truvada or Descovy due to one of the following: ○ DEXA scan showing T-Score < -2.0. ○ eGFR < 30 on at least two back to back labs. ○ Unable to take any oral medications documented by inability to swallow or digest or absorb oral medications (e.g., ongoing throat radiation therapy, gastrointestinal surgeries impacting absorption/digestion or oral meds) ○ Patient has a documented diagnosis of current substance use disorder, current psychosis, currently homeless, or currently another specific condition that would interfere with reliably taking oral medications. Reasons for Non-coverage: ▪ History of hypersensitivity reaction to cabotegravir

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	▪ Currently receiving therapy with oxcarbazepine, carbamazepine, phenobarbital, phenytoin, rifampin, rifapentine Initial approval: 6 months Continued approval: 12 months. Confirm patient meets all above criteria and without reasons for Non-coverage. Criteria for Discontinuation: ▪ Confirmed positive HIV-1 test ▪ Initiation of concurrent therapy with oxcarbazepine, carbamazepine, phenobarbital, phenytoin, rifampin, rifapentine For new members who were initiated on Apretude (cabotegravir) outside of KPGA: ▪ Patient has a history of allergy or intolerance to: ▪ Emtricitabine/TDF (generic Truvada) AND Descovy (emtricitabine/TAF) **-OR-** ▪ Patient has contraindication to generic emtricitabine/TDF (generic Truvada) or Descovy (emtricitabine/TAF) due to one of the following: o DEXA scan showing T-Score < -2.0.eGFR < 30 on at least two back to back labs. Unable to take any oral medications documented by inability to swallow or digest or absorb oral medications (e.g., ongoing throat radiation therapy, gastrointestinal surgeries impacting absorption/digestion or oral meds) o Patient has a documented diagnosis of current substance use disorder, current psychosis, currently homeless, or currently another specific condition that would interfere with reliably taking oral medications. Dosing and Administration: ▪ Optional oral lead in (OLI) therapy: 30mg oral tablet once daily for 28 days. Administer IM initiation injection on the last day of the OLI or within 3 days after ▪ Initiation doses: IM injection of 600mg once every 2 months starting 2 months after last initiation injection* *Note: Apretude initiation and continuation injections can be given up to 7 days before or after the date the patient is scheduled to receive the injections.
Aqneursa (Levacetylleucine)	**Candidates for treatment with Aqneursa should meet ALL the following criteria:** • Prescribed by or in consultation with a neurologist or geneticist • Diagnosed with Niemann-Pick disease type C (NPC) • Documented genetic testing showing pathogenic variants in either the NPC1 gene OR NPC2 gene • Patient is adult or pediatric weighing ≥ 15kg • Patient is NOT taking Miplyffa (arimoclomol) Reasons for Non-coverage:

Drug	Prior Authorization Criteria
	• Females who are pregnant or plan to become pregnant Initial Approval: 3 months with quantity limit of 4 tablets per day. Ordering Information: • Aqneursa enrollment form is downloaded from Aqneursa.com. • Aqneursa is distributed by Curant Health specialty pharmacy.

Aqvesme
(Mitapivat)
	Candidates for treatment with Aqvesme (mitapivat) should meet ALL the following criteria:
	
	• Age ≥ 18 years
	• Prescribed by hematologist or oncologist
	• Diagnosis of anemia with alpha- or beta-thalassemia
	• If receiving frequent transfusions, documentation of the following:
	  ○ A minimum of 6 RBC transfusions within 6 months prior to receiving treatment
	• If not receiving frequent transfusions, documentation of the following:
	  ○ No more than 5 RBC transfusions within 6 months prior to receiving treatment
	
	Reasons for Non-Coverage:
	• Liver cirrhosis (Child-Pugh Class A, B, or C)
	
	Initial Approval: 6 months
	
	Continued Approval: 12 months
	
	Ordering Information:
	Aqvesme is available only through the Aqvesme REMS program *(prescribers, pharmacies, and patients must be certified/enrolled);* further information available at **https://www.aqvesmerems.com**

Arcalyst
(Rilonacept)
	Candidates for use of Arcalyst for the treatment of cryopyrin-associated periodic syndromes (CAPS) should meet ALL the following criteria:
	
	• Diagnosis of cryopyrin-associated periodic syndromes (CAPS)
	• Patient has documented laboratory evidence of a genetic mutation in the Cold-Induced Auto-inflammatory Syndrome 1 (CIAS1- sometimes referred to as the NLRP3).
	• There is clinical documentation that the patient is experiencing classic symptoms of CAPS in either criteria below:
	  ○ Familial Cold Auto-Inflammatory Syndrome (FCAS) - recurrent episodes of rash, fever/chills, and joint pain following exposure to mild cold environment (e.g., cool breeze, air conditioning). Symptoms generally last for up to 24 hours.
	  ○ Muckle-Wells Syndrome (MWS) - chronic fever and rash sometimes exacerbated by generalized cold exposure. Episodes can last up to 2-3 days.
	• There is clinical documentation of significant functional impairment leading to limitations of activities of daily living (ADLs).
	• Failed, intolerant, or allergic to at least one of the following:
	  ○ Anakinra (Kineret) injection

Drug	Prior Authorization Criteria
	○ Canakinumab (Ilaris) injection Reasons for Non-coverage: • Concurrent use of live vaccines or tumor necrosis factor • Chronic or active infections • Untreated latent tuberculosis • Age ≤ 11 years Initial approval period: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued approval: 24 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continued approval will be based on based on physician documentation of disease stability and improvement. **Candidates for use of Arcalyst for the treatment or reduction in risk of recurrent pericarditis (RP) should meet ALL the following criteria**: • Patient has a history of Recurrent Pericarditis • Prescriber is a cardiologist or a rheumatologist • Age ≥ 12 years • The patient had at least 2 episodes of acute pericarditis • The patient has TWO of the following pericarditis related symptoms: chest pain, friction rub, ECG showing diffuse ST-segment elevation or PR-segment depression, and new or worsening effusion • CRP level of at least 1 mg per deciliter • The patient had a trial, failure or contraindication to at least two of the following: ○ Nonsteroidal anti-inflammatory drugs ○ Colchicine ○ Corticosteroids Reasons for Non-coverage: • Arcalyst will NOT be used concurrently with other IL-1 inhibitors (e.g., Ilaris [canakinumab], Kineret [anakinra]) Initial Approval: Approve for 4 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Initial dose: Approve for member to fill via the outpatient pharmacy benefit only (with nurse visit scheduled for injection teaching)**

Drug	Prior Authorization Criteria
	• **Maintenance dose: Approve for member to fill via the outpatient pharmacy benefit only.** Continued Approval: 12 months. Continued approval will be based on documented improvement in pericarditis symptoms For new members who were initiated on Arcalyst outside of KPGA: approve medication if patient is confirmed to be clinically stable on it by a Specialist in the last 6 months. For existing members who have previously met the full criteria above: documented adequate response and tolerance of medication during specialist follow up in the last 12 months
Arikayce (Amikacin Liposomal Inhalation)	**Candidates for treatment with Arikayce must meet ALL the following criteria:** • Documented Diagnosis of Mycobacterium Avium Complex (MAC) lung disease AND • Patient has not achieved negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy (e.g., macrolide, rifampin, & ethambutol) within the past 12 months. • Prescribed by Infectious Disease or Pulmonology • Documented reason member cannot utilize amikacin injection via nebulizer Initial approval: 6 months Continued approval: 12 months. Confirm patient meets all above criteria. In addition, continued approval will be based on with documentation of negative sputum cultures

Aubagio
(Teriflunomide)
 	
Preferred:
 	
Teriflunomide (generic Aubagio)
Available on the COM formulary
	Candidates for treatment with Aubagio should meet ALL the following criteria:
	
	• Documented diagnosis of relapsing-remitting multiple sclerosis (RRMS)
	• Prescribed by a Neurologist
	• Females of childbearing age (12-50 years of age) should have a baseline negative pregnancy test (within 1 month) AND agreement to be on two forms of reliable birth control (confirm order for IUD or another contraceptive)
	• Documented negative PPD (tuberculin) test
	• Patient has tried generic teriflunomide and had an intolerance or allergic reaction that is likely due to the **inactive** components of the generic medication and cannot be explained by other clinical or lifestyle factors
	  ○ Note: If the request for coverage of brand Aubagio is based upon disease progression or side effects due to the active ingredient teriflunomide (e.g., GI intolerance, LFT abnormalities, hair loss) the request will be denied unless the member meets the full criteria
	  ○ Note: If the physician's request for coverage of brand Aubagio is based upon the physician's and/or member's unwillingness to change to a preferred alternative, the request will be denied unless the member meets the full criteria
	• Documented persistent or severe intolerance or relative contraindication to ALL therapeutic alternatives: interferon beta 1b (Betaseron), glatiramer acetate (Glatopa) and dimethyl

Drug	Prior Authorization Criteria

	fumarate.
	Reasons for Non-coverage:
	
	Aubagio should NOT be used in patients with ANY of the following:
	• Pre-existing hepatic disease or total bilirubin, ALT or AST greater than 2 times the upper limit of normal
	• Clinical conditions or medications which could potentially affect or worsen hepatic function
	• Current leflunomide treatment
	• Pregnancy or lactation
	
	Initial approval period: 1 year
	
	Continued approval: 1 year. Continued approval for treatment with Aubagio should meet ALL the following criteria:
	
	• For new members who were initiated on Aubagio outside of KPGA: patient must meet the full criteria above for approval of Aubagio
	• For existing members who have previously met the full criteria above:
	  ○ Documented beneficial effect from therapy during neurology follow up
	  ○ Confirmed trial and failure of generic teriflunomide and all preferred alternatives as described above
	
	Ordering information:
	
	Aubagio is available through the KP Specialty Pharmacy. If approved for coverage, prescribers must complete the KP-SP Aubagio Order Form and fax it to the KP-Specialty Pharmacy (1-650-301-5790).

CAR-T Therapy **Aucatzyl** (Obecabtagene autoleucel)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** **Candidates for treatment with Aucatzyl (obecabtagene autoleucel) should meet ALL the following criteria:** • Prescribed by an Oncologist • Age ≥ 18 years • Diagnosed with relapsed/refractory B-cell precursor acute lymphoblastic leukemia (ALL) • Confirmed CD19 tumor expression • Confirmed morphological disease in the bone marrow (greater than or equal to 5% blasts) at screening • Patient received or plans to receive lymphodepleting chemotherapy prior to infusion of Aucatzyl ○ e.g., lymphodepleting chemotherapy regimen: fludarabine/ cyclophosphamide • Patient has not been previously treated with CAR-T therapy

Drug	Prior Authorization Criteria
	○ Examples of CAR-T therapy include: Aucatzyl (obecabtagene), Tecartus (brexucabtagene autoleucel), Breyanzi (lisocabtagene maraleucel), Kymriah (tisagenlecleucel), Yescarta (axicabtagene) and Abecma (idecabtagene vicleucel) • Additional criteria for patients with Philadelphia chromosome positive (Ph+) ALL: ○ Patient has documented inadequate response or intolerance to at least two tyrosine kinase inhibitors (TKIs) **OR** ○ Patient has documented contraindication to TKI therapy i. NOTE: examples of TKI therapy include imatinib (Gleevec), dasatinib (Sprycel), nilotinib (Tasigna), ponatinib (Iclusig), bosutinib (Bosulif) Reasons for Non-coverage: • Presence of fungal, bacterial, viral, or other infection that is uncontrolled or require intravenous (IV) antimicrobials for management. Simple urinary tract infection (UTI) and uncomplicated bacterial pharyngitis are permitted if responding to active treatment. • Known infection with HIV (detectable viral load) • Hepatitis B (HBsAG positive and detectable viral load) • Hepatitis C virus (anti-HCV positive and detectable viral load) • Active graft versus host disease • Diagnosis of Burkitt's lymphoma/leukemia • Diagnosis of Chronic Myelogenous Leukemia (CML) lymphoid in blast crisis Initial Approval: ONE TIME TREATMENT ONLY (split dose infusion). At this time, Aucatzyl is intended as a one-time (split dose infusion) treatment. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** Continued Approval: Not applicable. CAR-T is intended as a one-time (split dose infusion) treatment. Dosing and Administration: AUCATZYL CAR T-cell therapy is available only at Authorized Treatment Centers. Please see following link to locate a center: https://www.aucatzylhcp.com/atc-locator/
Augtyro (Repotrecitinib)	**Candidates for treatment with repotrectinib should meet ALL the following criteria:** • Prescribed by an oncologist • Patient is ≥18 years of age • Diagnosed with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) Reasons for Non-Coverage: • Pregnancy or lactation Initial Approval Period: 12 months

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Continued Approval Period: 12 months if patient meets ALL the initial criteria above and patient does not show evidence of progressive disease on Augtyro therapy.
Auvelity (Dextromethorphan/ Bupropion)	**Candidates for treatment with Auvelity should meet ALL the following criteria PLUS the individual disease state criteria that follow:** • Patient does not have diagnosis of seizures • Patient does not have current or prior diagnosis of bulimia or anorexia nervosa • Then, follow the disease state specific criteria below, based on diagnosis: Diagnosis of Moderate to Severe Major Depressive Disorder (MDD) • Patient is ≥18 years of age • Prescribed by Psychiatry • Inadequate treatment response after documented adequate therapeutic trial (defined as minimum or 6 weeks) to **at least 4** agents from various drug classes including the following unless contraindication: o One to two selective serotonin reuptake inhibitors (SSRIs) (e.g., sertraline, escitalopram) o One to two serotonin and norepinephrine reuptake inhibitors (SNRIs) (e.g., venlafaxine, duloxetine) o One to two atypical antidepressants (e.g., bupropion, mirtazapine) o One to two serotonin modulators (e.g., vilazodone, Trintellix) Diagnosis of Agitation Associated with Dementia due to Alzheimer's Disease • Prescribed by Geriatrics, Neurology, or Psychiatry • Inadequate response (trial of at least 2 months), intolerance, or contraindication to ALL the following: o One SSRI (e.g. citalopram, sertraline) o One atypical antipsychotic (e.g., aripiprazole, olanzapine, quetiapine, risperidone) Initial Approval: 12 months Continued Approval: 12 months. Continue approval if the following criteria are met: For new members who were initiated on Auvelity outside of KPGA: Confirm patient meets all medication trials in the initial coverage criteria and has a documented clinically significant benefit from the medication during Specialist follow-up in the last 12 months. For existing members who have previously met the full criteria above: Documented clinically significant benefit from the medication during Specialist follow-up in the last 12 months
Avastin Intravenous (Bevacizumab) **NOTE:** Avastin for ophthalmic related disorders does not	**Candidates for treatment with Avastin Intravenous should meet ALL the following criteria:** • Medication is prescribed by hematologist or oncologist • Patient has a diagnosis of ONE of the following: o AIDS-related Kaposi Sarcoma o Breast cancer o Cervical cancer o CNS cancer

Drug	Prior Authorization Criteria
require medical necessity review.	○ Colorectal cancer ○ Endometrial carcinoma ○ Epithelial ovarian, fallopian tube, or primary peritoneal cancer ○ Malignant pleural mesothelioma ○ Non-small cell lung cancer ○ Renal cell carcinoma ○ Soft tissue sarcoma ○ Vulvar cancer • Patient has documented intolerance, contraindication, adverse event, or disease progression after <u>at least 2</u> infusions of the following AND the same intolerance, contraindication, or adverse event would not be expected to occur with Avastin: ○ Mvasi (KP's preferred bevacizumab biosimilar product **AND** ○ One additional bevacizumab biosimilar product (e.g., Alymsys, Vegzelma, Zirabev, etc) ○ **NOTE:** Bevacizumab biosimilar products do not require medical necessity review. <u>Approval period</u>: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service) for BRAND Avastin ONLY.** <u>Continued approval:</u> 12 months. Continue approval if the following criteria are met: • Member continues to meet the above coverage criteria • Member is responding positively to therapy as defined by stabilization or disease or decrease in size of tumor or tumor spread • Absence of unacceptable toxicity from the drug. ○ Examples of unacceptable toxicity include gastrointestinal perforation, surgical/wound healing complications, hemorrhage, arterial and venous thromboembolic events, uncontrolled hypertension, posterior reversible encephalopathy syndrome (PRES), nephrotic syndrome, severe infusion reactions, ovarian failure, congestive heart failure AND • Not prescribed for CNS cancer symptom management • Treatment for CNS symptom management may NOT be renewed • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service) for BRAND Avastin ONLY.**
Avlayah (Tividenofusp alfa-eknm)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** **Candidates for treatment with Avlayah (tividenofusp alfa-eknm) should meet ALL of the following criteria:**

Drug	Prior Authorization Criteria

	**Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel*
	
	• Prescribed by a geneticist
	• Patient is a male that weighs ≥ 5 kg
	• Documented diagnosis of Hunter syndrome (Mucopolysaccharidosis type II, MPS II) confirmed by a geneticist with ALL of the following:
	  ○ Mutation in theiduronate-2-sulfatase (IDS) gene
	  ○ At least one of the following:
	  ▪ Positive/elevated urinary glycosaminoglycans (GAGs) or
	  ▪ Reduced IDS activity in plasma, white blood cells, and/or skin fibroblasts consistent with MPS II (≤10% of the lower limit of the normal range)
	• Documentation that the patient does not have advanced neurologic impairment, such as severe cognitive decline, minimal ability to communicate or interact meaningfully, or profound functional dependence.
	• Patient is not receiving Avlayah in combination with Elaprase (idursulfase) or other enzyme replacement therapy.
	• Documentation that patient does not have non-neuronopathic MPS II
	
	<u>Initial Approval:</u> 6 months
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	<u>Continued Approval:</u> 12 months. Continue approval if the following criteria are met:
	
	<u>For new members who were initiated Avlayah outside of KPGA</u>: Confirm patient meets all above coverage criteria has a documented clinically significant benefit from the medication during Geneticist follow-up in the last 12 months.
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	<u>For existing members who have previously met the full criteria above</u>:
	
	• Documented clinical benefit or has stable disease [e.g., reduced cerebrospinal fluid heparan sulfate (CSF HS), maintained neurologic or functional status, preserved development, or caregiver-reported benefit] during Geneticist follow up in the past 12 months.
	• Documented adherence to infusion appointments or follow-up labs and assessments
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	<u>Ordering Information:</u>
	
	• Avlayah is available through Cardinal Health (specialty distributor) or Orsini Specialty Pharmacy.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
Avmapki-Fakzynja (Avutometinib-defactinib)	**Candidates for treatment with Avmapki-Fakzynja (avutometinib-defactinib) should meet ALL the following criteria:** • Prescribed by Hematologist/Oncologist • Age ≥ 18 years • Diagnosed with KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) • Patient has received prior systemic therapy including platinum-based therapy Reasons for Non-coverage: • Lactation Initial Approval: 6 months Continued Approval: 12 months • Documented benefit and/or tolerance to therapy

Awiqli (insulin icodec-abae)	**Candidates for treatment with Awiqli should meet ALL the following criteria:**
	
	Diagnosis of T2D:
	• Prescribed by a Kaiser Permanente affiliated Endocrinology or Primary Care clinician
	• Age ≥ 18 years
	• A1c >7% in past 1 month
	• Inadequate response, intolerance, or contraindication to ALL of the following:
	  ○ Insulin glargine-yfgn or comparable (e.g. Lantus)
	  ○ Tresiba 100 or 200 unit/mL
	  ○ Insulin glargine 300 unit/mL or insulin glargine max 300 unit/mL
	
	Initial Approval: 6 months
	• Approve for member to fill via the outpatient pharmacy benefit only
	
	Continued Approval: 12 months. Continue approval if the following criteria are met: A1C lowering since initiation or A1C now at goal

Ayvakit (Avapritinib)	**Candidates for treatment with avapritinib (Ayvakit) must meet ALL the following criteria:**
	
	• Prescribed by a hematologist or oncologist
	• Patient is ≥18 years of age
	• Patient has the diagnosis of ONE of the following:
	  ○ Non-metastatic, locally advanced, bulk gastrointestinal stromal tumor (GIST) that may benefit from neoadjuvant therapy to reduce surgical morbidity **AND** presence of platelet-derived growth factor receptor alpha (PDGFRA) Exon 18 D842V mutation
	  ○ Metastatic, unresectable GIST **AND** presence of PDGFRA Exon 18 D842V mutation
	  ○ Advanced systemic mastocytosis (AdvSM) (e.g., aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (MS-AHN), and mast cell leukemia) **AND** platelet count ≥50 x 10^9/L

Drug	Prior Authorization Criteria
	○ Symptomatic indolent systemic mastocytosis despite use of 2 or more supportive care agents (e.g., H1 or H2 antihistamine, leukotriene inhibitor, proton pump inhibitors, corticosteroids, cromolyn sodium, omalizumab, or osteoclast inhibitors) **AND** platelet count ≥50 x 10^9/L Initial Approval: 12 months with quantity limited to 30 tablets per 30 days. Continued Approval: 12 months with quantity limited to 30 tablets per 30 days. For continued approval for treatment with Ayvakit, patient should meet ALL the following criteria: • Patient continues to meet the above criteria • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread For new members who were initiated on Ayvakit outside of KPGA: Patient should meet ALL the following criteria: • Prescribed by hematology/oncology • Patient is ≥18 years of age • Patient has a diagnosis of ONE of the following: ○ Metastatic unresectable GIST AND a PDGFRA mutation ○ AdvSM ○ ISM • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread • Quantity limited to 30 tablets per 30 days.
Bafiertam (Monomethyl fumarate)	**Candidates for treatment with Bafiertam should meet ALL the following criteria:** • Age ≥ 18 years • Documented diagnosis of relapsing multiple sclerosis (MS) • Prescribed by a neurologist • Bafiertam is prescribed for use as monotherapy disease-modifying treatment for MS • CBC within the past 6 months shows normal WBC and lymphocyte counts • For females of child-bearing age (12-50 years of age), a baseline negative pregnancy test within the past month AND either a prescription for birth control (IUD or other contraceptive) or documentation of the patient declining contraception and being counseled of the potential risk of pregnancy • Documented persistent or severe intolerance* or contraindication to ALL therapeutic alternatives: Interferon beta 1b (Betaseron), glatiramer acetate (Glatopa) and teriflunomide • Documented adequate trial of dimethyl fumarate with persistent GI intolerance despite attempts to mitigate as evidenced by the following ○ Confirm dimethyl fumarate was initiated by titration: 120 mg twice a day for 7 days followed by maintenance dose of 240 mg twice a day ○ Confirm documented attempts to manage GI side effects including administering with food and counseling that GI side effects may reduce after 1 month on therapy ○ Confirm prescription was filled by patient for at least 90 days and intolerance persisted despite documented attempts to manage and mitigate the GI side effects

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• Documented trial of diroximel fumarate (Vumerity) with persistent GI intolerance despite attempts to mitigate *NOTE: Injection fatigue or fear of needles is not a reason for intolerance or inadequate response. Reasons for Non-coverage: Monomethyl fumarate (Bafiertam) should NOT be used in patients with any of the following: • Lymphocyte count < 0.5 x 10^9/L for over 6 months • Signs and symptoms of serious infection • JCV antibody positive, previously treated with Tysabri and sustained lymphocyte count < 0.8 x 10^9/L on two or more lab tests over ≥ 3 months • ALT or AST elevation 3X normal or higher or severe liver disease • Pregnancy Initial approval period: 1 year Continued approval period: 1 year For new members who were initiated on monomethyl fumarate (Bafiertam) outside of KPGA, continue approval for treatment with Bafiertam if ALL the following criteria are met: • Confirm documentation that patient had a persistent GI intolerance to dimethyl fumarate (generic Tecfidera) AND diroximel fumarate (Vumerity) that was reduced with Bafiertam • Confirm documented history of persistent or severe intolerance or contraindication to ALL therapeutic alternatives: Interferon beta 1b (Betaseron), glatiramer acetate (Glatopa) and teriflunomidePatient has had a visit with MS Specialist and confirmed to be stable on the therapy and discussed consideration of IV rituximab as a DMT alternative with convenient dosing. For existing members who have previously met the full criteria above, continue approval for treatment with Bafiertam if ALL the following criteria are met: • Documented beneficial effect from therapy during neurology follow up • CBC with differential including lymphocyte count obtained 6 months after initiation of treatment then at least once every 12 months • Lymphocyte count > 0.5 x 10^9/L • No signs and symptoms of serious infection
Balversa (Erdafitinib)	**Candidates for treatment with Balversa should meet ALL the following criteria:** • Diagnosis of locally advanced or metastatic urothelial carcinoma (mUC) with fibroblast growth factor receptor (FGFR) 3 genetic alterations • Patient has FGFR3 genetic alterations in tumor specimens as detected by an FDA-approved companion diagnostic ○ Information on FDA-approved tests for the detection of FGFR3 alterations in urothelial cancer is available at: http://www.fda.gov/CompanionDiagnostics • Prescribed by hematology/oncology.

Drug	Prior Authorization Criteria

	• Patient is ≥18 years of age
	• Disease has progressed during or following at least one line of systemic therapy. Such as: prior platinum-containing chemotherapy (e.g., cisplatin, oxaliplatin) or checkpoint inhibitor therapy (e.g., Keytruda (pembrolizumab), Opdivo (nivolumab), Tecentriq (atezolizumab), Imfinzi (durvalumab), and Bavencio (avelumab)).
	• Patient has ONE of the following:
	  ○ Patient is NOT eligible for treatment with PD-1 (e.g., pembrolizumab, nivolumab, cemiplimab) or PD-L1 (e.g., atezolizumab, avelumab, duravalumab) inhibitor therapy
	  ○ Patient is eligible for treatment with PD-1 or PD-L1 inhibitor therapy AND has received treatment with a PD-1 or PD-L1 inhibitor but disease continues to progress or is intolerant
	
	Reasons for Non-coverage:
	• Unable to swallow whole tablets
	Initial Approval: 6 months. Quantity limit: 30 day supply / 30 days
	
	Continued Approval: 12 months. Quantity limit: 30 day supply / 30 days.
	Continued approval for treatment with Balversa should meet ALL of the criteria above in addition to the criteria below:
	• Patient does not show evidence of progressive disease while on Balversa therapy
	• Serum phosphate is <9 mg/dL
	• Absence of significant toxicity (e.g., ocular disorders, Grade 2 or greater adverse reactions, etc)
	• Continued monitoring by Hematology/Oncology

Benlysta (Belimumab)	Criteria for the diagnosis of lupus nephritis (LN) class III, IV or V • Prescribed by a Nephrologist or Rheumatologist • Kidney biopsy confirmed lupus nephritis of class III (focal lupus nephritis) or class IV (diffuse lupus nephritis) or class V (membranous lupus nephritis) • Prescribed concomitant standard immunosuppressive regimen consisting of one or more of the following: cyclophosphamide, mycophenolate, azathioprine, calcineurin inhibitor or corticosteroid Reasons for Non-coverage: • Prescribed concomitant voclosporin (Lupkynis) • Baseline eGFR < 30 ml per min per 1.73m^2 of BSA • Patient is currently pregnant Initial Approval: 12 months Continued Approval: 24 months.

Drug	Prior Authorization Criteria
	Approve if confirmed adequate tolerance to medication during Nephrologist or Rheumatologist follow up in the last 6 months. For new members who were initiated on Benlysta for lupus nephritis outside of KPGA: Approve if confirmed history of lupus nephritis per biopsy or lab markers and adequate tolerance to medication during Nephrologist or Rheumatologist follow up in the last 3 months. Criteria for the diagnosis of systemic lupus erythematosus (SLE) • Prescribed by a Rheumatologist or Pediatric Rheumatologist. • Patient has autoantibody-positive SLE (antinuclear antibody titers ≥ 1:80, anti-double-stranded DNA antibodies or both). • Patient does NOT have severe active central nervous system lupus. • Benlysta will not be used in combination with biologics (e.g., Rituxan). • Patient is on concomitant standard-of care with hydroxychloroquine unless contraindicated or intolerant. • History of contraindication, intolerance or inadequate clinical response to at least one of the following: corticosteroid, methotrexate, azathioprine, or mycophenolate. • History of contraindication, intolerance or inadequate clinical response to Saphnelo (anifrolumab) Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Continued Approval: 24 months. Approve if confirmed adequate tolerance to medication during Rheumatologist follow up in the last 6 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** For new members who were initiated on Benlysta for SLE outside of KPGA: Approve if confirmed adequate tolerance and response to medication during Rheumatologist follow up in the last 3 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Dosage and Administration: • SQ administration: Initial use is recommended under supervision of physician; self-injection may occur after proper training.

Drug	Prior Authorization Criteria
Berinert (Human C1 Inhibitor)	**Candidates for treatment with Berinert should meet ALL the following criteria:** • Diagnosis of acute abdominal, facial, or laryngeal hereditary angioedema attacks (HAE) • Prescriber must be an allergist Reasons for Non-coverage: • Long term prophylaxis against angioedema in pediatric or adult patients with HAE. Berinert can be used off label for short-term/pre-procedural prophylaxis Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Continued Approval: 24 months. Confirm patient meets all above criteria. In addition, continued approval will be based on clinical documentation of functional improvement, a decrease in frequency of HAE attack, and an improvement in severity and duration of attacks. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
Besremi (Ropeginterferon alfa-2b)	**Candidates for Besremi should meet ALL of the following criteria:** • Prescribed by Hematologist or Oncologist • Age ≥ 18 years • Diagnosis of polycythemia vera (PV) • Documented inadequate response, intolerance, or contraindication to hydroxyurea or peginterferon alfa-2a Reasons for Non-coverage: • Existence or history of severe psychiatric disorders (e.g., severe depression, suicidal ideation, or suicide attempt) • Hypersensitivity to interferon • Hepatic impairment (Child-Pugh B or C) • Presence or history of active serious or untreated autoimmune disease • Immunosuppressed transplant recipients Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Continued Approval: 12 months. Continued approval for treatment with Besremi should meet ALL the following criteria:

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** <u>For new members who were initiated outside of KPGA:</u> • Hematologist or Oncologist visit • The patient is confirmed stable on therapy • The patient has tried and failed hydroxyurea or peginterferon alfa-2a <u>For existing members who have previously met the full criteria above:</u> • Documented beneficial effect during Hematologist or Oncologist visit
Bimzelx (Bimekizumab)	**Candidates for treatment with Bimzelx should meet ALL the following criteria PLUS the individual disease state criteria below:** • Prescriber is a dermatologist or rheumatologist • Medication is not being used in combination with another biologic or advanced small molecule (e.g., tofacitinib, upadacitinib, apremilast) for the same indication • Then follow the disease state specific criteria below, based on diagnosis: <u>Criteria for diagnosis of plaque psoriasis:</u> • Documented moderate-to-severe plaque psoriasis • Age ≥ 18 years • Inadequate response (of at least a 3-month trial), intolerance and/or contraindication to each of the following: o At least 1 preferred TNF inhibitor (e.g., infliximab (Infliximab-dyyb/Inflectra [preferred]), adalimumab (Amjevita [preferred], Humira) o Ustekinumab product (Yesintek [ustekinumab-kfce] o Cosentyx (secukinumab) o Tremfya (guselkumab) o Skyrizi (risankizumab) • Prescribed 320 mg SC every 8 weeks (without loading dose) for patients transitioning to Bimzelx from another biologic agent. If loading dose is ordered, documented clinical rationale must be provided (ie. actively flaring, BSA >50%, prior ER visits for psoriasis). <u>Criteria for diagnosis of psoriatic arthritis:</u> • Inadequate response (of at least a 3-month trial), intolerance, or contraindication to each of the following: o 1 TNF inhibitor i. Infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade) ii. Adalimumab product (Amjevita [preferred], Humira) iii. Others: Golimumab (Simponi), Certolizumab (Cimzia), Etanercept (Enbrel) o 1 Ustekinumab product (e.g., Yestinek [preferred], Stelara) unless patient has documented axial disease o 1 IL-17 Inhibitor (e.g., Cosentyx (secukinumab), Taltz (ixekizumab)) o 1 IL-23 Inhibitor (e.g., Tremfya (guselkumab), Skyrizi (risankizumab))

Drug	Prior Authorization Criteria
	○ 1 Janus Kinase (JAK) Inhibitor i. Tofacitinib ii. Upadacitinib (Rinvoq)) ○ Abatacept (Orencia) <u>Criteria for diagnosis of spondyloarthritis:</u> • Diagnosis of ankylosing spondylitis or nonradiographic axial spondyloarthritis (nr-axSpA) • Inadequate response (of at least a 3-month trial), intolerance, or contraindication to each of the following: ○ 2 TNF Inhibitors: i. Infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade) ii. Adalimumab product (Amjevita [preferred], Humira) iii. Others: Golimumab (Simponi), Certolizumab (Cimzia), Etanercept (Enbrel) ○ 1 IL-17 Inhibitor: i. Secukinumab product (Cosentyx) ii. Others: Ixekizumab (Taltz) ○ 1 Janus Kinase (JAK) inhibitor: i. Tofacitinib ii. Others: Upadacitinib (Rinvoq) <u>Criteria for diagnosis of hidradenitis suppurativa:</u> • Documented moderate-to-severe hidradenitis suppurativa • The patient has a documented trial, intolerance or contraindication to ALL of the following therapies: ○ Topical clindamycin 1% solution/lotion/gel (minimum of 12 weeks) ○ Intralesional corticosteroids (minimum of 4 weeks) ○ Oral antibiotics (e.g., doxycycline, tetracycline, clindamycin +/- rifampin, erythromycin) (minimum of 10 weeks) ○ Preferred adalimumab product Amjevita (adalimumab-atto) (minimum of 12 weeks) OR Infliximab (minimum of 12 weeks) ○ Cosentyx (Secukinumab) <u>Initial Approval</u>: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Services).** • **Approve for member to fill via the outpatient pharmacy benefit only** <u>Continued Approval:</u> 12 months. Continue approval if the following criteria are met: • <u>For new members who were initiated outside of KPGA</u>: Confirm patient meets all above coverage criteria without reasons for non-coverage and is confirmed to be clinically stable by a specialist during follow-up in the last 6 months.

Drug	Prior Authorization Criteria
	• For existing members who have previously met the criteria: Documented clinically significant benefit (adequate response or optimizing therapy to achieve adequate response) from the medication during specialist follow up in the last 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Services).** • **Approve for member to fill via the outpatient pharmacy benefit only**

Bizengri
(Zenocutuzumab)
	Candidates for treatment with Bizengri (zenocutuzumab) should meet ALL the following criteria:
	
	• Prescribed by an oncologist.
	• Patient is ≥ 18 years of age
	• Patient has ONE of the following:
	  ○ Diagnosis of advanced, unresectable or metastatic non-small cell lung cancer (NSCLC) with neuregulin 1 (NRG1) gene fusion who has disease progression on or after prior systemic therapy
	  ○ Diagnosis of advanced, unresectable or metastatic pancreatic adenocarcinoma with neuregulin 1 (NRG1) gene fusion who has disease progression on or after prior systemic therapy
	  ○ Diagnosis of advanced, unresectable, or metastatic cholangiocarcinoma with a NRG1 gene fusion who has disease progression on or after prior systemic therapy
	
	Reasons for Non-coverage:
	• Grade ≥ 2 interstitial lung disease or pneumonitis
	• Symptomatic congestive heart failure (CHF) (e.g., NYHA Class II-IV)
	• LVEF < 45%
	
	Initial Approval: 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	• **Approve for back-office administration in KP infusion center ONLY.**
	
	Continued Approval: 12 months if the patient has experienced any of the following:
	• Patient continues to meet the above criteria
	• No evidence of progressive disease
	• Absence of unacceptable toxicity from the drug
	  ○ Grade 4 Infusion-related reactions, Hypersensitivity, anaphylactic reactions
	  ○ Grade ≥ 2 Interstitial lung disease (ILD)/Pneumonitis
	  ○ Left ventricular dysfunction (LVEF < 45%) **OR** LVEF less than 50% which has not recovered to within 10% of the baseline
	  ○ Symptomatic congestive heart failure (CHF) (e.g., NYHA Class II-IV)
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	• **Approve for back-office administration in KP infusion center ONLY.**
	
	Dosage and Administration:
	• 750 mg as an IV infusion every 2 weeks until disease progression or unacceptable toxicity

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

Blenrep (Belantamab mafodotin)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	
	Candidates for treatment with Blenrep (belantamab mafodotin) should meet ALL the following criteria:
	• Prescribed by a hematologist/oncologist certified through the Blenrep REMS program
	• Age ≥ 18 years
	• Documented diagnosis of relapsed or refractory multiple myeloma (RRMM)
	• Patient meets ONE of the following criteria:
	  ○ Medication will be prescribed in combination with bortezomib and dexamethasone AND patient has a documented trial of TWO or more prior lines of therapy, including:
	  ▪ A proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib, etc) **AND**
	  ▪ An immunomodulatory agent (e.g., lenalidomide, pomalidomide, thalidomide, etc)
	  ○ Medication will be used as monotherapy AND patient as a documented trial of at least FOUR prior lines of therapy, including at least ONE drug from each of the following categories:
	  ▪ A proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib, etc)
	  ▪ An immunomodulatory agent (e.g., lenalidomide, pomalidomide, thalidomide, etc)
	  ▪ An anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc)
	• Patient has NOT received prior treatment with any BCMA-directed CAR T-cell therapy
	  ○ Examples of BCMA-directed CAR-T cell agents include elranatamab-bcmm (Elrexfio), decabtagene vicleucel (Abecma), and teclistamab-cqyv (Tecvayli)
	
	Initial Approval: 12 months
	• **Please approve for back-office administration only**
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	
	Continued Approval: 12 months. Continue approval if the following criteria are met:
	• No evidence of unacceptable toxicity or disease progression
	• **Please approve for back-office administration only**
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	
	Ordering Information:
	• Blenrep is only available through a restricted Risk Evaluation and Mitigation Strategy (REMS) program that requires the participation of prescribers, patients, and pharmacies (GSK BLENREP REMS)

Drug	Prior Authorization Criteria

Bosulif
(Bosutinib)
	Bosutinib will only be considered for use after a trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction) to KP's preferred therapies, imatinib or dasatinib, OR when there is a medical contraindication to the preferred product, imatinib or dasatinib.
	
	Adult (Age ≥ 18 years) Criteria for treatment with bosutinib for hematologic/oncologic indications. Patient must meet ALL the following:
	• Prescribed by a hematologist/oncologist
	• Age ≥ 18 years
	• Requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
	• Confirmed by detection of the Ph chromosome or BCR-ABL gene by cytogenetic and/or molecular testing prior to initiation of therapy
	• Patient has a diagnosis of **ONE** of the following:
	  ○ Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)
	  ▪ If the patient has had prior therapy with a TKI then ONE of the following requirements must be met:
	  • Resistance to prior therapy with TKI
	  ○ T315I mutation negative
	  • Toxicity or intolerance to prior therapy with a TKI
	  ○ Relapsed or refractory Ph+ acute lymphoblastic leukemia (ALL)
	  ▪ If the patient has had prior therapy with a TKI then ONE of the following requirements must be met:
	  • Resistance to prior therapy with TKI
	  ○ T315I mutation negative
	  • Toxicity or intolerance to prior therapy with a TKI
	
	Pediatric (Ages 1-17 years) Criteria for treatment with bosutinib (patient must meet ALL the following):
	• Prescribed by a hematologist/oncologist
	• Age 1-17 years old
	• Requested dose and frequency is in accordance with FDA-approved labeling, national recognized compendia, and/or evidence-based practice guidelines
	• Diagnosis of Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) **OR** toxicity or intolerance to prior therapy with KP preferred TKI (e.g., imatinib or dasatinib)
	
	Reasons for Non-coverage:
	• T315I mutation positive
	
	Approval period: 1 year
	
	Continued Approval: 1 year. Patient should meet ALL the following:
	• Member continues to meet the above criteria AND
	• Continues to be seen by a hematologist/oncologist AND

Drug	Prior Authorization Criteria
	• Member is responding positively to therapy as defined by stabilization of disease/lack of disease progression or decrease in size of tumor or tumor spread AND • Absence of unacceptable toxicity from the drug AND • NO dual therapy with another tyrosine kinase inhibitor

Blujepa (Gepotidacin Mesylate)	**Candidates for treatment with Blujepa (gepotidacin mesylate) should meet ALL of the following criteria:**
	
	<u>For uncomplicated urinary tract infections:</u>
	• Prescribed by a pediatrician, internal medicine or family practice clinician, urologist, gynecologist, emergency medicine, or infectious disease specialist
	• Patient is female weighing at least 40kg
	• Age ≥ 12 years
	• Diagnosed with uncomplicated urinary tract infection (uUTI)
	• The patient's infection is caused by susceptible Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, or Enterococcus faecalis
	• One of the following is met:
	  ○ Documented culture demonstrating uUTI is caused by a bacteria with sensitivity to gepotidacin AND resistance or contraindication to all alternatives **(**e.g.,Pivya [pivmecillinam], trimethoprim-sulfamethoxazole, nitrofurantoin, fosfomycin, penicillins [e.g., amoxicillin-clavulanate], cephalosporins [e.g., cephalexin], fluoroquinolones [e.g., ciprofloxacin]
	  ○ Blujepa therapy is being continued from an inpatient setting
	
	<u>For uncomplicated urogenital gonorrhea:</u>
	• Prescribed by a pediatrician, internal medicine or family practice clinician, urologist, gynecologist, emergency medicine, or infectious disease specialist
	• Age 12 years or older
	• Weighing at least 45kg
	• Diagnosed with uncomplicated urogenital gonorrhea (uGC)
	• Documented culture demonstrating uGC is caused by *Neisseria gonorrhoeae* with sensitivity to gepotidacin AND resistance or contraindication to ALL alternatives listed below
	  ○ IM ceftriaxone, IM gentamicin PLUS oral azithromycin, and oral cefixime
	
	<u>Reasons for Non-coverage:</u>
	
	▪ Severe renal impairment or kidney failure (eGFR <30 mL/min); or dialysis
	▪ Severe hepatic impairment (Child-Pugh Class C)
	
	<u>Approval:</u>
	
	Please note: Contact the QRM Doctor of the Day for requests for uUTI or uGC treatment for expedited review.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	uUTI: 5 days (one treatment course) uGC: 1 day (one treatment course
Botulinum Toxins: **Preferred:** Botox (Onabotulinum Toxin A) Daxxify (Daxibotulinum Toxin A) **Non-preferred:** **Dysport Type A Injection** **Myobloc Type B Injections** **Xeomin Type A Injection** ****NOTE:** Botox and Daxxify are floor stock for Neurology and Ophthalmology. QRM review is not required for migraine, blepharospasm, or hemifacial spasm indications. Patients should be referred to Neurology for migraine indications or Ophthalmology for blepharospasm or hemifacial spasm indications.	**Candidates for treatment with Botulinum Toxin products should meet ALL the following criteria:** **Non-preferred botulinum toxin products: only approve after trial and failure of preferred products.** Botulinum products are not interchangeable; potency differences may exist between the products. Diagnosis of Migraine: • Botox and Daxxify are floor stock for Neurology. • Patients should be referred to Neurology for migraine indications. • QRM review is not required for internal Neurology prescribers. Diagnosis of Hyperhidrosis • Receive recommendation from Dermatology after failed medical treatment with Drysol and Robinul. • No history of neuromuscular disease. • No recent infection or malignancy in affected area. • No history of hyperthyroidism. Diagnosis of Blepharospasm or hemifacial spasm • Botox and Daxxify are floor stock for Ophthalmology • Patients should be referred to Ophthalmology for blepharospasm or hemifacial spasm • QRM review is not required for internal Ophthalmology prescribers Diagnosis of Cervical Dystonia • Diagnosis of primary cervical dystonia (CD) • Negative impact on quality of life (pain, motor function impairment, abnormal appearance leading to isolation) • Muscles involved can be adequately localized to treat with botulinum toxins • No history of neuromuscular disease • No known hypersensitivity to botulinum toxins, serum albumin, or sucrose • No treatment with botulinum toxins for any other indications within the past 16 weeks Diagnosis of Overactive Bladder • Diagnosis of overactive bladder • Symptoms of urge urinary incontinence, urgency, and frequency • Documented inadequate response to or are intolerant to at least 2 of the following: ○ Oxybutynin

Drug	Prior Authorization Criteria
	○ Trospium ○ Solifenacin ○ Darifenacin Diagnosis of Detrusor Overactivity Associated with a Neurologic Condition • Diagnosis of a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] • Symptoms of urge urinary incontinence, urgency, and frequency • Documented inadequate response to or are intolerant to at least 2 of the following: ○ Oxybutynin ○ Trospium ○ Solifenacin ○ Darifenacin Diagnosis of Upper Limb Spasticity • Complete neurological evaluation. • Trial and failure of two standard therapies as clinically appropriate including muscle relaxant (baclofen or tizanidine), dantrolene and benzodiazepine (e.g., diazepam). • Spasticity in biceps, wrist, or fingers. • No weakness, atrophy, or infection in the target muscle. Diagnosis of Cerebral Palsy • Complete neurological evaluation. • Trial and failure of muscle relaxant (baclofen). • Use limited to the muscles of the arms and legs. • No weakness, atrophy, or infection in the target muscle. Diagnosis of post parotidectomy • Patient must have one of the following diagnoses: ○ Frey's Syndrome ○ Sialoceles ○ Sialorrhea • Must be prescribed by Otolaryngology Diagnosis of Spasmodic dysphonia and muscle tension dysphonia • Patient must have one of the following diagnoses: ○ Synkinesis ○ Spasmodic dysphonia • Must be prescribed by Otolaryngology Initial approval: 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**

Drug	Prior Authorization Criteria

	Continued Approval: Up to 4 treatments per 12 months. Confirm patient meets all above criteria. In addition, continued approval will be based on evidence of response to therapy.
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	Diagnosis of temporomandibular joint (TMJ) disorders
	• Must be prescribed by Otolaryngologist
	• Documented diagnosis of one of the following:
	  ○ TMJ related jaw dysfunction
	  ○ TMJ related pain
	• Documented inadequate control of pain, intolerance, or contraindication to a 6-week trial of:
	  ○ NSAIDs or acetaminophen
	  ○ Skeletal muscle relaxants (e.g., cyclobenzaprine, tizanidine) in patients < 65 years of age
	  ○ TMJ physiotherapy
	  ○ Dental splints if indicated
	
	Diagnosis of masseter hypertrophy
	• Must be prescribed by Otolaryngology
	• Documented masseter hypertrophy accompanied by at least ONE of the following symptoms
	  ○ Chronic bruxism
	  ○ Chewing weakness
	  ○ Dizziness
	  ○ Headache
	  ○ Pain
	• Documented inadequate control of symptoms, intolerance, or contraindication to a 6-week trial of:
	  ○ NSAIDs or acetaminophen for pain symptoms
	  ○ Skeletal muscle relaxants (e.g., cyclobenzaprine, tizanidine) in patients < 65 years of age
	  ○ TMJ physiotherapy
	  ○ Dental splints if indicated
	
	Initial approval: 6 months
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	Continued approval: Up to 4 treatments per 12 months. Confirm patient meets all above criteria. In addition, continued approval will be based on documented improvement in symptoms.

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** NOTES: Botulinum Toxin is Pregnancy Category C and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The FDA has received reports of systemic adverse reactions including respiratory compromise and death following the use of Botulinum toxins types A (Botox, Botox Cosmetic) and B (Myobloc) for both FDA-approved and unapproved uses. The reactions reported are suggestive of botulism, which occurs when Botulinum toxin spreads in the body beyond the site where it was injected. The most serious cases had outcomes that included hospitalization and death, and occurred mostly in children treated for cerebral palsy-associated limb spasticity. Consider these adverse events when reviewing requests.
Braftovi (Encorafenib)	**Candidates for treatment with Braftovi should meet ALL the following criteria:** Diagnosis of Melanoma • Prescribed by a hematologist or oncologist. • Age ≥ 18 years • Cancer is positive for BRAF V600E or BRAF V600K mutation. • Patient has advanced or metastatic melanoma. • Patient has a documented treatment failure, intolerance, or contraindication to vemurafenib (Zelboraf) PLUS cobimetinib (Cotellic). • The medication will be prescribed in combination with binimetinib (Mektovi). Diagnosis of non-small cell lung cancer • Prescribed by a hematologist or oncologist. • Age ≥ 18 years • Patient has advanced or metastatic disease. • Cancer is positive for BRAFV600E mutation. • Patient has a documented treatment failure, contraindication or intolerance to dabrafenib (Tafinlar) PLUS trametinib (Mekinist), KP's preferred treatment, OR vemurafenib (Zelboraf) PLUS cobimetinib (Cotellic), KP's preferred alternative treatment. • The medication will be prescribed in combination with binimetinib (Mektovi). Diagnosis of colorectal cancer • Prescribed by a hematologist or oncologist. • Age ≥ 18 years • Diagnosis of advanced or metastatic colon or rectal cancer • Cancer is positive for BRAFV600E mutation. • Disease has progressed following at least 2 prior treatment regimens. • Medication will be prescribed in combination with Erbitux (cetuximab) OR Vectibix (panitumumab) Reasons for non-coverage: • Patient with wild-type BRAF melanoma, wild-type BRAF colorectal cancer, or wild-type BRAF NSCL.

Drug	Prior Authorization Criteria
	Initial Approval: 12 months • The following quantity limits will apply – 180 capsules per 30 days. Continued Approval: 12 months. For continued approval for treatment with Tafinlar, patient should meet ALL the following criteria: • Patient continues to meet the above criteria. • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. • Quantity limits – 180 capsules / 30 days For new members who were initiated on Tafinlar outside of KPGA: Patient should meet ALL the following criteria: • Prescribed by a hematologist or oncologist. • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. • For melanoma or non-small cell lung cancer, medication will be prescribed in combination with binimetinib (Mektovi). • For colon or rectal cancer, the medication will be prescribed in combination with Erbitux (cetuximab) OR Vectibix (panitumumab)

Brexafemme
(Ibrexafungerp)
	Candidates for treatment with Brexafemme should meet ALL the following criteria:
	
	Criteria for the treatment of vulvovaginal candidiasis (VVC):
	
	• Prescribed by or in consultation with an Infectious Disease or Obstetrics and Gynecology (OB/GYN) specialist
	• Age > 12 years and post-menarche
	• Inadequate treatment response after documented adequate therapeutic trial (defined as full treatment course) of the following OR has contraindication:
	  ○ Oral fluconazole 100, 150 or 200 mg or documented azole resistance demonstrated by culture/sensitivity (C/S) testing AND
	  ○ Intravaginal azole (e.g., miconazole 2% vaginal cream or suppository)
	• Other causes (include but not limited to bacterial vaginosis or trichomoniasis) have been adequately treated or ruled out
	
	Initial Approval: ONE TIME TREATMENT
	
	Continued Approval: N/A
	
	Criteria for reduction in incidence of recurrent vulvovaginal candidiasis (RVVC):
	• Prescribed by or in consultation with an Infectious Disease or Obstetrics and Gynecology (OB/GYN) specialist
	• Age ≥ 12 years and post-menarche
	• Documentation **of 3 or more** VVC episodes in past 12 months
	• Failure of a maintenance course of oral fluconazole defined as 100 mg, 150 mg or 200 mg taken weekly for 6 months or documented intolerance, contraindication, azole resistance demonstrated by C/S testing

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• Other causes (include but not limited to bacterial vaginosis or trichomoniasis) have been adequately treated or ruled out Initial Approval: 6 months Continued Approval: N/A Reasons for Non-coverage: • Concurrent use of Vivjoa (osteseconazole) • Pregnancy • Treatment for non-approved indication such as bacterial vaginosis or trichomoniasis Dosing and Administration: • VVC dose: Take 2 tablets (300 mg) orally every 12 hours for 1 day • RVVC dose: Take 2 tablets (300 mg) orally every 12 hours for 1 day THEN once monthly for 6 months

CAR-T Therapy
 	
Breyanzi
(Lisocabtagene Maraleucel)
	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	
	Candidates for treatment with Breyanzi should meet ALL the following criteria:
	
	• **MUST verify member's benefit information. If member's coverage is through Target, CLOSE the request.** Member must go through Aradigm for this therapy.
	
	For treatment of lymphoma:
	• Prescribed by an Oncologist with expertise in malignant hematology
	• Age ≥ 18 years
	• Histologically confirmed lymphoma consistent with an FDA approved indication for the specific CAR-T therapy.
	• Chemotherapy-refractory disease, defined as one or more of the following:
	  ○ Refractory to two or more lines of therapy with less than partial response to last line of therapy OR
	  ○ Refractory post-autologous hematopoietic stem cell transplantation (HSCT)
	• Subjects must have received adequate prior therapy including at a minimum:
	  ○ anti-CD20 monoclonal antibody unless tumor is CD20-negative AND
	  ○ an anthracycline containing chemotherapy regimen
	  ○ For subjects with transformed FL must have received prior chemotherapy for follicular lymphoma and subsequently have chemo-refractory disease after transformation to DLBCL
	• Adequate organ function defined as (patients with borderline organ function may still be eligible based on center of excellence standards):
	  ○ Left Ventricular Ejection Fraction ≥ 40%
	  ○ Creatinine clearance ≥ 30 mL/min
	  ○ ALT ≤ 5 times the upper limit of normal (ULN) for age

Drug	Prior Authorization Criteria
	○ Total bilirubin < 2 mg/dL ○ Baseline oxygen saturation >91% on room air Reasons for Non-coverage: • Presence of fungal, bacterial, viral, or other infection that is uncontrolled or requiring intravenous (IV) antimicrobials for management. Simple urinary tract infection (UTI) and uncomplicated bacterial pharyngitis are permitted if responding to active treatment. • Known infection with HIV (detectable viral load) • Hepatitis B (HBsAG positive and detectable viral load) • Hepatitis C virus (anti-HCV positive and detectable viral load) Initial Approval: ONE TIME DOSE ONLY. At this time, CAR-T therapy is intended as a one-time (single infusion) treatment. Repeat treatment of any CAR-T therapy is considered investigational and is not recommended outside of enrollment in a clinical trial. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** Continued Approval: Not applicable. CAR-T is intended as a one-time (single infusion) treatment. **For the treatment refractory/relapsed chronic lymphocytic leukemia (CLL) OR small lymphocytic lymphoma (SLL):** • Prescribed by an Oncologist with expertise in malignant hematology • Patients ≥ 18 years old • Subjects must have received adequate prior therapy including at a minimum: ○ are intolerant to or have failed a Bruton tyrosine kinase inhibitor (BTK) **AND** ○ are intolerant to or have failed a B-cell lymphoma 2 (BCL-2) inhibitor • Adequate organ function defined as (patient with borderline organ function may still be eligible based on center of excellence standards): ○ Left Ventricular Ejection Fraction ≥40% ○ Glomerular filtrate rate >30 mL/min ○ ALT ≤5 times the upper limit of normal (ULN) for age ○ Total bilirubin <2 mg/dL ○ Baseline oxygen saturation >91% on room air Reasons for Non-coverage: • Burkitt's lymphoma/leukemia • Active hepatitis B, C, or any uncontrolled infection • Active Grade 2 to 4 Graft versus Host Disease (GVHD) • Central Nervous System (CNS) 3 disease (white blood cell count ≥5/mL with blasts on cytocentrifuge and/or signs of CNS leukemia (e.g., cranial nerve palsy).

Drug	Prior Authorization Criteria
	Initial Approval: ONE TIME DOSE ONLY. Lisocabtagene Maraleucel is intended as a one-time (single infusion) treatment. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** Continued Approval: Not applicable. Lisocabtagene Maraleucel is intended as a one-time (single infusion) treatment. Dosing and Administration: • **KP members will be referred out to institutions that are certified to administer CAR-T therapies.** • **Breyanzi is only through restricted programs under a Risk Evaluation and Mitigation Strategy (REMS) Breyanzi REMS.**
Brinsupri (Brensocatib)	**Candidates for treatment with Brinsupri (brensocatib) should meet ALL of the following criteria:** • Prescribed by a pulmonologist • Diagnosed with non-cystic fibrosis bronchiectasis (NCFB) • Age ≥ 12 years old • Documentation of at least 2 exacerbations in the past 12 months requiring an antibiotic prescription, urgent care or emergency room visit, or hospitalization Reasons for Non-coverage: • Bronchiectasis due to cystic fibrosis Initial Approval: 6 months Continued Approval: 12 months. For continued approval for treatment, patient should meet ALL the following criteria: ○ Documented clinical benefit demonstrated by decreased symptoms and/or exacerbations
Briumvi (Ublituximab)	**Candidates for Briumvi should meet ALL of the following criteria**: • Diagnosis of relapsing multiple sclerosis • Prescribed by a neurologist • Age ≥ 18 years • Severe infusion reactions, persistent infusion reactions or loss of therapeutic response (recent clinical relapse or increased MRI activity) after initial adequate clinical response to intravenous rituximab infusion that may be due to suspected development of drug binding or neutralizing antibodies ○ NOTE: The clinical significance of drug binding and neutralizing antibodies is debatable and has not been shown to impact the efficacy or severity of adverse events. In patients with no other reason for loss of therapeutic effect, a switch from rituximab to ublituximab may be considered. • Patient has been screened for hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (HBcAb) and is seronegative or liver specialist consult has been obtained for

Drug	Prior Authorization Criteria

	chronically infected patients (carriers of HBsAg) or patients with unclear status (HBsAg negative but HBcAb positive).
	• Not used in combination with another MS disease modifying agent
	
	Reasons for Non-Coverage
	• Active infection including active HBV virus infection
	
	***NOTE**: Kaiser Permanente Inter-Regional Practice Recommendations for Multiple Sclerosis recommend rituximab as a preferred highly effective disease modifying agent and is clinically appropriate for patients with positive JCV antibody status
	
	Initial Approval: 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	• **Approve for administration ONLY in KPGA infusion center, absent director level approval**
	
	Continued Approval: 12 months. Continue approval if patient has documented clinical benefit from medication and no reported severe adverse events to Briumvi.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	• **Approve for administration ONLY in KPGA infusion center, absent director level approval**
	
	For new members who were initiated on Briumvi outside of KPGA: patient must meet the full criteria above for approval without reasons for non-coverage.
	• **Approve for administration ONLY in KPGA infusion center, absent director level approval**
	
	Dosing and Administration:
	• Briumvi is given via intravenous infusion
	  ○ First infusion: 150 mg IV infusion
	  ○ Second infusion: 450 mg IV infusion given 2 weeks after the first infusion
	  ○ Subsequent infusions: 450 mg IV infusion given 24 weeks after the first infusion and every 24 weeks thereafter
	  ○ Monitor patients closely during and for at least one hour after the completion of the first two infusions. Post-infusion monitoring of subsequent infusions is at physician discretion unless infusion reaction and/or hypersensitivity has been observed in association with the current or any prior infusion
	  ○ Administer pre-medication (e.g., methylprednisolone or an equivalent corticosteroid, and an antihistamine) to reduce the frequency and severity of infusion reactions

Bronchitol (Mannitol inhalation powder)	**Candidates for Bronchitol should meet ALL the following criteria:** Bronchitol (mannitol inhalation powder) is indicated for add-on maintenance therapy to improve pulmonary function in patients with cystic fibrosis (CF). • Documented diagnosis of cystic fibrosis (CF) • Age ≥ 18 years

Drug	Prior Authorization Criteria

	• Prescribed by a pulmonologist who specializes in the treatment of CF.
	• Patient has an inadequate response, contraindication, or intolerance to dornase alfa (Pulmozyme) AND is not a candidate for inhaled hypertonic saline.
	• Patient has completed and passed the Bronchitol Tolerance Test (BTT) (Note: BTT kit is supplied as back-office medication and is not dispensed by retail pharmacy.)
	• Patient has been prescribed an inhaled short-acting bronchodilator (e.g., albuterol) to be taken before each dose of inhaled mannitol.
	
	Reasons for Non-coverage:
	
	Bronchitol (mannitol inhalation powder) should NOT be used in patients with any of the following:
	
	• Hypersensitivity to mannitol or to any of the capsule components
	• Failure to pass the BTT
	• Patients are who are unable to perform spirometry or complete the BTT
	• Concurrent use of hypertonic saline or non-selective oral beta-blockers
	• Patient has a known cerebral, aortic or abdominal aneurysm
	• Uncontrolled hypertension (systolic BP >190 mmHg and/or diastolic BP >100 mmHg)
	• Any one of the following within the past 3 months:
	  ○ Significant episode of hemoptysis (>60 mL)
	  ○ Myocardial infarction
	  ○ Cerebral vascular accident
	  ○ Major ocular, abdominal, chest, or brain surgery
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months
	• Documentation of positive clinical response to therapy (e.g., improvement in lung function [forced expiratory volume in one second, FEV1])
	• Confirm patient meets all above coverage criteria and does not meet any criteria for discontinuation listed below.
	
	Criteria for discontinuation:
	• Intolerance to medication
	• Non-adherence to medication or follow-up labs and assessments
	
	Ordering Information:
	• BRONCHITOL is OUTSOURCED TO Accredo Specialty Pharmacy at 855-315-3408 or Accredo referral form

Bylvay (Odevixibat)	**Candidates for Bylvay should meet ALL of the following criteria:** Diagnosis of moderate to severe cholestatic pruritis associated with Alagille syndrome: • Prescribed by pediatric or adult hepatologist/gastroenterologist • Patient is ≥12 months of age • Documented inadequate response, intolerance or contraindication to Livmarli (maralixibat)

Drug	Prior Authorization Criteria
	• Documented baseline liver function test Reasons for Non-coverage: • Presence or history of other types of liver disease (biliary atresia, benign recurrent intrahepatic cholestasis, etc.) • History of liver transplant • History or presence of liver cirrhosis • History of decompensated liver disease Diagnosis of progressive familial intrahepatic cholestasis (PFIC) with the presence of moderate to severe pruritis: • Prescribed by pediatric or adult hepatologist/gastroenterologist • Patient is ≥3 months of age • Documented inadequate response, intolerance or contraindication to ALL of the following therapies (of at least a 3-month trial): o Ursodiol o Rifampin (if patient is ≥ 4 months of age) o Cholestyramine o Naltrexone (if patient is ≥ 18 years of age) o Documented baseline liver function test Reasons for Non-coverage: • Genetic testing indicative of PFIC type 2 with *ABCB11* variants encoding for nonfunction or absence of BSEP-3 • Presence or history of other types of liver disease (biliary atresia, benign recurrent intrahepatic cholestasis, etc.) • History of biliary diversion surgery within 6 months • History of liver transplant • History or presence of liver cirrhosis • History of decompensated liver disease Initial Approval: 12 months Continued Approval: 24 months. Continued approval for treatment with Bylvay should meet ALL the following criteria: For new members who were initiated outside of KPGA: • Hepatologist or gastroenterologist visit • The patient is confirmed stable on therapy, and safety screenings (e.g., liver enzyme tests) have been ordered or completed • For Progressive familial intrahepatic cholestasis (PFIC) with the presence of moderate to severe pruritis: o Documented inadequate response, intolerance or contraindication to ALL of the following therapies (of at least a 3-month trial) of: ▪ Ursodiol,

Drug	Prior Authorization Criteria
	▪ Rifampin (if patient is ≥ 4 months of age) ▪ Cholestyramine ▪ Naltrexone (if patient is ≥ 18 years of age). • For Alagille syndrome with the presence of moderate to severe cholestatic pruritis: ○ Documented inadequate response, intolerance or contraindication to (of at least a 3-month trial) of Livmarli (maralixibat). For existing members who have previously met the full criteria above: • Patient is receiving annual follow-up by hepatologist or gastroenterologist to monitor liver function and beneficial effect of treatment • Reduction in serum bile acid of ≥70% or reaching a bile acid level ≤70 µmol/L Notes: • Oral pellets are intended for use by patients weighing less than 19.5 kg • Capsules are intended for use by patients weighing 19.5 kg or above
Bysanti (Milsaperidone)	**Candidates for treatment with Bysanti should meet ALL the following criteria:** • Prescribed by Psychiatry • Age ≥ 18 years • Documented diagnosis of schizophrenia or bipolar I disorder • Documented inadequate response, intolerance or contraindication **to 4 or more atypical antipsychotics or mood stabilizers** ○ Examples of atypical antipsychotics include lurasidone, aripiprazole, quetiapine ○ Examples of mood stabilizers include lithium, lamotrigine, valproate • Patient does not have a QTc measurement of >500 ms (in past 12 months) or currently prescribed other drugs that prolong QTc interval Initial Approval: 12 months • **Approve for member to fill via the outpatient pharmacy benefit only** • **Quantity Limit: 60 per 30 days** Continued Approval: 12 months. Continue approval if the following criteria are met: • Documented improvement in S/S of schizophrenia or bipolar d/o and prescriber deems clinically stable For new members who were initiated Bysanti outside of KPGA: Confirm patient meets all above coverage criteria and has a documented clinically significant benefit from the medication during Psychiatry follow-up in the last 12 months. • **Approve for member to fill via the outpatient pharmacy benefit only** • **Quantity Limit: #60 per 30 days**
Cabenuva (Cabotegravir and Rilpivirine)	**Candidates for treatment with cabotegravir and rilpivirine (Cabenuva®) and cabotegravir (Vocabria®) should meet all the following criteria:** • Prescribed by an Infectious Disease Specialist or HIV Specialist

Drug	Prior Authorization Criteria

Vocabria
(Cabotegravir)*
	• Cabenuva is prescribed for every other month dosing.
	• Age ≥ 12 years
	• Weight ≥ 35kg
	• Diagnosis of HIV-1 infection
	• Documented viral suppression (HIV-1 RNA ≤ 20 copies/ml) for at least 6 months unless any one of the following are true:
	  ○ Unable to take any oral medications documented by inability to swallow digest or absorb oral medications (i.e.,ongoing throat radiation therapy, gastrointestinal surgeries impacting absorption/digestion of oral meds)
	• Documented severe, complicated mental health or socioeconomic factors making adherence to standard oral drug regimens improbable. No prior virologic failure demonstrated as:
	  ○ History of a detectable viral load (HIV-1 RNA > 200 copies/ml) while on ARV therapy
	  ○ History of drug resistance
	• No baseline resistance to either cabotegravir or rilpivirine documented by full viral sensitivity/susceptibility testing
	• Documented agreement between Provider and Patient that demonstrates the following:
	  ○ Patient understands the risks of missed doses of cabotegravir or rilpivirine
	  ○ Patient can adhere to required monthly or bi-monthly injection appointments
	• For Vocabria only: Candidates must also meet one of the following:
	  ○ Will be used in conjunction with rilpivirine (Edurant) to bridge for therapy interruption with Cabenuva (cabotegravir and rilpivirine)
	  ○ Will be used in conjunction with rilpivirine (Edurant) as oral lead-in (OLI) therapy to assess tolerability to Cabenuva (cabotegravir and rilpivirine).
	
	Reasons for Non-coverage:
	• Known hypersensitivity reaction to cabotegravir or rilpivirine
	• Active HBV infection (unless currently taking HBV active regimen)
	• Pregnant or planning to become pregnant
	• Concurrent use with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifapentine, St. John's Wort or dexamethasone (more than a single dose).
	
	Initial Approval**:** 6 months
	• **Approve for administration at a KPGA facility only**
	
	Continued Approval**:** 12 months
	• Patient meets all above coverage criteria without reasons for Non-coverage AND
	• Physician confirms that the patient has achieved and maintained viral suppression (HIV-1 RNA less than 20 copies/mL) while on Cabenuva therapy
	• **Approve for administration at a KPGA facility only**
	
	Dosage and Administration:

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• Optional tolerability testing confirms that tolerability will be assessed using a 28-day oral lead-in (OLI) therapy with Vocabria (cabotegravir) 30mg tablet and Edurant (rilpivirine) 25mg tablet. • Every 2 Month Dosing Regimen: Initiate IM injection 600 mg/900 mg for two doses (1 month apart) then continue IM injections of 600 mg/900 mg once every 2 months thereafter (every 8 weeks). <u>For new members who were initiated on Cabenuva® outside of KPGA, approve if</u>: • Prescribed by an Infectious Disease Specialist or HIV Specialist AND • Confirmed achievement and maintenance of viral suppression (HIV-1 RNA less than 20 copies/mL) by a Specialist, while on Cabenuva in the past 6 months.

Cablivi
(Caplacizumab-yhdp)
	Candidates for Cablivi (caplacizumab-yhdp) should meet ALL the following criteria:
	
	• Documented diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP)
	• The patient is ≥12 years of age
	• Prescribed by, or in combination with, a hematologist
	• The diagnosis is confirmed by ONE of the following:
	  ○ BOTH of the following:
	  ▪ The patient has severe thrombocytopenia defined as a platelet count < 100 x 10^9/L **AND**
	  ▪ The patient has microangiopathic hemolytic anemia (e.g., hemoglobin and hematocrit below the lower limit of the reference range, low haptoglobin, elevated lactase dehydrogenase, or the presence of schistocytes in peripheral blood smear)
	  ○ The patient has a positive ADAMTS13 activity result (e.g., <10 IU/dL [or <10% of normal])
	• Cablivi was initiated in the inpatient setting administered by a healthcare provider, in combination with plasma exchange therapy
	• Medication will be used in combination with immunosuppressive therapy (e.g., corticosteroids, rituximab or rituximab-biosimilar product, cyclosporine, cyclophosphamide, mycophenolate mofetil, hydroxychloroquine, bortezomib)
	• Total treatment duration will be limited to 58 days beyond the last therapeutic plasma exchange
	
	<u>Reasons for Non-coverage:</u>
	• If patient has previously received Cablivi, they have had >2 recurrences of aTTP while on Cablivi
	• Prior hypersensitivity reaction to caplacizumab-yhdp or any of the excipients
	
	<u>Initial Approval:</u> 2 months.
	• Authorization is limited to no more than 2 months beyond the last therapeutic plasma exchange.

Drug	Prior Authorization Criteria
	• The 2 month approval allows for 30 days following the last daily plasma exchange and for a 28-day extension in patients with persistent underlying disease after the initial treatment course. Continued Approval: 2 months. • Continued approval can ONLY be granted if the request is for a NEW (different) episode requiring the re-initiation of plasma exchange for the treatment of aTTP. • Documentation of date of prior episode documentation date of new episode is required. • If the patient has previously received Cablivi, the patietn has had no more than two recurrences of aTTP while on Cablivi • Continued treatment during is limited to 58 days beyond the last therapeutic plasma exchange. Criteria for Discontinuation: • Patient experiences more than two recurrence of aTTP while on therapy. Dosing and Administration: • **Day 1 of treatment with plasma exchange:** 11 mg bolus IV injection at least 15 minutes prior to plasma exchange, followed by an 11 mg SQ injection after completion of plasma exchange on day 1. • **Subsequent treatment with plasma exchange:** 11 mg SQ injection daily after completion of plasma exchange • **Treatment after the plasma exchange period:** 11 mg SQ injection daily for 20 days after the last plasma exchange • If after initial treatment course, sign(s) of persistent underlying disease such as suppressed ADAMTS13 activity levels remain present, treatment may be extended for a maximum of 28 days. • **Discontinue treatment if the patient experiences more than 2 recurrences of aTTP while on Cablivi.**
Cerdelga (Eliglustat)	**Candidates for treatment with Cerdelga should meet ALL the following criteria:** • Documented diagnosis of Type 1 Gaucher's Disease • Patient is symptomatic (i.e.,radiologic evidence of skeletal disease, platelet count <60,000 microL, liver >2.5 times normal size, spleen > 15 times normal size). • Age ≥ 18 years • Patient has been evaluated by a Geneticist • Patient has been tested using an FDA cleared test to determine the patient's CYP2D6 genotype • Patient's CYP2D6 genotype has been classified as an extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) • Tried and failed or unable to tolerate enzyme replacement therapy (Cerezyme, Vpriv, Elelyso) enzyme replacement therapy for at least 6 months Initial approval period: 12 months

Drug	Prior Authorization Criteria
	Continued approval: 24 months. Confirm patient meets all above criteria. In addition, continued approval will be based on evidence of response to treatment (improving platelet count, decreased hepatomegaly and splenomegaly). Ordering information: Cerdelga is available through the KP Specialty Pharmacy. If approved for coverage, prescribers must complete the KP-SP Cerdelga Order Form and fax it to the KP-Specialty Pharmacy (1-650-301-5790).
Calcitonin gene-related peptide (CGRP) inhibitors **Preferred:** **Ajovy** (Fremanezumab) *Does not require QRM PA review* **Non-Preferred:** **Aimovig** (Erenumab-aooe) **Emgality** (Galcanezumab-gnlm) **Vyepti** (Eptinezumab-jjmr)	**Candidates for treatment should meet ALL the following criteria PLUS the individual disease state criteria that follows:** • Age 18-75 years • Prescribed by a Neurologist or providers in the Department of Neurology who specialize in headache management **For Chronic or Episodic Migraine Diagnosis:** • Documented chronic migraine (≥15 days/month or frequent episodic migraine (≥8 days/month or ≥2 disabling migraines/month lasting at least 72 hours) [Use is for prevention of migraine] AND • Documented adequate trial of 3 preventative agents with strong evidence for migraine (e.g., tricyclic antidepressant, beta-blocker, topiramate, valproate, serotonin-norepinephrine reuptake inhibitor, ACE-inhibitor or angiotensin-receptor blocker) AND • Adequate trial defined as **at least 2 months** of a maximally tolerated dose AND • Documented compliance with a headache diary for at least 1 month prior to initiation AND • If on botunlinum toxin, documented partial response (e.g., reduction in headache days, MIDAS score or missed school/workdays) while on botulinum toxin with an incremental benefit expected with the combination of CGRP inhibitor treatment • **Aimovig only:** Documented treatment failure or intolerance to Emgality AND Ajovy • **Emgality only:** Documented treatment failure or intolerance to preferred agent Ajovy • **Vyepti only:** Documented treatment failure or intolerance to preferred agent Ajovy, Emgality, Aimovig, AND botulinum toxin (Botox or Daxxify) For Cluster Headache Diagnosis (EMGALITY only): • Documented Episodic Cluster Headache (>2 cluster periods lasting 7 days to 1 year, separated by a pain-free remission of ≥ 1 month) AND • Currently with ≥ 1 attack every other day AND • Documented adequate trial of or contraindication to ≥ 2 treatments for episodic CH (lithium, melatonin, memantine, occipital nerve block prednisone, verapamil, or topiramate) AND • Compliant with headache diary with number of cluster attacks (or triptan doses) per day for > 1 week prior to CGRP inhibitor initiation. Reasons for Non-coverage:

Drug	Prior Authorization Criteria
	• **Migraine Prophylaxis Only:** medication-overuse headache (MOH) without a documented treatment plan to taper acute treatment to the recommended limits. a. **Definition of MOH:** headache occurring 15 days/month or more in a patient with a pre-existing primary headache condition and occurs as a consequence of regular overuse of acute or symptomatic medication for more than 3 months Initial approval: 6 months • **Aimovig and Emgality:** ○ **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** ○ **Approve for member to fill via the outpatient pharmacy benefit only** • **Vyepti:** ○ **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Continued approval: 12 months. Continued approval will be based on if the following criteria are met: • Documented beneficial effects and tolerance of the medication. • If on concomitantbotulinum toxin, documentation by neurologist of continued need for combination therapy including history of incremental benefit on combination therapy compared to partial response on either individual therapy. • For new members who were initiated on therapy outside of KPGA, approve if patient has previously tried and failed three or more preventive migraine therapies including the preferred CGRP injectable medications indicated below • **Aimovig:** Confirmed history of treatment failure or persistent/severe intolerance to Ajovy OR Emgality. • **Emgality:** Confirmed history of treatment failure or persistent/severe intolerance to preferred agent Ajovy. • **Vyepti only:** Confirmed history of treatment failure or persistent/severe intolerance to two or more of the following agents: Ajovy, Emgality, Aimovig, botulinum toxins (Botox, Daxxify). • **Aimovig and Emgality:** ○ **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** ○ **Approve for member to fill via the outpatient pharmacy benefit only** • **Vyepti: Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**

Drug	Prior Authorization Criteria
	Criteria for Discontinuation: • Non-adherence to headache diary*, or follow-up assessments • Pregnancy is diagnosed, or woman is breastfeeding ***Please note the headache diary is for tracking headaches not medication adherence**
Calquence (Acalabrutinib)	**Candidates for treatment with Calquence should meet all the following criteria:** • Prescribed by, or in consultation with an Oncology Specialist • Age ≥18 years • For the treatment of chronic lymphocytic leukemia (CLL) OR small lymphocytic leukemia (SLL) a. As monotherapy **OR** b. In combination with Venclexta (venetoclax) for the first-line treatment of CLL or SLL with a fixed duration of 14 cycles • For the treatment of mantle cell lymphoma (MCL) with at least one prior therapy AND without progression on B-Cell receptor (BCR) inhibitor (e.g., idelalisib, venetoclax and zanubrutinib). • For the treatment of recurrent, relapsed, refractory or progressive B-Cell lymphomas (Nodal Marginal Zone Lymphoma, Extranodal Marginal Zone Lymphoma of Nongastric sites (noncutaneous), Extranodal Marginal Zone Lymphoma of the Stomach, Splenic Marginal Zone Lymphoma. • For the treatment of Waldenstrom's macroglobulinemia (WM) who are relapsed or progressive or did not respond to primary therapy. Initial Approval: 12 months Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, must meet criteria below: • Patient does not show evidence of progressive disease while on acalabrutinib therapy • Absence of significant toxicity (e.g., hemorrhage, infections, cytopenias, second primary malignancies, cardiac arrhythmias) • Continued monitoring by Hematology/Oncology
Camzyos (Mavacamten)	**Candidates for treatment with Camzyos should meet ALL the following criteria:** **Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).* • Age ≥ 18 years • Prescribed by a Cardiologist with expertise in hypertrophic cardiomyopathy • Diagnosed with obstructive hypertrophic cardiomyopathy (oHCM) consistent with current AHA/ACC guidelines and satisfies both of the following: ○ Left ventricular ejection fraction (LVEF) ≥55% via ECHO ○ NYHA class II or III • Documented peak Valsalva left ventricular outflow tract (LVOT) gradient ≥50 mmHg

Drug	Prior Authorization Criteria

	• Symptomatic oHCM despite highest tolerated dose of a non-vasodilating beta-blocker (e.g., bisoprolol) (or non-dihydropyridine calcium channel blocker if beta-blocker is not tolerated, e.g., verapamil)
	• If clinically indicated, consider other AHA/ACC Guideline Class 1 therapies before mavacamten:
	  ○ Disopyramide
	  ○ Septal reduction therapy for NYHA class III patients
	• Absence of pregnancy and using effective contraception, if of childbearing potential
	• Prescriber must be certified through the Camzyos REMS program
	• Patient must be enrolled in the Camzyos REMS program
	
	Reasons for Non-coverage:
	• Known infiltrative or storage disorder causing cardiac hypertrophy that mimics oHCM (e.g., Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy)
	• History of syncope or sustained ventricular tachyarrhythmia with exercise within 6 months prior to initiation of mavacamten
	• History of resuscitated sudden cardiac arrest (at any time) or known history of appropriate implantable cardioverter defibrillator discharge for life-threatening ventricular arrhythmia within 6 months prior to initiation of mavacamten
	• Poorly controlled atrial fibrillation. Treatment of atrial fibrillation should be optimized prior to considering mavacamten
	• Treatment with disopyramide or ranolazine within 14 days prior to initiation of mavacamten
	• Taking a beta-blocker in combination with a calcium channel blocker. Either the beta-blocker or calcium channel blocker should be discontinued 14 days prior to initiation of mavacamten
	• Successfully treated with invasive septal reduction therapy within 6 months prior
	• QTc interval >500 milliseconds
	• Concomitant strong CYP2C19 inhibitors (e.g fluconazole) or strong CYP3A4 inhibitors (e.g.,ketoconazole, clarithromycin)
	• Concomitant use of weak to moderate to strong CYP2C19 inducers (e.g rifampin) or moderate to strong CYP3A4 inducers (e.g., phenobarbital, phenytoin)
	
	Initial Approval: 6 months
	
	Continued Approval: 6 months. For continued approval for treatment with Camzyos, patient should meet ALL the following criteria:
	
	For new members who were initiated on Camzyos outside of KPGA:
	• Patient should continue to meet all above coverage criteria without reasons for non-coverage or discontinuation (criteria for discontinuation listed below).
	
	For existing members who previously met the full criteria above:
	• Patient should continue to meet all above coverage criteria without reasons for non-coverage or discontinuation (criteria for discontinuation listed below).
	
	Criteria for Discontinuation:
	• LVEF <50% while taking mavacamten:

Drug	Prior Authorization Criteria
	○ Interrupt treatment and follow the algorithm for Interruption (see Figure 3 in product labeling) for guidance on interrupting, restarting, or discontinuing mavacamten. Discontinue permanently if LVEF <50% twice while on 2.5 mg daily. • Patient develops heart failure symptoms or worsening clinical status • Documented intolerance to medication • Documented non-adherence to medication, recommended diet and lifestyle measures, or follow-up labs and assessments. Ordering Information: • Only available through the Camzyos REMS program
Carvykti (Ciltacabtagene autoleucel)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** **Candidates for Carvykti should meet ALL of the following criteria:** • **MUST verify member's benefit information. If member's coverage is through Target, CLOSE the request.** Member must go through Aradigm for this therapy. • Diagnosis of relapsed or refractory multiple myeloma (RRMM) • Prescribed by an Oncologist • Patient is ≥ 18 years • Progression on, or intolerant to at least one prior line of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), and are refractory to lenalidomide. ○ Examples of therapies: ▪ Immunomodulatory agents: lenalidomide, pomalidomide ▪ Proteasome inhibitors: carfilzomib, bortezomib, ixazomib ▪ Anti-CD38 monoclonal antibodies: isatuximab, daratumumab • Absolute neutrophil count ≥500/µL • Absolute lymphocyte count >100/µL • Platelet count ≥50,000/µL Reasons for Non-coverage: • Previous treatment with a CAR T-cell-targeted or B-cell maturation antigen (BCMA)-targeted therapy • Patient has not received prior allogeneic hematopoietic stem cell transplant within 6 months prior to therapy • Autoimmune disease with or without use of chronic immunosuppressants • Diagnosed or treated for invasive malignancy other than multiple myeloma • Central nervous system (CNS) involvement with myeloma or clinically relevant CNS pathology (e.g., seizure disorder) • Plasma cell leukemia • Solitary plasmacytomas • Systemic corticosteroid therapy of greater than 5 mg/day of prednisone within 2 weeks prior to apheresis • Pregnancy • Known infection with HIV (detectable viral load) • Hepatitis B (HBsAG positive and detectable viral load) • Hepatitis C virus (anti-HCV positive and detectable viral load)

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• Presence of fungal, bacterial, viral, or other infection that is uncontrolled or requiring intravenous antimicrobials for management. ○ Simple urinary tract infection and uncomplicated bacterial pharyngitis are permitted if responding to active treatment. • Detectable cerebrospinal fluid malignant cells or brain metastases or with a history of CNS lymphoma, cerebrospinal fluid malignant cells, or brain metastases Initial Approval: ONE TIME DOSE ONLY. At this time, CAR-T therapy is intended as a one-time (single infusion) treatment. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** Continued Approval: Not applicable. CAR-T is intended as a one-time (single infusion) treatment Dosage and administration: KP members will be referred out to institutions that are certified to administer CAR-T therapies.

Cayston
(Aztreonam)
	Candidates for treatment with aztreonam inhalation solution should meet all the following criteria:
	• Diagnosis of cystic fibrosis (CF)
	• Prescribed by a Pulmonologist
	• Age ≥ 7 years
	• Pseudomonas aeruginosa is present in recent airway culture or sputum culture
	• Documented FEV1 ≥ 25% and ≤ 75% predicted
	• Patient meets one of the following
	  ○ Inadequate response, contraindication or intolerance to inhaled tobramycin (i.e., inhalation solution or inhaled capsules)
	  ○ Antibiotic susceptibility testing indicates that tobramycin is not effective or aztreonam is more effective than tobramycin.
	• Prescribed dose does not exceed 225mg per day administered on a 28 days on/28 days off cycle.
	
	Reasons for Non-coverage:
	• Hypersensitivity to aztreonam
	• Colonization with Burkholderia cepacian
	• FEV1 ≤ 25% and ≥ 75% predicted
	
	Initial approval**:** 6 months
	
	Continued approval**:** 12 months. Confirm patient meets all above coverage criteria without reasons for non-coverage.
	
	For new members who were initiated on aztreonam inhalation solution outside of KPGA:
	• Confirm patient meets all above coverage criteria without reasons from non-coverage.

Drug	Prior Authorization Criteria
	Dosage and Administration: • The recommended dose of CAYSTON for both adults and pediatric patients 7 years of age and older is one single-use vial (75 mg of aztreonam) reconstituted with 1 mL of sterile diluent administered 3 times a day for a 28-day course (followed by 28 days off CAYSTON therapy). • Doses should be taken at least 4 hours apart. • CAYSTON is administered by inhalation using an Altera® Nebulizer System. • Patients should use a bronchodilator before administration of CAYSTON. Other Considerations: • Distribution of aztreonam inhalation solution is currently restricted through the Cayston Access Program. • Only those specialty pharmacies (e.g., Cystic Fibrosis Foundation Pharmacy) contracted with the manufacturer can distribute aztreonam inhalation solution and the Altera nebulizer. • Kaiser Permanente Specialty Pharmacy does not currently have a contract with the manufacturer for direct distribution of aztreonam inhalation solution or the nebulizer device.

CeQur Simplicity Insulin Patch	**Candidates for Cequr should meet ALL the following criteria:**
	
	• Prescribed by Endocrinology
	  ○ Endocrinology team educates patient on proper insulin delivery device use
	• Age ≥ 21 years
	• Documented diagnosis of diabetes
	• A1C >7% in past 3 months
	  ○ Document baseline A1C
	• Administration of **at least three daily insulin injections** currently including RAPID ACTING mealtime insulin
	  ○ Rapid acting insulin examples: Kirsty or insulin aspart, insulin lispro or Humalog
	  ○ Total rapid acting insulin requirement < 200 units per 4 days
	• Documented frequency of **glucose self-testing of at least 3 times per day** or regular use of calibrated CGM
	• Documented medical rationale of need for Cequr to achieve and maintain A1C control rather than vial or preferred rapid acting insulin pen, Kirsty pen
	  ○ Document trial and failure to Kirsty pen or similar prefilled rapid acting insulin pen device
	  ○ Medical rationale examples include hx of recurring hypoglycemia, hx of severe glycemic excursions, wide fluctuations in blood glucose before mealtime, A1C remains >7, “brittle” diabetes
	• **Coverage is not authorized for patients with existing coverage for an alternate insulin pump device**
	
	Reasons for Non-coverage:
	
	• Does not meet criteria for rapid acting insulin

Drug	Prior Authorization Criteria
	• Unable or unwilling to test blood sugar as recommended by healthcare provider • Unable or unwilling to return for routine diabetes follow-up Initial Approval: 6 months. Continued Approval: 12 months. Confirm patient continues to meet all criteria above without reasons for non-coverage. In addition, documentation of a positive clinical response=decrease in A1C level from baseline Qty Limits: 10 patches per 30 days Dosage and administration: Insulin is provided separately. Patient must fill patch with up to 200 units of rapid acting insulin using a fill syringe provided in patient starter kit. CeQur Simplicity doses rapid-acting insulin in 2-unit increments. CeQur Simplicity has an adhesive that is designed to stay adhered for up to 4 days.
Ctexli (Chenodiol)	**Candidates for treatment with chenodiol should meet all the following criteria:** • Prescribed by or in consultation with an Endocrinologist, Geneticist, or Neurologist with a focus in the treatment of cerebrotendinous xanthomatosis • Age ≥ 18 years • Documented diagnosis cerebrotendinous xanthomasis confirmed by ONE of the following: a. Molecular genetic test demonstrating a pathogenic variant in the cytochrome P450 27A1 (CYP27A1) gene b. Lab test demonstrates elevated serum cholestanol levels (as determined by the lab's usual values) Initial approval**:** 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued approval**:** • 12 months if documented clinical benefit or patient is confirmed to be clinically stable by a specialist in the last 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** For new members who were initiated on chenodiol outside of KPGA: • Confirm patient meets all above coverage criteria and documented clinical benefit or patient is confirmed to be clinically stable by a specialist in the last 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
Cholbam (Cholic acid)	**Candidates for treatment with Cholbam should meet ALL the following criteria:** • Ordering providers are restricted to pediatric gastroenterology and adult hepatology/gastroenterology • Must have a diagnosis of bile acid synthesis disorder o Bile acid disorders due to single enzyme defects (SEDs) OR

Drug	Prior Authorization Criteria
	○ Adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption • Must provide baseline liver function tests Reasons for Non-coverage: • Patients with extrahepatic manifestations of bile acid synthesis disorders due to SEDs or PDs including Zellweger spectrum disorders Initial approval period: 3 months Continued approval: Every 3 months for the first year; then, every 6 months, thereafter. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continued approval is based on: • Documented beneficial effect from therapy including all of the following: ○ Body weight increased by 10% or is stable at ≥50th percentile ○ Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) <50U/L or baseline levels reduced by 80% ○ Total bilirubin level reduced to ≤1mg/dL ○ Must not have evidence of cholestasis on liver biopsy Monitoring: • Every month for the first 3 months, every 3 months for the next 9 months, and every 6 months during the next three years, and annually thereafter: ○ Bilirubin ○ ALT/AST/GGT Liver function tests ○ INR Reasons for Discontinuation: • Liver function does not improve within 3 months of starting treatment • Complete biliary obstruction develops • Persistent clinical or laboratory indicators of worsening liver function or cholestasis Ordering information: Cholbam is available through the Cholbam Total Care Hub. If approved for coverage, prescribers must complete the Patient Enrollment Form for Cholbam Total Care Hub and fax it to 877-473-3171.
Cibinqo (Abrocitinib)	**Candidates for treatment with Cibinqo should meet ALL the following criteria:** • Patient has had a negative interferon-gamma release assay test for TB Infection within the past 24 months or is positive for latent TB and has completed treatment in the past or is currently on treatment. • Medication is NOT being used in combination with another biologic medication [omalizumab (Xolair), rituximab (Rituxan), adalimumab (Amjevita, Humira), etc], Janus kinase inhibitor [abrocitinib (Cibinqo), baricitinib (Olumiant), tofacitinib, or other potent immunosuppressants [azathioprine, cyclosporine].

Drug	Prior Authorization Criteria

	• Then follow the disease-state specific criteria below:
	
	Diagnosis of Atopic Dermatitis:
	• Prescribed by a dermatologist
	• Age ≥ 12 years
	• Documented diagnosis of moderate-to-severe atopic dermatitis (BSA > 10%)
	• Documented inadequate response, intolerance or contraindication to at least a 16-week trial of each of the following:
	  ○ Adbry (tralokinumab-ldrm) **OR** Dupixent (dupilumab) **AND**
	  ○ Nemluvio (nemolizumab)
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. Continue approval if the following criteria are met:
	
	• For new members who were initiated on abrocitinib prior to joining KPGA: Patient must meet the full initial criteria above and have documented adequate response and tolerance of medication during specialist follow-up in the past 6 months.
	
	• For existing members who have previously met the full criteria above: documented adequate response and tolerance of the medication during specialist follow-up in the last 12 months.

Cimzia (Certolizumab Pegol)	**Candidates for Cimzia should meet all of the following criteria PLUS the individual disease state criteria that follow:**
	
	• Patient has had a negative interferon-gamma release assay test for TB infection within the past 24 months or is positive for latent TB and has completed treatment in the past or is currently on treatment
	• Medication is not being used in combination with another biologic or advanced small molecule (e.g., tofacitinib, upadacitinib, apremilast) for the same indication
	• Then follow the disease state specific criteria below, based on diagnosis:
	
	For diagnosis of rheumatoid arthritis, psoriatic arthritis or axial spondyloarthritis:
	
	• Prescriber is a rheumatologist or dermatologist
	• If patient is currently pregnant, proceed to initial approval
	• Documented treatment failure, intolerance, or contraindication to ≥ 2 TNF inhibitors:
	  ○ Infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade)
	  ○ Adalimumab product (Amjevita [preferred], Humira)
	  ○ Others: Enbrel, Simponi
	
	For diagnosis of plaque psoriasis:
	
	• Prescriber is a dermatologist

Drug	Prior Authorization Criteria

	• If patient is currently pregnant, proceed to initial approval
	• Documented treatment failure, intolerance, or contraindication to ≥ 2 TNF inhibitors
	  ○ Infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade)
	  ○ Adalimumab product (Amjevita [preferred], Humira)
	  ○ Others: Enbrel
	• Documented treatment failure, intolerance, or contraindication to ALL of the following: ustekinumab (Yesintek [preferred]), secukinumab (Cosentyx), guselkumab (Tremfya), risankizumab (Skyrizi)
	
	Initial approval: 6 months or 6 weeks post pregnancy due date
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	Continued approval: 6 weeks post pregnancy due date or 12 months if the following criteria are met:
	
	For new members who were initiated on Cimzia outside of KPGA:
	
	• Confirm patient meets all above coverage criteria without reasons for non-coverage
	• Approve Cimzia if patient is currently pregnant
	
	For existing members who have previously met the full criteria above:
	
	• If Cimzia was approved due to pregnancy for a patient who has not met the full criteria, Cimzia will no longer be covered after delivery (may be covered up to 6 weeks after delivery to allow transition to alternate therapy)
	• For all other patients, must have documentation of adequate response and tolerance of Cimzia during specialist follow up in the last 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	Criteria for Crohn's disease:
	• Age ≥ 18 years
	• Prescribed by a gastroenterologist
	• Will not be used for induction therapy
	• Documented moderately to severely active Crohn's Disease (CD)
	• Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL the following:
	  ○ Infliximab product (e.g., Inflectra [preferred])*
	  ○ Adalimumab product (e.g., Amjevita [preferred])*
	  ○ Ustekinumab product (e.g., Yesintek [preferred])
	  ○ Entyvio (vedolizumab) – a trial is not required for CD, if documentation of small bowel, perianal or fistulizing / penetrating disease
	  ○ Rinvoq (upadacitinib). If patient is pregnant, Rinvoq trial is NOT required
	  ○ Tremfya (guselkumab)
	
	Initial Approval: 12 months

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Induction and maintenance: Approve for member to fill via the outpatient pharmacy benefit only** Continued Approval: 12 months. • For new members and existing members Documented clinical benefit (asymptomatic or in remission) from therapy, by a gastroenterology specialist within the past 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Induction and maintenance: Approve for member to fill via the outpatient pharmacy benefit only**
Cinqair (Reslizumab)	**Candidates for treatment with Cinqair should meet ALL the following criteria:** • Documented failure of, contraindication or intolerance to benralizumab (Fasenra) [KPGA's **preferred** interleukin-5 antagonist] AND dupilumab (Dupixent) • Prescribed by a pulmonologist or allergy specialist • Age ≥ 18 years • Has a diagnosis of severe asthma with an eosinophilic phenotype: a. Documented blood eosinophil count of ≥ 400 cells/µl. • Uncontrolled asthma* despite an aggressive drug therapy regimen including: a. High-dose inhaled corticosteroid (ICS), plus a long-acting beta-agonist (LABA)—e.g., fluticasone 500 mcg/salmeterol 50 mcg (Wixela Inhub) 1 puff twice daily WITH b. Daily use of oral corticosteroids (OCS)—e.g., prednisone 5 – 20 mg daily • **NOTE:** Patients who are not on daily OCS but who otherwise meet the above criteria and who have had frequent and/or severe exacerbations in the past 12 months requiring systemic corticosteroids for > 3 days can be considered for reslizumab (Cinqair). • NOT being used for the treatment of other eosinophilic conditions such as hypereosinophilic syndromes (e.g., Churg-Strauss, EGPA), neoplastic disease, or parasitic disease. • NOT being treated for relief of acute bronchospasm or status asthmaticus. • NOT currently receiving another monoclonal antibody for the treatment of asthma—e.g., omalizumab (Xolair), mepolizumab (Nucala), benralizumab (Fasenra). • Does NOT have any current diagnosis of cancer or history of cancer in remission for less than 12 months prior to starting therapy. *Indicators of uncontrolled asthma: Two or more exacerbations in the past 12 months requiring systemic corticosteroids for > 3 days, serious exacerbations, at least one hospitalization, ICU stay or mechanical ventilation in the past 12 months, or Asthma control test (ACT) is consistently < 20. Initial Approval: 6 months **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**

Drug	Prior Authorization Criteria

	Continued Approval: 12 months if the member has experienced any of the following:
	• Reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath
	• Decrease in administration of rescue medication, short acting beta-agonist (e.g., albuterol inhaler or nebulizing solution)
	• Decrease in exacerbation frequency (no increase in ICS dose or OCS dose)
	• Increase in predicted FEV1 from the pretreatment baseline
	• Objective improvement in quality of life: Asthma Control Test (ACT)
	• **NOTE:** Do not approve if member has:
	  ○ Documented hypersensitivity reactions related to Cinqair administration (e.g., anaphylaxis, angioedema, shortness of breath, hypotension, itching, rash)
	  ○ Documented diagnosis of malignancy
	Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)
	
	Dosage and Administration:
	• The recommended dose is 3 mg/kg every 4 weeks as an IV infusion over 20-50 minutes
	• Should be prepared and administered by a healthcare professional

Cobenfy (Xanomeline and Trospium)	Candidates for treatment with Cobenfy (xanomeline and trospium) must meet ALL the following criteria:
	
	• Age 18 to 65 years
	• Patient is diagnosed of schizophrenia
	• Prescribed by Behavioral Health
	• Documented inadequate response, intolerance or contraindication to **4 or more atypical antipsychotics**
	  ○ Lurasidone
	  ○ Aripiprazole
	  ○ Quetiapine
	  ○ Risperidone
	  ○ Olanzapine
	  ○ Ziprasidone
	  ○ Paliperidone
	  ○ Clozapine
	• Documented baseline liver enzymes and bilirubin within the past 1 month of initiating treatment
	• Documented baseline Positive and Negative Syndrome Scale (PANSS) score between 80 and 120 OR clinical symptoms of moderate to moderately severe disease.
	
	Reasons for Non-coverage:
	
	• Urinary retention (i.e., Overactive bladder (OAB), benign prostatic hyperplasia (BPH)
	• Moderate (Child Pugh Class B)_or severe hepatic impairment (Child-Pugh Class C)
	• Gastric retention (i.e., Irritable bowel syndrome (IBS))
	• Untreated narrow-angle glaucoma
	• Pregnancy or breastfeeding
	• Concurrent use with any other antipsychotic medication

Drug	Prior Authorization Criteria
	Initial Approval: 6 months **Continued Approval**: 12 months. Confirm patient meets all above coverage criteria without reasons for non-coverage. In addition, continued approval with Cobenfy should meet ALL the following criteria • Documented improvement in schizophrenia signs and symptoms and/or prescriber deems clinically stable • Documented decrease in PANSS total score
Columvi (Glofitamab-gxbm)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** **Candidates for treatment with Columvi (glofitamab-gxbm) must meet ALL the following criteria:** • Prescribed by Hematology / Oncology Specialist • Patient is ≥ 18 years old • Patient has a diagnosis of relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) **OR** large B-cell lymphoma (LBCL) arising from follicular lymphoma (FL). • Patient has received two or more prior lines of therapy, including at least one anti-CD20 monoclonal antibody (e.g., rituximab, ofatumumab, ocrelizumab, obinutuzumab, ublituximab, etc.) • Documentation patient will receive pre-treatment with a single dose of obintuzumab (Gazyva) 7 days prior to starting Columvi. Approval period: 12 months • Columvi should only be continued for a maximum of 12 cycles (including Cycle 1 step up dosing) with completion in less than 12 months. • Cycle 1 may be approved for administration at a KP-affiliated inpatient facility. • Subsequent cycles should be approved for back-office administration in a KP-infusion center ONLY. ○ **NOTE:** Patients who experienced > grade 2 cytokine release syndrome with the previous infusion should be hospitalized during infusion and for 24 hours following the next infusion. If patient experiences a treatment delay >14 days, an additional cycle may be approved for administration at a KP-affiliated inpatient facility for therapy re-initiation. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** Continued Approval: Not applicable. • Columvi should only be continued for a maximum of 12 cycles (including Cycle 1 step-up dosing) and is intended to be completed in less than 12 months. Dosing and Administration:

Drug	Prior Authorization Criteria

	• Cycle 1 (step up dosing): obintuzumab (Gazyva) followed by Columvi
	  ○ Day 1: Pretreat with a sign 1,000 mg dose of obintuzumab IV 7 days before initiation of Columvi
	  ○ Day 8: Step-up dose 1: Columvi 2.5 mg
	  ○ Day 15: Step-up dose 2: Columvi 10 mg IV
	  ○ **NOTE:** The manufacturer recommends hospitalization during infusion and for 24 hours following completion of step-up dose 1. Patients who experienced cytokine release syndrome (CRS) during step-up dose 1, should be hospitalized during infusion and for 24 hours following completion of step-up dose 2.
	• Cycle 2-12: Columvi 20 mg IV every 21 days

Cometriq (Cabozantinib)	**Candidates for Cometriq should meet ALL the following criteria:** <u>Diagnosis of Non-Small Cell Lung Cancer:</u> • Prescribed by a hematologist or oncologist. • Age ≥18 years • Diagnosis of recurrent, advanced (stage IIIb or IIIc) or metastatic (stage IV) non-small cell lung cancer • Disease is positive for RET gene rearrangement • Documented treatment failure, intolerance, or contraindication to selpercatinib (Retemvo) <u>Diagnosis of Thyroid Cancer:</u> • Prescribed by a hematologist or oncologist. • Age ≥18 years • Diagnosis of medullary thyroid carcinoma • Disease is refractory to radioactive iodine therapy • Documented treatment failure or intolerance to at least ONE of the following: vandetanib (Caprelsa), lenvatinib (Lenvima), sorafenib (Nexavar), etc <u>Initial Approval:</u> 12 months <u>Continued Approval:</u> 12 months. For continued approval for treatment with Cometriq, patient should meet ALL the following criteria: • Patient continues to meet the above criteria. • Patient is responding positively to therapy based on stabilization of disease or no disease progression
Contrave (Naltrexone/ Bupropion)	**Candidates for treatment with Contrave (naltrexone/bupropion) should meet ALL the following criteria:** • Must verify the Member's Benefits to <u>confirm</u> in a Plan with the Class III (formerly "Morbid Obesity") Rider AND **documented in office baseline body weight taken within the past 1 month (patient reported weight is not acceptable).** • Age ≥ 12 years • For adults, whose current baseline body weight recorded in the office meets or exceeds calculated body mass index (BMI) of:

Drug	Prior Authorization Criteria
	○ BMI 40 kg/m2 or greater with or without comorbid conditions OR ○ BMI 35 kg/m2 or greater **with at least one weight-related comorbid condition**, such as Type 2 diabetes, hypertension, established cardiovascular disease or stroke, congestive heart failure, chronic kidney disease • Documented contraindication*, intolerance or failure to lose and maintain greater than or equal to 5% body weight after a 3- month trial of one of the following: ○ Phentermine ○ Qsymia∞ (phentermine/topiramate ER) or separate prescriptions ∞Most effective options. KP Practice Recommendations, given the wide clinical prescribing of phentermine for more than 20 years and the lack of evidence for serious side effects, even in the absence of long-term controlled safety and efficacy data, it seems reasonable for clinicians to prescribe phentermine long term. *Maintained on a stimulant medication for **ADHD** is a contraindication to phentermine use. Phentermine contraindicated with uncontrolled HTN (blood pressure >140/90 on 2 or more appropriately dose adjusted htn meds), hx of ASCVD, hyperthyroidism, glaucoma, agitated states, hx of drug abuse. **<u>NOTE:</u>** Weight management agents should only be prescribed as an adjunct to a lifestyle modification program. <u>Initial Approval</u>: 4 months <u>Continued Approval:</u> 12 months. • Patient has achieved ≥ 5% weight loss during 1st 4 months of therapy and continues to maintain weight loss.
Copaxone 40 mg/ml (Glatiramer Acetate) **Copaxone 20 mg/ml** (Glatiramer Acetate)	**Candidates for treatment with Copaxone should meet ALL the following criteria:** • Documented diagnosis of relapsing multiple sclerosis AND • Glatiramer acetate is prescribed by a neurologist AND • Glatiramer acetate is to be used as monotherapy disease-modifying treatment of MS AND • Documented trial, severe intolerance, or contraindication to Betaseron. • Documented persistent or severe intolerance or relative contraindication to dimethyl fumarate • Patient has had a visit in the last year with the TSPMG Multiple Sclerosis specialist for evaluation of disease activity and necessary level of treatment has been confirmed as moderate (highly effective therapy not needed) AND • Patient has tried and had a potential intolerance or allergic reaction to the ***inactive*** components of at least one generic product Glatopa or Glatiramer acetate that cannot be explained by other clinical or lifestyle factors. ○ Note: If the request for coverage of brand Copaxone is based upon disease progression or side effects due to the active ingredient glatiramer acetate (e.g.,

Drug	Prior Authorization Criteria
	injection site reactions, lipoatrophy, dyspnea, tachycardia) the request will be denied unless the member meets the full criteria above. ○ Note: If the physician's request for coverage of brand Copaxone is based upon the physician's and/or member's unwillingness to change to a preferred alternative, the request will be denied unless the member meets the full criteria. Initial Approval: 1 year Continued approval: 1 year if the following: For new members who were initiated outside of KPGA: patient must meet the full criteria above for approval of Copaxone. For existing members who have previously met the full criteria above: Documented beneficial effect from therapy on Neurology follow-up.
Copiktra (Duvelisib)	**Candidates for treatment with Copiktra must meet ALL the following criteria:** • Prescribed by a hematologist or oncologist • Patient is ≥18 years of age • Patient has a diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). • Patient has history of failure, contraindication, intolerance, or predicted toxicity to at least two prior therapies including a Bruton tyrosine kinase inhibitor (e.g., zanubritinib (Brukinsa), acalabrutinib (Calquence), ibrutinib (Imbruvica)) **AND** one Venclexta-based regimen. • Prescriber must be certified through the Copiktra REMS Program • Patient will be provided with prophylaxis for *pneumocystis jirovecii (PJP)* during treatment with the intent to continue prophylaxis until the CD4+ T cell count is great than 200 cells/uL Reasons for non-coverage: • Patient with suspected *pneumocystis jirovecii (PJP)* of any grade and discontinue if PJP is confirmed Initial Approval: 12 months with quantity limit of 60 tablets per 30 days. Continued Approval: 12 months with quantity limit of 60 tablets per 30 days. For continued approval for treatment with Copiktra, patient should meet ALL the following criteria: • Patient continues to meet the above criteria • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread For new members who were initiated on Copiktra outside of KPGA: Patient should meet ALL the following criteria: • Prescribed by hematology/oncology • Patient is ≥18 years of age • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread • Quantity limit of 60 tablets per 30 days.

Drug	Prior Authorization Criteria
Corticotropin Gel: **Acthar** (repository corticotropin) gel **Cortrophin** (repository corticotropin) gel	**Candidates for treatment with corticotropin gel (Cortrophin® or Acthar®) should meet the following pertinent criteria:** <u>For multiple sclerosis: Do not approve for coverage/use.</u> Cortrophin or Acthar gel is NOT available for coverage for this indication due to expert consensus and lack of evidence of superiority to corticosteroids or plasma exchange. <u>Corticotropin or Acthar gel will not be covered in patients with any of the following diagnoses:</u> • Congestive heart failure • Uncontrolled Hypertension • Osteoporosis • History of or presence of peptic ulcer • Primary adrenocortical insufficiency or adrenocortical hyperactivity • Scleroderma • Hypersensitivity to porcine protein • Thromboembolic disorder • Ocular herpes simplex • Systemic fungal infections • Multiple Sclerosis <u>Additional criteria for use for diagnosis of infantile spasms:</u> • Diagnosis of infantile spasms • Less than 2 years of age • Prescribed by pediatric neurologist or neurologist • Acthar gel may be approved if the above conditions are met <u>Additional criteria for use for Nephrotic Syndrome:</u> • A diagnosis of idiopathic nephrotic syndrome • Prescriber must be a nephrologist • Patient failed to achieve a sustained partial or complete remission of nephrotic syndrome after 6 months of therapy with first line therapy (i.e., corticosteroids) AND after 6 months of therapy with second line therapies with demonstrated efficacy (i.e., cyclosporine, tacrolimus, rituximab, and mycophenolate mofetil). Patient is expected to continue therapy for at least 3 months and is able to afford the cost of therapy in order to prevent abrupt discontinuation of therapy. • Cortrophin gel: approve if the above conditions are met • Acthar gel: must meet above criteria AND documented history of trial and failure of Cortrophin gel <u>Additional criteria for use for rheumatologic conditions:</u> • Documented diagnosis of ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus or polymyositis AND • Patient is experiencing an acute exacerbation of illness AND • Corticotropin is prescribed as short-term therapy to tide the patient over during an acute episode or exacerbation AND • Patient has a contraindication or has experienced a severe intolerance to IV or high-dose oral steroids in the past OR

Drug	Prior Authorization Criteria
	• Patient is experiencing a limited response to IV or high dose oral steroids prescribed either during the current exacerbation or during two or more previous exacerbations • Cortrophin gel: approve if the above conditions are met • Acthar gel: must meet above criteria AND documented history of trial and failure of Cortrophin gel Additional criteria for use for FDA-approved corticosteroid responsive conditions: • Treatment of serum sickness • Treatment of symptomatic sarcoidosis • Ophthalmic disease (keratitis, iritis, optic neuritis, anterior segment inflammation) • Dermatological diseases (severe erythema multiforme or Stevens Johnson syndrome) • Patient experienced a limited response or experienced intolerance to IV or high dose oral steroids • Cortrophin gel: approve if the above conditions are met • Acthar gel: must meet above criteria AND documented history of trial and failure of Cortrophin gel Approval period: • Rheumatic disorder or collagen disease (ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus or polymyositis): 3 months approval. One-time approval per exacerbation. Not eligible for continuation. • Nephrotic syndrome: 6 months • All other indications: 3 months Monitoring: Laboratory monitoring for BMP, blood pressure, pulse, A1C, weight, and TSH, cholesterol (i.e., TC, LDL, HDL and triglycerides) should be completed at baseline and every 3 months for the duration of treatment with Cortrophin® gel or Acthar® gel

Cosentyx
(Secukinumab)
 	
Preferred:
Cosentyx subcutaneous injection
 	
Non-preferred:
Cosentyx intravenous infusion
	Candidates for treatment with Cosentyx must meet ALL the following criteria PLUS the individual disease state criteria below:
	• Prescribed by a dermatologist or rheumatologist
	• Medication is not being used in combination with another biologic or advanced small molecule (e.g., tofacitinib, upadacitinib, apremilast) for the same indication
	• Cosentyx 150mg/mL Sensoready pen or prefilled syringe is preferred.
	  ○ If request is for IV formulation: approve ONLY for administration by a health care provider for patients meeting all other criteria with a documented significant nonmodifiable barrier that prohibits a self-administered or caregiver-administered subcutaneous injection (such as blindness, hand tremors, limitations in dexterity or cognitive impairment).
	  ○ If request is for Cosentyx 300mg/2ml UnoReady pen or prefilled syringe: approve ONLY for patients meeting all other criteria with a documented latex allergy or very severe injection site reactions or pain with the preferred products.
	• Then follow the disease state specific criteria below, based on diagnosis:

Drug	Prior Authorization Criteria

	Diagnosis of psoriatic arthritis:
	• Prescribed 150 mg SC every 4 weeks (without loading dose) for patients under 100 kg without severe plaque psoriasis
	• Patient has a documented inadequate response, intolerance, or contraindication to at least 1 conventional synthetic DMARD (unless documented axial disease or severe disease (e.g. dactylitis, multiple (>=5) joint involvement, erosive disease, or functional limitation)):
	  ○ Methotrexate
	  ○ Sulfasalazine
	  ○ Leflunomide
	• Patient has a documented inadequate response, intolerance, or contraindication to at least 1 preferred TNF Inhibitor:
	  ○ Infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade)
	  ○ Adalimumab product (Amjevita [preferred], Humira)
	• Patient has a documented inadequate response, intolerance, or contraindication to the following (unless documented axial disease):
	  ○ Ustekinumab product (Yestinek [preferred], Stelara)
	
	Diagnosis of spondyloarthritis
	• Prescribed 150 mg SC every 4 weeks (without loading dose) for patients weighing less than 100 kg without severe plaque psoriasis
	• Patient has a documented inadequate response, intolerance, or contraindication to at least 1 preferred TNF inhibitor:
	  ○ Infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade)
	  ○ Adalimumab product (Amjevita [preferred], Humira)
	
	Diagnosis of hidradenitis suppurativa:
	• Documented moderate-to-severe hidradenitis suppurativa
	• Documented inadequate response (of at least 16 week trial), intolerance, or contraindication to one of the following:
	  ○ Adalimumab product (adalimumab-atto/Amjevita [preferred])
	  ○ Infliximab product (Infliximab-dyyb/Inflectra[preferred], Remicade)
	• For patients who have NOT been treated with a biologic for hidradenitis suppurativa in the past 6 months, confirm the following additional criteria:
	  ○ Documented inadequate response, intolerance or contraindication to all of the following therapies:
	  ▪ Topical clindamycin 1% solution/lotion/gel (minimum of 12 weeks)
	  ▪ Intralesional corticosteroids (minimum of 4 weeks)
	  ▪ Oral antibiotics (e.g., doxycycline, tetracycline, clindamycin +/- rifampin, erythromycin) (minimum of 10 weeks)
	
	Diagnosis of plaque psoriasis:

Drug	Prior Authorization Criteria

	• Prescribed 150 mg SC every 4 weeks (without loading dose) for patients under 100 kg without severe psoriasis, unless a special circumstance exists (e.g. BSA >50%, resistant disease, prior ER visits for psoriasis)
	• Inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL of the following:
	  ○ 1 TNF inhibitor (e.g., infliximab (Infliximab-dyyb/Inflectra [preferred]), adalimumab (Amjevita [preferred], Humira) unless the patient is < 18 years old
	  ○ 1 IL12/23 inhibitor (e.g. ustekinumab (Yesintek [preferred], Stelara))
	• For patients who have NOT been treated with a biologic for psoriasis in the past 6 months, confirm the following additional criteria are met:
	  ○ >10% Body Surface Area affected (Unless palmar-plantar involvement is severe)
	  ○ Inadequate response (of at least a 3-month trial), intolerance or contraindication to Phototherapy (PUVA, UVB with coal tar or dithranol, UVB standard or narrow-band, or home UVB) <u>excluding</u> patients with:
	  ▪ Involvement of sensitive areas (e.g. hands, feet, face, body folds or genitals)
	  ▪ Concomitant use of medications that cause photosensitivity
	  ▪ History of a photosensitivity disorder (e.g. Lupus, Dermatomyositis, Porphyria, Xeroderma pigmentosum)
	  ▪ History of melanoma or abnormal moles, history of multiple non-melanoma skin cancers
	  ▪ **NOTE: light box trial required unless member has a High Deductible Health Plan**
	• For pediatric patients (<18 years) (Must try in order of preference): Ustekinumab product (Yesintek [preferred])→ Cosentyx → Enbrel → Taltz
	
	<u>Initial Approval:</u> 6 months
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	<u>Continued Approval:</u> 12 months. Continue approval if the following criteria are met:
	
	• <u>For new members who were initiated on Cosentyx outside of KPGA</u>: approve medication if patient is confirmed to be clinically stable on it by a Specialist in the last 6 months
	
	• <u>For existing members who have previously met the criteria</u>:
	  ○ For plaque psoriasis: documented clinically significant benefit from the medication during specialist follow up (office visit or video visit) after initiation of Cosentyx or in the last 12 months, then every 24 months thereafter.
	  ○ For all other indications: documented clinically significant benefit and tolerance of the medication during specialist follow-up in the last 12 months.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**

Crenessity (Crinecerfont)	Candidates for treatment with Crenessity should meet ALL the following criteria:
	• Age ≥ 4 years
	• Confirmed diagnosis of **classic** congenital adrenal hyperplasia (CAH) due to 21-hydroxylase deficiency (21-OHD)
	• Prescribed by endocrinology
	• Crenessity used as an adjunct to glucocorticoid replacement therapy (e.g., hydrocortisone)
	• Requires a supraphysiologic glucocorticoid dose (e.g., total dose >12 to 13 mg/m^2/day in hydrocortisone dose equivalents)
	  ○ Document starting glucocorticoid dose
	• Uncontrolled androgen levels/androstenedione despite maximally tolerated glucocorticoid dose (level >500 ng/dL)
	  ○ Document starting level
	
	Reasons for non-coverage:
	• Any other form of CAH
	• Severe renal impairment or ESRD
	
	Initial Approval: 6 months
	• Crenessity will be used as an adjunct treatment with glucocorticoid therapy.
	
	Continued Approval: 12 months. Confirm patient continues to meet all criteria above without reasons for non-coverage. In addition, endocrinologist documents
	• Reduction in glucocorticoid dose and/or 30% improvement in androgen levels/androstenedione.
	
	For new members who were initiated on Crenessity outside of KPGA: Patients should continue to meet all above coverage criteria without reasons for non-coverage.

Cresemba (Isavuconazonium)	**Candidates for treatment with Cresemba should meet ALL the following criteria:** • Age ≥ 18 years • Prescribed by Infectious Disease, Bone Marrow Transplant, Transplant, or Hematology/Oncology Specialist. • Prescribed for the prevention of invasive mold infections in vulnerable patients (i.e patients undergoing bone marrow transplantation) with documentation that use of other agents is not feasible **OR** • Patient diagnosed with invasive aspergillosis OR mucormycosis

Drug	Prior Authorization Criteria
	○ If diagnosed with invasive aspergillosis: i. Documented failure, intolerance or contraindication to voriconazole (Vfend) **OR** lipid formulation amphotericin B ○ If diagnosed with invasive mucormycosis: i. Documented failure, intolerance or contraindication to noxafil (posaconazole) **OR** lipid formulation amphotericin B • Documented laboratory report indicating causative organism(s) sensitive to isavuconazonium • Baseline liver function tests Reasons for Non-coverage: • Patient has familial short QT syndrome • Co-administration with strong CYP3A4 inhibitors (i.e., ketoconazole or high dose ritonavir) • Co-administration with strong CYP3A4 inducers (i.e., rifampin, carbamazepine, St. John's Wort, long acting barbiturates) Initial Approval Duration: 3 months Continued Approval Duration: 3 months if the patient meets all criteria above in addition to the following: • Positive treatment response (i.e clinical signs/symptoms infection is resolving, radiographic abnormalities are improving, and/or no evidence of disease progression) • Patient has not developed any significant adverse effects (i.e liver toxicity, exfoliative cutaneous reactions, or Stevens Johnson syndrome) Dosage and Administration: • Loading Dose: 372 mg isavuconazonium sulfate (equivalent to 200 mg of isavuconazole) every 8 hours for 6 doses (48 hours) via oral or IV administration. • Maintenance Dose: 372 mg isavuconazonium sulfate (equivalent to 200 mg of isavuconazole) once daily via oral or IV administration starting 12 to 24 hours after the last loading dose. • Switching between the IV and oral formulations of Cresemba is acceptable as bioequivalence has been demonstrated. Loading dose in not required when switching between formulations.
Crysvita (Burosumab-twza)	**Candidates for treatment with Crysvita must meet ALL the following criteria:** • Documented diagnosis of X-linked hypophosphatemia (XLH) supported by at least one of the following: ○ Genetic testing (PHEX mutation) of patient ○ Family member with X-linked inheritance

Drug	Prior Authorization Criteria
	○ Serum FGF23 Level > 30 pg/ml • Prescribed by Endocrinology (Pediatric or Adult) or Nephrology (Pediatric or Adult) • Fasting serum phosphorus below the reference range for age at treatment initiation. ***If on oral phosphate and active vitamin D analogs, discontinue 1 week prior to initiation of treatment*** • Pediatric Patients: ○ Radiographic evidence of active bone disease (rickets in wrists and/or knees and/or femoral/tibial bowing) OR abnormal growth velocity (if open epiphyseal growth plates) ○ For patients age < 2 years without radiographic evidence but with confirmed genetic testing or family history, strong clinical suspicion, and low fasting serum phosphorus, consider treatment per clinical judgement • Adults and adolescents who have reached final adult height (epiphyseal growth plates are closed): ○ Non-healing fractures (defined as visible fracture line) ○ May consider treatment if persistent symptoms (e.g., limited mobility, musculoskeletal pain) of XLH and inadequate response, contraindication, or intolerance to standard treatment with oral phosphate and active vitamin D analogs. Consider deprescribing if no improvement in symptoms after 12 months of treatment. <u>Reasons for Non-coverage:</u> • Age < 6 months • eGFR <30 mL/min/1.73m^2 • Serum phosphorus is within or above the normal range for age prior to treatment initiation • Evidence of tertiary hyperparathyroidism • Concomitant use with oral phosphate and active vitamin D analogs <u>Initial approval:</u> 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** <u>Continued approval:</u> 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continued approval if the following: • Tolerating Medication • Adherence to medication, lab monitoring, renal ultrasound and follow-up assessments • Normalization of serum phosphorus • Positive clinical response (improvement in growth velocity, deformities, fractures, or bone pain) • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**

Drug	Prior Authorization Criteria

	Dosage and Administration:
	
	CRYSVITA is administered by subcutaneous injection and should be administered by a healthcare professional.
	
	• **Pediatric XLH (6 months and older):**
	  • For patients who weigh less than 10 kg, starting dose regimen is 1 mg/kg of body weight rounded to the nearest 1 mg, administered every two weeks.
	  • For patients who weigh 10 kg and greater, starting dose regimen is 0.8 mg/kg of body weight rounded to the nearest 10 mg, administered every two weeks. The minimum starting dose is 10 mg up to a maximum dose of 90 mg.
	  • Dose may be increased up to approximately 2 mg/kg (maximum 90 mg), administered every two weeks to achieve normal serum phosphorus.
	• **Adult XLH:** Dose regimen is 1 mg/kg body weight rounded to the nearest 10 mg up to a maximum dose of 90 mg administered every four weeks.
	
	Criteria for use for diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO)
	• Documented diagnosis of TIO not amenable to surgical excision of the offending tumor/lesion
	• Prescribed by Endocrinology (Pediatric or Adult) or Nephrology (Pediatric or Adult)
	• Fasting serum phosphorus <2.5 mg/dL**.
	• Elevated serum FGF23 level (assay specific)
	• Ratio of renal tubular maximum phosphate reabsorption rate to glomerular filtration rate (TmP/GFR) <2.5 mg/dL**
	• Corrected serum calcium <10.8 mg/dL**
	
	**For pediatric patients, use age-adjusted value for below normal reference range
	
	Reasons for Non-coverage:
	
	• Age < 2 years
	• eGFR <30 mL/min/1.73m^2
	• Serum phosphorus is within or above the normal range for age prior to treatment initiation
	• Evidence of tertiary hyperparathyroidism
	• Concomitant use with oral phosphate and active vitamin D analogs
	• If receiving (or planning to receive) chemotherapy for TIO or other malignant tumors, **consult with oncologist**
	
	Initial approval: 6 months
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Continued approval: 12 months. Confirm patient meets all above coverage criteria without reasons for non-coverage. In addition, continued approval of all of the following:

Drug	Prior Authorization Criteria

	• Tolerating Medication
	• Adherence to medication, lab monitoring, renal ultrasound and follow-up assessments
	• Normalization of serum phosphorus
	• Patient does not have planned chemotherapy or surgical excision of tumor/lesion
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Dosage and Administration:
	
	CRYSVITA is administered by subcutaneous injection and should be administered by a healthcare professional. Do not adjust dose more frequently than every 4 weeks.
	
	• **Pediatric TIO (2 years and older):**
	  ○ Starting dose is 0.4 mg/kg of body weight rounded to the nearest 10 mg every 2 weeks.
	  ○ Dose may be increased up to 2 mg/kg not to exceed 180 mg, administered every two weeks.
	• **Adult TIO:** Starting dose is 0.5 mg/kg every four weeks. Dose may be increased up to 2 mg/kg not to exceed 180 mg, administered every two weeks.

Cuvrior (Trientine Tetrahydrochloride)	**Candidates for treatment with Cuvrior should meet ALL the following criteria:** • Prescribed by a hepatologist or gastroenterologist • Age ≥ 18 years • Patient diagnosed with Wilson's disease • The patient has a prior or current Leipzig score of 4 or greater • The patient has a non-ceruloplasmin copper (NCC) level between 50 to 150 mcg/L or a 24-hour urinary copper excretion (UCE) of between 100 to 500 mcg/24 hours • Documentation that the patient is willing to maintain a diet that avoids high copper foods (e.g., shellfish, nuts, chocolate, mushrooms, organ meat) • The patient had a trial of penicillamine (Depen, Cuprimine) for at least one year prior to starting Cuvrior • The patient had a trial of trientine hydrochloride (Syprine) Initial Approval Period: 6 months Continued Approval Period: 12 months if patient meets ALL the initial criteria above and the following: • Documentation of positive response to Cuvrior therapy
Danyelza (Naxitamab-gqgk)	**Candidates for Danyelza should meet ALL of the following criteria:** • Prescribed by an Oncologist • Used in combination with granulocyte-macrophage colony stimulating factor (GM-CSF) (i.e sargramostim) • Documented relapsed/refractory high-risk neuroblastoma in the bone or bone marrow.

Drug	Prior Authorization Criteria
	• Documentation that patient has had prior therapy with partial, minor response, or stable disease. • Age ≥ 1 year of age • Patient does NOT have any systemic anti-cancer therapy, including chemotherapy or immunotherapy, within 3 weeks before the first dose of GM-CSF. Reasons for Non-coverage: • Pregnancy • Breastfeeding • Active life-threatening infection • Existing major organ dysfunction > Common Terminology Criteria for Adverse Events (CTACE) grade 2, with the exception of hearing loss and hematologic toxicity (defined as suppression of all subtypes of WBCs, RBCs, and platelets) • Progressive disease to prior therapy Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: 12 months if the patient meets ALL the following: • Member continues to meet above criteria • Stabilization of disease or absence of disease progression • Absence of unacceptable toxicity from the drug (i.e infusion-related and hypersensitivity reactions, myelosuppression, infections, etc.) • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Dosage and Administration: • 3 mg/kg/day (maximum: 150 mg/day per the manufacturer's labeling) on days 1, 3, and 5 of each 4-week treatment cycle (in combination with sargramostim [GM-CSF]) • Treatment cycles are repeated every 4 weeks until complete or partial response, followed by 5 additional cycles (every 4 weeks). • Subsequent cycles may be repeated every 8 weeks. Discontinue (naxitamab and GM-CSF) with disease progression or unacceptable toxicity. • IV: Infuse the first infusion (day 1, cycle 1) over 60 minutes. Administer over 30 to 60 minutes as tolerated for subsequent infusions. • Do not administer as an IV push or bolus. • Observe patients for a minimum of 2 hours following each infusion. Premedication and pain management prior to infusions are required
Daraprim (Pyrimethamine) tablets	**Candidates for treatment with Daraprim Oral Tablets should meet ALL the following criteria:** • Prescribed by Infectious Disease or Transplant Specialist • Documented diagnosis of Toxoplasmosis or primary or secondary prophylaxis of toxoplasmosis • FOR Treatment: Documented intolerance or contraindication to pyrimethamine compound OR pyrimethamine compound not readily available.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• For Prophylaxis: Documented Failure, intolerance or contraindication to trimethoprim-sulfamethoxazole (TMP-SMZ) AND atovaquone AND documented intolerance or contraindication to pyrimethamine compound OR pyrimethamine compound not readily available. Approval: 12 months
Darzalex Faspro (Daratumumab-hyaluronidase-fihj)	**Candidates for Darzalex Faspro should meet ALL the following criteria:** • Age ≥ 18 years • Patient must meet **ONE** of the following: ○ Patient has a new diagnosis of light chain amyloidosis (in combination with bortezomib, cyclophosphamide, and dexamethasone) with the exception of patient who has NYHA class IIIB or Class IV cardiac disease or Mayo stage IIIB outside of controlled clinical trials. **OR** ○ Patient with high-risk smoldering multiple myeloma as monotherapy **OR** ○ Patient has a new diagnosis of multiple myeloma AND meets ALL the following criteria: ▪ Darzalex Faspro will be used in combination with bortezomib (Velcade), melphalan and prednisone OR in combination with lenalidomide and dexamethasone, OR in combination with bortezomib, thalidomide, and dexamethasone **OR** ▪ The patient is eligible for an autologous stem cell transplant **AND** Darzalex Faspro will be used in combination with bortezomib (Velcade), lenalidomide, and dexamethasone for induction and consolidation **OR** ▪ Treatment of newly diagnosed multiple myeloma (in combination with lenalidomide and dexamethasone) in adults who are ineligible for autologous hematopoietic cell transplant **OR** ○ Patient has diagnosis of relapsed or refractory multiple myeloma AND meets all the following criteria: ▪ Patient has received at least one prior therapy AND ▪ Darzalex Faspro will be used in combination with lenalidomide and dexamethasone **OR** Tecvayli (teclistamab-cqyv) **OR** ○ Patient has a diagnosis of multiple myeloma AND meets ALL the following criteria: ▪ Patient has received at least one prior therapy AND ▪ Darzalex Faspro will be used in combination with bortezomib and dexamethasone **OR**

Drug	Prior Authorization Criteria
	○ Patient has a diagnosis of multiple myeloma AND meets all the following criteria: ▪ Patient has received at least one to 3 prior lines of therapy AND ▪ Darzalex Faspro will be used in combination with Carfilzomib and dexamethasone **OR** ○ Patient has a diagnosis of multiple myeloma (as monotherapy) AND meets ALL the following criteria: ▪ Patient has received at least three prior therapies, including agents from BOTH of the following drug classes: • Proteasome inhibitors (PI) [e.g., bortezomib (Velcade), carfilzomib (Kyprolis), ixazomib (Ninlaro)] • Immunomodulatory agents [e.g., lenalidomide (Revlimid), pomalidomide (Pomalyst), thalidomide (Thalomid)] AND ▪ Darzalex Faspro will be used as monotherapy (not in combination with a proteasome inhibitor or immunomodulatory agent) • Documented trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction) to KP's preferred therapy, isatuximab (Sarclisa) AND the same intolerance, contraindication, or adverse event would not be expected to occur with Darzalex Faspro. Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for administration ONLY in KPGA infusion center, absent director level approval.** Continued Approval: 12 months. Confirm patient meets all above criteria. In addition, patient should meet the following: • No evidence of disease progression or unacceptable toxicity • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Approve for administration ONLY in KPGA infusion center, absent director level approval.** Dosing and Administration • 15 mL subcutaneously over approximately 3-5 minutes according to recommended schedule. • Requires administration by a healthcare professional

Drug	Prior Authorization Criteria

Datroway (Datopotamab Deruxtecan)	**Candidates for treatment with Datroway (datopotamab deruxtecan) should meet ALL of the following criteria:**
	• Prescribed by a hematologist/oncologist
	• Diagnosed of **ONE** of the following:
	  ○ Unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer in adults who have received all of the following:
	  ▪ Endocrine-based therapy (e.g., anastrazole, letrozole, fulvestrant, etc)
	  ▪ A CDK4/6 inhibitor (e.g., abemaciclib, palbociclib, ribociclib, etc)
	  ▪ At least two additional systemic therapies
	  ▪ Documentation why Trodelvy (sacituzumab govitecan-hziy) is not appropriate for use in this patient
	  ○ Locally advanced or metastatic, epidermal growth factor receptor (EGFR)-mutated, non–small cell lung cancer who have received all the following:
	  ▪ Prior EGFR-directed therapy (e.g., afatinib, erlotinib, osimertinib)
	  ▪ Platinum-based chemotherapy (e.g., cisplatin or carboplatin)
	• Age ≥ 18 years old
	
	<u>Reasons for Non-coverage:</u>
	• Presence of brain metastases unless:
	  ○ Previously treated and disease/symptom-free with no evidence of progression for ≥3 months; AND
	  ○ Not receiving high-dose steroids (>20 mg prednisone or equivalent) for ≥4 weeks
	
	<u>Initial Approval:</u> 6 months
	
	<u>Continued Approval:</u> 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, confirm patient meets all the following:
	• Approve for administration ONLY in KPGA infusion center, absent director level approval
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread
	• Absence of unacceptable toxicity from therapy (any ≥ grade 3 toxicity that does not improve with dose reduction and/or holding therapy)

Daurismo (Glasdegib)	**Candidates for treatment with Daurismo must meet ALL the following criteria:**
	
	• Prescribed by a hematologist or oncologist.
	• Diagnosis of acute myeloid leukemia (AML)
	• Patient meets one of the following:
	  ○ Age ≥75 years
	  ○ Inability to use intensive induction chemotherapy due to comorbidities (e.g., severe cardiac disease, ECOG performance ≥2, baseline creatinine >1.3 mg/dL, etc.).
	• Medication will be prescribed in combination with low-dose cytarabine for a minimum of 6 cycles

Drug	Prior Authorization Criteria

	Reasons for non-coverage:
	• Pregnant or planning to become pregnant.
	• Breastfeeding
	
	Initial Approval: 12 months.
	• Quantity limits:
	  ○ For 25 mg tablets, 90 tablets per 30 days.
	  ○ For 100 mg tablets, 30 tablets per 30 days.
	
	Continued Approval: 12 months. For continued approval for treatment with Daurismo, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria.
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	• Quantity limits:
	  ○ For 25 mg tablets, 90 tablets per 30 days.
	  ○ For 100 mg tablets, 30 tablet per 30 days.
	  ○
	For new members who were initiated on Daurismo outside of KPGA: Patient should meet ALL the following criteria:
	• Prescribed by a hematologist or oncologist.
	• Age ≥ 75 years **OR** inability to use intensive induction chemotherapy due to comorbidities (e.g., severe cardiac disease, ECOG performance ≥2, baseline creatinine >1.3 mg/dL).
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	• Quantity limits:
	  ○ For 25 mg tablets, 90 tablets per 30 days.
	  ○ For 100 mg tablets, 30 tablet per 30 days.

Dawnzera
(Donidalorsen)
	Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval
	
	Candidates for treatment with Dawnzera (donidalorsen) should meet ALL of the following criteria:
	
	• Prescribed by an allergist or immunologist
	• Patient is 12 years of age or older
	• Diagnosed with hereditary angioedema (HAE) confirmed by ONE of the following:
	  ○ C1 esterase inhibitor (C1-INH) antigenic level below the lower limit of normal; OR
	  ○ C1-INH functional level below the lower limit of normal; OR
	  ○ Normal C1-INH levels and ONE of the following:
	  ▪ Confirmed presence of variant(s) in the F12, ANGPT1, PLG, KNG1, MYOF, and HS3ST6 gene(s)
	  ▪ Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

Drug	Prior Authorization Criteria
	▪ Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de novo mutation(s) (i.e. no family history; HAE-unknown) • Dawnzera will be used for prophylaxis against HAE attacks • Documentation that other causes of angioedema have been ruled out (e.g. angiotensin-converting enzyme [ACE] inhibitor-induced angioedema, angioedema related to an estrogen-containing drug) • Documented trial of or contraindication to ONE of the following agents: Haegarda (C1 esterase inhibitor), Takhzyro (lanadelumab-flyo), or Orladeyo (berotralstat) Reasons for non-coverage: • Concurrent use with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], Orladeyo [berotralstat], danazol, Andembry [garadacimab-gxii]) • Moderate or severe hepatic impairment (NCI-ODWG Criteria: total bilirubin >1.5 x ULN regardless of AST level) Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, must have improvement in HAE attacks (reductions in attack frequency or attack severity) compared to baseline. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
Daybue **Daybue Stix** (Trofinetide)	**Candidates for treatment with Daybue/ Daybue Stix (trofinetide) must meet ALL the following criteria:** • Patient is ≥2 years old • Prescribed by or in consultation with developmental pediatrician, geneticist, neurologist or psychiatrist • Diagnosis of classic or typical Rett based on Rett Diagnostic Criteria • Documented *MECP2* mutation • Weight ≥ 9 kg; stable weight gain, and does not have progressive weight loss prior to therapy initiation • Patient has failed behavioral, rehabilitative and/or pharmacological therapies targeting Rett syndrome related characteristics (e.g., physical therapy, occupational therapy, applied behavioral analysis [ABA], behavioral health treatment [BHT], and/or anxiolytics)

Drug	Prior Authorization Criteria
	• At least six months "post regression" at treatment initiation (i.e., no loss or degradation in ambulation, hand function, speech, nonverbal communicative or social skills within six months of treatment initiation) • Clinical Global Impression Scale-Severity (CGI-S) score of ≥4 • Has a stable pattern of seizures or has had no seizures within eight weeks of treatment initiation • Normal eGFR and QTc within previous year prior to treatment initiation Reasons for Non-coverage: • QTc interval > 450 ms, history of risk factor for torsade de pointes, or clinically significant QT prolongation deemed to increase risk • Recent or dynamic seizure status Initial Approval: 12 weeks Continued Approval: 12 months Patient must meet all criteria above without reasons for non-coverage in addition to the following: • The patient has improvement in signs and symptoms of Rett as assessed by the Clinical Global Impression- Improvement score of 3 or less. Ordering Information: Daybue is available from AnnovoRx Specialty Pharmacy. Information on ordering and forms can be accessed at AcadiaConnect.
Demser (Metyrosine)	**Candidates for treatment with Metyrosine (Demser) should meet ALL the following criteria:** • Prescribed by hematology/oncology, neurology, or endocrinology • Patient is ≥12 years of age • Diagnosis of pheochromocytoma • Indicated for one of the following: a. Prior to procedure to remove pheochromocytoma blood pressure control b. Management of patients when surgery is contraindicated c. Chronic treatment of patients with malignant pheochromocytoma • Patient has inadequate response, intolerance, or contraindication to **combined** alpha- AND beta-adrenergic blockade (alpha-adrenergic blocker and beta- adrenergic blocker must be used in **combination** prior to Demser): a. Alpha-adrenergic blocker: trial of doxazosin or other selective alpha-adrenergic blocker (terazosin, prazosin) or phenoxybenzamine (Debenzyline) b. Beta-adrenergic blocker: trial of metoprolol IR or propranolol or other beta-adrenergic blocker • For brand name Desmer, must have a documented allergy/intolerance to the components of generic metyrosine.

Drug	Prior Authorization Criteria
	Reasons for Non-coverage: • Treatment of essential hypertension Initial Approval: • Prior to procedure to remove pheochromocytoma blood pressure control: 3 months • For all other indications: 12 months Continued Approval: • Prior to procedure to remove pheochromocytoma: continue until date of the procedure • For all other indications: 12 months • Continued approval for treatment with metyrosine should meet ALL of the criteria above in addition to the criteria below: o Member has documentation of positive clinical response and/or stabilization of disease
Denosumab 60 mg products **Preferred:** **Stoboclo** (Denosumab-bmwo) **Non-preferred:** **Enoby** (Denosumab-qbde) **Bildyos** (Denosumab-nxxp) **Bosaya** (Denosumab-kyqq) **Jubbonti** (Denosumab-bddz) **Ospomyv** (Denosumab-dssb) **Osvyrti** (denosumab-desu) **Prolia** (Denosumab)	**Candidates for treatment with denosumab 60 mg product should meet ALL the following criteria:** Diagnosis of osteopenia, osteoporosis or osteoporotic fracture requiring treatment AND o For patients with osteoporosis only- a T-Score (confirmed by DEXA) of < -2.5. o For patients with osteopenia only: high risk for fracture: WHO Fracture Risk Assessment (FRAX) 10-year risk of major osteoporotic fracture ≥20% **OR** 10-year risk of hip fracture ≥3% Link to FRAX tool: frax.shef.ac.uk/FRAX/ • Prescribed by Endocrinologist, Rheumatologist, Oncologist, Adult Primary Care/Family Practice/No Sleepless Night clinicians addressing bone health, or Urologist • Documented intolerance/contraindication or inadequate response of a minimum of 12 months with adherence ≥ 80%. If MRAR < 80%, reviewer can confirm adherence based on medication sold dates found in Health Connect medication tab (e.g., 12 one month fills or four 90 day fills to **one** oral bisphosphonate (i.e., alendronate, ibandronate, risedronate*) AND IV bisphosphonate (i.e., zoledronic acid) UNLESS o Provider denotes very high risk for osteoporotic fractures, bisphosphonate trial not required. Very high risk is defined as: ▪ Fractures while on bisphosphonate therapy and taking as prescribed (as evidenced by refills, MRAR ≥ 80%. If MRAR < 80%, reviewer can confirm adherence based on medication sold dates found in Health Connect medication tab (e.g., 12 one month fills or four 90 day fills) ▪ Unstable or decreasing BMD despite adequate therapeutic trial of bisphosphonate (at least 3 years) (with > 80% adherence) ▪ History of multiple vertebral compression fractures ▪ Fractures while on drugs causing skeletal harm (ie glucocorticoids) ▪ **BMD with T-score less than -3.0** ▪ High risk for falls or history of injurious falls ▪ Very high fracture risk based on FRAX score (major osteoporosis fracture >30%, hip fracture >4.5%)

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• Calcium levels have been checked and any pre-existing hypocalcemia has been corrected. • For requests for Prolia or non-preferred denosumab biosimilar products: patient has a documented trial and failure (e.g., allergic reaction, injection site reaction, etc.) to Stoboclo (denosumab-bmwo, [preferred]) and one additional denosumab biosimilar. * If GI intolerance documented to the preferred bisphosphonate (i.e., alendronate), patient must either have a trial of risedronate OR trial an IV bisphosphonate. Reasons for Non-coverage: • Pediatric patients (<18 years old) • Pregnant/nursing women • Hypocalcemia • Non-FDA approved indications • Stage 5 CKD or receiving hemodialysis Initial Approval: 12 months (2 doses) Continued Approval: 12 months (2 doses) • For patients started on denosumab, please approve subsequent treatments with denosumab. Approve Stoboclo for clinic/back-office administration only **For existing members who have previously met the full criteria above:** Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, continue approval if patient has documented clinical benefit from medication **For new members who were initiated outside of KPGA: Approve Stoboclo if the following are met:** • Endocrinology, Rheumatology, Oncology, or Urology visit in the past 6 months, confirming patient is clinically stable on current therapy • Stoboclo is the preferred denosumab product at KP Note: 3-month approval while awaiting specialist evaluation

Denosumab 120 mg products
 	
Preferred
Osenvelt
(denosumab-bmwo)
 	
Non-Preferred:
Xtrenbo
(Denosumab-qbde)
	Candidates for treatment with denosumab 120 mg products should meet ALL the following criteria:
	
	• Diagnosis of ONE of the following:
	  ○ Bone metastases from prostate cancer **OR**
	  ○ Bone metastases from solid tumors OTHER THAN Prostate AND
	  ▪ A therapeutic trial and clinical failure with zoledronic acid (Zometa) or
	  ▪ Documented renal dysfunction (CrCl< 30 ml/min)
	  ➢ ***NOTE:** Clinical failure defined as development of new skeletal related event (SRE) while receiving treatment with zolendronic acid for at least 3 months **OR**

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
Bilprevda (Denosumab-nxxp) **Aukelso** (Denosumab-kyqq) **Wyost** (Denosumab-bbdz) **Jubereq** (Denosumab-desu) **Bomyntra** (Denosumab-bnht) **Xgeva** (Denosumab) **Xbryk** (Denosumab-dssb)	○ Prevention of skeletal related events in patient with Multiple Myeloma AND ▪ A therapeutic trial and documented clinical failure, intolerance, or contraindication with zoledronic acid (Zometa) or ▪ Documented renal dysfunction (CrCl< 30 ml/min) **OR** ○ Hypercalcemia of malignancy and refractory to bisphosphonate treatment **OR** ○ Giant cell tumor of the bone AND ▪ Patient is an adult or skeletally mature adolescent weighing greater than or equal to 45 kg and ▪ Tumor is unresectable or where surgical resection is likely to result in severe morbidity • Must be prescribed by a hematologist or oncologist. • Calcium levels have been checked and any pre-existing hypocalcemia has been corrected. • Patient has had a baseline dental exam prior to initiating denosumab therapy. • For requests for Xgeva or non-preferred denosumab biosimilar products: patient has a documented trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction, etc.) to Osenvelt (denosumab-bmwo), KP's preferred denosumab biosimilar product. <u>Reasons for Non-coverage:</u> • Hypocalcemia • Non-FDA approved indications <u>Initial Approval</u>: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** <u>Continued Approval</u>: 12 months. Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, continue approval if patient has documented clinical benefit from medication and no reported adverse events to denosumab product. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** <u>Use caution in the following patients</u>: • Pregnant/nursing women (Pregnancy Category D)
Desoxyn (Methamphetamine)	**Candidates for treatment with Desoxyn should meet ALL the following criteria:** • Patient has a documented diagnosis of ADHD • Age ≥ 6 years • Patient has failed a trial of at least 4-weeks to or patient has experienced a clinically significant intolerance to: ○ One formulary methylphenidate product AND ○ One formulary amphetamine product AND ○ One formulary dexmethylphenidate product AND

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ Atomoxetine AND ○ Guanfacine, guanfacine ER, OR clonidine Initial Approval: 3 months Continued Approval: 12 months. For continued approval for treatment with Desoxyn, patient should have 2 provider visits in 270 days to assess response AND meet ALL the following criteria: For new members who were initiated on Desoxyn outside of KPGA: Confirm patient meets all the above coverage criteria without reasons for non-coverage. For existing members who previously met the full criteria above: Continued approval will be based on clinical documentation of the following: • Patient is responding positively to therapy. Response is defined as TWO of the following ○ Achieved and maintains at least a 50% reduction from baseline in core symptoms of hyperactivity, impulsivity, and attention ○ Documented improvement in target goal created by patient and physician (e.g., turning in assignments on time, improved classroom behavior) ○ Documented improved attention and social skills ○ No aggressive behaviors documented Notes: Methamphetamine is not addressed in guidelines as a therapeutic option for treatment of ADHD; use has been replaced by other agents (AACAP [Pliszka 2007]; AAP 2011; NICE 2018)
Diacomit (Stiripentol)	**Candidates for treatment with Diacomit should meet all the following criteria:** • Prescribed by a Neurologist • Age ≥ 2 years • Documented diagnosis of Dravet Syndrome • Diacomit is prescribed as adjunctive therapy with clobazam • Documentation of inadequate treatment response to 2 antiepileptic drugs (AEDs) (e.g., clozabam, valproic acid, levetiracetam, topiramate, clonazepam, zonisamide or ethosuximide) • Inadequate response intolerance or contraindication to cannabidiol (Epidiolex) **OR** patient is currently established on treatment with stiripentol (Diacomit) Initial Approval: 12 months Continued Approval: 12 months. Confirm patient meets all above coverage criteria. In addition, confirm patient meets the following: • Continued use in combination with clobazam. • Clobazam total daily dose is no more than 20 mg unless clinical reason for higher dose is documented. • Documented reduction in the frequency of seizures since starting stiripentol AND • Documentation of CBC, liver enzymes and weight in the last 6 months. Ordering information:

Drug	Prior Authorization Criteria
	Diacomit is available through US Bioservices Specialty Pharmacy. If approved for coverage, prescribers must complete the Diacomit Patient Enrollment Form and fax both the form and the prescription for Diacomit to US Bioservices Specialty Pharmacy at 833-971-4137.

DPP-4 inhibitors:
KP Preferred:
Sitagliptin (authorized equivalent for Zituvio) and Sitagliptin/metformin (authorized equivalent for Zituvimet)
 	
Non-Preferred:
Nesina (Alogliptin)
 	
Onglyza (Saxagliptin)
 	
Januvia (Sitagliptin)
 	
Tradjenta (Linagliptin)
 	
Jentadueto (Linagliptin and metformin)
 	
Non-Covered combination products (separate prescriptions required for ingredients in combination products):
 	
Kazano
	Candidates for treatment with DPP-4 Inhibitors must meet ALL the following criteria:
	
	The preferred DPP-4 inhibitor coverage criteria current KP newly starting treatment who meet ALL of the following criteria:
	
	• Documented diagnosis of type 2 diabetes mellitus in patients ≥ 18 years of age
	• A1C </=8% in the past 3 months
	• Currently prescribed ALL of the following at maximum tolerated dose for at least 3 months with MRAR >80% or documented failure, intolerance or contraindications
	  ○ Metformin
	  ○ Documented failure, intolerance, or contraindications to Liraglutide or Ozempic (GLP-1 RA). MUST stop GLP-1 if initiating DPP-4 inhibitor.
	  ○ Dapagliflozin
	• Documented trial, intolerance or contraindication to Sitagliptin (Zituvio) then alogliptin, if request is for non-preferred DPP-4 inhibitor
	
	Non-preferred DPP-4 inhibitors: Only to be used when the preferred DPP-4 inhibitor (Zituvio) then alogliptin (Nesina) have failed. If request is for non-preferred Januvia, patient has tried sitagliptin (Zituvio) and had an intolerance or allergic reaction that is likely due to the **inactive** components of the Zituvio and cannot be explained by other clinical or lifestyle factors.
	
	For non-preferred combination product:
	• Patient must meet criteria for DPP-4 inhibitor (below) AND
	• Separate prescriptions are required for ingredients in non-preferred combination products
	
	Initial approval period: 12 months.
	
	Continued approval: 12 months. Confirm patient meets all above coverage criteria without reasons for non-coverage. In addition, continued approval is based on:
	• Current A1C shows documented lowering of 0.5% from initial A1Cor A1C now at goal
	
	The preferred DPP-4 inhibitor coverage criteria for **new members**. Must meet ALL the following:
	• Documented diagnosis of type 2 diabetes mellitus in patients ≥ 18 years of age
	• A1C </=8.5% in past 3 months
	• Currently prescribed BOTH metformin and SGLT2 inhibitor (e.g. dapagliflozin) at maximum tolerated dose or documented failure, intolerance or contraindication
	  ○ When clinically appropriate, switch DPP-4 inhibitor to dapagliflozin. Dapagliflozin is the formulary option
	• Documented trial, intolerance or contraindication to Zituvio then alogliptin, if request is for non-preferred DPP-4 inhibitor

Drug	Prior Authorization Criteria
(Alogliptin and metformin) **Oseni** (Alogliptin and pioglitazone) **Kombiglyze ER** (Saxagliptin and metformin extended-release) **Janumet and Janumet XR** (Sitagliptin and metformin) **Zituvimet XR** (Sitagliptin/metformin HCL ER) **Glyxambi** (Empagliflozin and linagliptin) **Qtern** (Saxagliptin and dapagliflozin) **Steglujan** (Sitagliptin and ertugliflozin) **Jentadueto XR** (Linagliptin and metformin ER) **Trijardy XR** (Empagliflozin, linagliptin, and metformin ER)	Continued Approval: 12 months. Continued approval is based on: A1c of ≤8% or prescriber deems clinically stable (must be performed within the past 3-6 months)
Dojolvi (Triheptanoin)	Candidates for treatment with Dojolvi should meet ALL the following criteria: • Confirmed diagnosis via molecular genetic testing for one of the following deficiencies: ○ very long-chain acylCoA dehydrogenase (VLCAD)

Drug	Prior Authorization Criteria
	○ carnitine palmitoyltransferase 2 (CPT2) ○ mitochondrial trifunctional protein (TFP) ○ long-chain 3-hydroxyacyl-CoA dehydrogenase (LCHAD) ○ carnitine acylcarnitine translocase (CACT) • Documentation of one of the following ○ Recurrent episodes of rhabdomyolysis requiring intervention and not improving with standard medical therapy* or recommended lifestyle measures. ○ Cardiomyopathy/cardiac involvement that is not improving or stabilizing to an acceptable degree with standard medical therapy* i. *Standard medical therapy consists of reduced dietary intake of long-chain fats plus supplementation with medium chain triglycerides (MCT). • Patient will discontinue MCT before initiating triheptanoin. Reasons for Non-coverage: • No prior trial of standard medical therapy. • Nonadherent to standard medical therapy. • Physiologically stable on standard medical therapy without anticipated complications (i.e., stable cardiac disease, no rhabdomyolysis or infrequent rhabdomyolysis). • Use for off-label indication(s) - such patients should be referred to a clinical trial or compassionate use program. Initial Approval: 12 months Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continue approval if the following is met: • Lack of response to therapy (e.g., having multiple episodes of rhabdomyolysis or cardiomyopathy continues to progress) after 12 months or more of treatment. • Intolerance to medication. Non-adherence to medication, recommended diet and lifestyle measures, or follow-up labs and assessments.
Doptelet (Avatrombopag)	**Candidates for treatment with Doptelet should meet ALL the following criteria:** For patients with chronic liver disease and thrombocytopenia undergoing scheduled, high bleeding risk invasive procedure: • Age ≥ 18 years • Prescribed by gastroenterologist • Diagnosis of thrombocytopenia (platelet count < 50 x 10^9/L) AND Chronic liver disease who are undergoing a scheduled, high bleeding risk invasive procedure (See KPGA Perioperative Anticoagulation Management Guidelines for examples of high bleeding risk procedures) For the treatment of chronic immune thrombocytopenia

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	• Age ≥ 1 year
	• Prescribed by oncologist
	• Diagnosis of thrombocytopenia (platelet count <50 x 10^9/L) AND chronic immune thrombocytopenia
	• Patient has had insufficient response to previous treatment with corticosteroids, immunoglobulins, or splenectomy.
	• Trial and failure or contraindication to of rituximab or rituximab biosimilar
	  ○ Note: Treatment failure can be considered if no improvement after at least 4 weekly infusions within at least 6 weeks after the first infusion
	• Trial and failure or contraindication to KP preferred agent eltrombopag
	  ○ Note: treatment failure can be considered after at least 2 months of treatment with the preferred agent
	• Doptelet Sprinkle oral granules only to be approved for children 1 to < 6 years of age
	
	Reasons for Non-coverage:
	
	• Treatment of thrombocytopenia outside of a scheduled high-risk invasive procedure in a patient with chronic liver disease and for chronic thrombocytopenia in adults who had sufficient response to a previous treatment
	
	Initial Approval:
	
	• **Chronic immune thrombocytopenia**: 12 months
	• **Chronic liver disease who are undergoing a scheduled, high bleeding risk invasive procedure:** 5 days
	
	Continued Approval:
	
	• **Chronic immune thrombocytopenia:** 12 months if patient meets all the initial criteria above is still responding to treatment
	• **Chronic liver disease who are undergoing a scheduled, high bleeding risk invasive procedure:** Continued approval is NOT warranted with this medication as the patient should only get a 5 day supply prior to a scheduled procedure

Dupixent (Dupilumab)	**Candidates for treatment with Dupixent should meet ALL the following criteria PLUS the individual disease state criteria below** • Prescribed by an allergist, dermatologist, gastroenterologist, otolaryngologist, or pulmonologist. • Patient is not receiving Dupixent in combination with any other biologic or advanced small molecule for the same indication (e.g. Nucala, Fasenra, Xolair, infliximab, Adbry, Nemluvio, adalimumab, upadacitinib). **Diagnosis of Allergic Fungal Rhinosinusitis (AFRS):** • Age ≥ 6 years old and weighing at least 15kg. • Documented full endoscopic sinus surgery

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	• History of failure, intolerance, or contraindication to **all** of the following after full endoscopic sinus surgery:
	  ○ Two or more courses of systemic corticosteroids in the last 12 months
	  ○ Intranasal steroid spray or rinse (i.e., fluticasone, triamcinolone, mometasone spray and/or budesonide rinse) for 3 months
	
	Diagnosis of asthma:
	• Documented diagnosis of **ONE** of the following:
	  ○ Age ≥ 6 years, diagnosis of severe eosinophilic asthma with a documented blood eosinophil count of 150 to 1500 cells/mm^3 in the past 12 months (unless current or recent [prior 6 months] biologic use) **AND** an inadequate response (trial ≥ 4 months), intolerance, or contraindication to Fasenra (benralizumab)
	  ○ Age ≥ 6 years, diagnosis of asthma with non-eosinophilic and non-allergic phenotype and is oral corticosteroid (OCS) dependent (i.e., ≥ 2 asthma exacerbations requiring oral or systemic corticosteroids in the past 12 months)*
	  *E.g., oral prednisone, IM triamcinolone and/or IV methylprednisolone
	  ○ Age ≥ 12 years, diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) and severe eosinophilic asthma with a documented blood eosinophil count of > 300 cells/mm^3 (unless current or recent [prior 6 months] biologic use) in the past 12 months
	• Documented uncontrolled asthma defined as ONE of the following:
	  ○ Two or more asthma exacerbations in the past 12 months requiring systemic corticosteroids for ≥ 3 days OR at least one serious exacerbation requiring hospitalization or ER visit in the past 12 months
	  ○ Asthma Control Test (ACT) consistently < 20 over the past 12 months
	  ○ Dependence on OCS for asthma control
	• Receiving high-dose or maximally tolerated inhaled corticosteroid plus long-acting beta-agonist (ICS/LABA)$^{\pm}$ with or without OCS
	  $^{\pm}$For age ≥ 12 years: fluticasone/salmeterol 500/50 mcg 1 puff twice daily or budesonide/formoterol 160/4.5 mcg 2 puffs BID
	  For ages 6 to < 12 years: fluticasone /salmeterol 100/50 mcg 1 puff twice daily or budesonide/formoterol 80/4.5 mcg 2 puffs BID
	• Dupixent (dupilumab) is used as add-on therapy to a high-dose, or maximally tolerated, ICS and at least one additional asthma controller medication, such as a LAMA, LABA, or LRTA
	
	Diagnosis of chronic obstructive pulmonary disorder COPD:
	• Age ≥ 18 years
	• Diagnosis of moderate to severe COPD with an eosinophilic phenotype with blood eosinophil count of ≥ 300 cells/mm^3 in the past 12 months, (unless current or recent [prior 6 months] biologic use)
	• Documented exacerbation history in the past 12 months as demonstrated by one of the following:
	  ○ ≥ 2 moderate exacerbations requiring systemic glucocorticoids
	  ○ ≥ 1 severe exacerbation requiring hospitalization, ER visit or IV glucocorticoids
	• Documented inadequate response (trial of ≥ 3 months), intolerance, or contraindication to **ONE** of the following:
	  ○ High-dose triple (ICS/LABA/LAMA) combination therapy*

Drug	Prior Authorization Criteria
	*Fluticasone/salmeterol 500/50 mcg 1 puff BID plus Spiriva Respimat 2.5mcg 2 puffs daily OR Stiolto Respimat 2 puffs daily plus Alvesco 160 mcg 1 puff BID OR Breyna 160/4.5 mcg 2 puffs BID plus Spiriva Respimat 2 puffs daily OR Trelegy 1 puff daily OR Breztri 2 puffs BID ○ High-dose dual (LAMA/LABA) combination therapy** **Stiolto Respimat 2 puffs daily OR Anoro Ellipta 1 puff daily • Patient will continue to use dual or triple maintenance therapy for COPD **Diagnosis of eosinophilic esophagitis (EoE)** • Age ≥ 1 year AND weighing at least 15 kg (33 lb) • Confirmed diagnosis of EoE by upper endoscopy and biopsy with a maximum eosinophil count of at least 15 eosinophils per high-power microscopy field • Two or more episodes of dysphagia per week • Documented inadequate response, intolerance or contraindication to **ALL** of the following therapies: ○ Proton pump inhibitor therapy with titrated dose to twice daily (8 week minimum) and continued therapy if response ○ Topical glucocorticoid (8 week minimum) and continued therapy if response: budesonide oral viscous slurry or fluticasone swallowed (not inhaled) **Diagnosis of nasal polyposis:** • Age ≥ 12 years • Otolaryngologist documentation of bilateral nasal polyposis after full endoscopic sinus surgery • History of failure, intolerance, or contraindication to **ALL** of the following after full endoscopic sinus surgery: ○ Two or more short courses of systemic corticosteroids in the last 12 months ○ Intranasal steroid spray or rinse (i.e., fluticasone, triamcinolone, mometasone spray and/or budesonide rinse) for 3 months ○ Montelukast for 3 months • Patient will continue a nasal corticosteroid with Dupixent unless contraindicated or intolerance to nasal corticosteroids. **Diagnosis of atopic dermatitis:** • Prescribed by dermatologist only • Age ≥ 6 months • If patient has been treated with a biologic drug or oral JAK inhibitor for atopic dermatitis in the past 6 months, proceed to initial approval. For all other patients, confirm additional criteria below are met: • Documented moderate-to-severe atopic dermatitis (such as BSA ≥ 10%, involvement of high-impact areas [e.g., face, hands, feet, genitals, skin folds], or documented major impact on quality of life) • Inadequate response, intolerance, or contraindication to ONE of the following: ○ Topical calcineurin inhibitors [e.g., pimecrolimus (Elidel) or tacrolimus (Protopic)] ○ Medium to very high potency topical corticosteroid [listed from lower to higher potency in each category]

Drug	Prior Authorization Criteria

Medium Potency	High and Very High Potency
Triamcinolone acet 0.025% O, C	Fluocinonide 0.05% O, C, G
Triamcinolone acet 0.1% O,C	Fluocinonide-emollient 0.05% C
Betamethasone val 0.1% C	Desoximetasone 0.25% C
Mometasone 0.1% O, C	Betameth diprop aug 0.05% C
Triamcinolone acet 0.5% C	Betamethasone diprop aug 0.05% O, G
Betamethasone diprop 0.05% C	Clobetasol 0.05% O, C

O = oint, C = cream, G = gel, L = lotion

- Documented inadequate response, intolerance, or contraindication to phototherapy; or documentation supporting an exception to the phototherapy requirement, including:
  - Pediatric patients who are developmentally unable to independently stand in light unit or unable to reliably attend frequent in-office treatments
  - Involvement of sensitive areas (e.g., hands, feet, face, body folds, genitals)
  - History of photosensitivity disorder (e.g., Lupus, Dermatomyositis, Porphyria, Xeroderma pigmentosum)
  - History of melanoma or abnormal moles or multiple non-melanoma skin cancers
  - **NOTE: Light box trial required unless member has a High Deductible Health Plan**
- For patients age 6 years and older: Documented inadequate response or intolerance to at least ONE of the following (or documented contraindications to all): mycophenolate, cyclosporine, azathioprine, or methotrexate.

Diagnosis of prurigo nodularis:

- Prescribed by dermatologist only
- Age ≥ 18 years
- Inadequate response (trial of at least 2 months), intolerance, or contraindication to **ALL** of the following:
  - High or super-high potency topical corticosteroid (e.g., betamethasone dipropionate, augmented 0.05% cream, clobetasol propionate 0.05% ointment, lotion, gel)
  - Topical vitamin D analog (e.g., calcipotriene 0.005% solution, calcitriol 3mcg/g ointment)
  - Topical calcineurin inhibitor (e.g., tacrolimus 0.1% ointment)
- Phototherapy (PUVA, UVB with coal tar or dithranol, UVB standard or narrow-band, or home UVB) of at least a 3-month trial, excluding patients with:
  - Involvement of sensitive areas (e.g. hand, feet, face, body folds or genitals)
  - Concomitant use of medications that cause photosensitivity, history of photosensitivity disorder (e.g. Lupus, Dermatomyositis, Porphyria, Xeroderma

Drug	Prior Authorization Criteria

	pigmentosum), history of melanoma or abnormal moles, history of multiple non-melanoma skin cancers
	
	Diagnosis of chronic spontaneous urticaria:
	• Age ≥ 12 years
	• Inadequate response (trial of at least 4 weeks), intolerance, or contraindication to at least ONE of the following:
	  ○ A single high-dose second generation H1-antihistamines (e.g., loratadine, cetirizine) prescribed at 4 times normal dose daily dose
	  ○ Two second-generation H1 antihistamines used in combination (e.g., fexofenadine 180 mg daily in the am plus cetirizine 10-20 mg daily at bedtime)
	• Inadequate response (trial of at least 4 months), intolerance, or contraindication to Xolair (omalizumab).
	
	Diagnosis of bullous pemphigoid
	• Age ≥ 18 years
	• Inadequate response, intolerance or contraindication to **ALL** of the following:
	  ○ 1 High-potency corticosteroid (e.g. augmented betamethasone dipropionate 0.05% cream/oint/gel, fluocinonide 0.05% oint/cream/gel, clobetasol propionate 0.05% oint/gel)
	  ○ 1 Systemic corticosteroid (e.g. prednisone, prednisolone)
	  ○ 1 Tetracycline antibiotic (e.g. doxycycline, minocycline)
	  ○ 1 Immunosuppressant (e.g. methotrexate, mycophenolate, azathioprine)
	• Treatment with Dupixent is initiated in combination with oral corticosteroids unless contraindicated or not tolerated.
	
	Initial Approval: 6 months for all indications
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or PCS prior to providing QRM PA approval.**
	• **Approve for member to fill via the outpatient pharmacy benefit only.**
	
	Continued Approval: 12 months for all indications if patient meets ALL the following criteria PLUS the individual disease criteria if applicable:
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or PCS prior to providing QRM PA approval.**
	• **Approve for member to fill via the outpatient pharmacy benefit only.**
	
	For new members who were initiated on Dupixent outside of KPGA:
	• **For Dermatology**: Approve if patient is confirmed clinically stable by a specialist in the past 6 months. **Atopic dermatitis**: Adults on Dupixent for >12 months with clear or almost clear skin should use extended interval dosing (300mg SC every 3 to 4 weeks), unless there is a special clinical situation documented (e.g., resistant disease, flare with previously attempted at dose extension).

Drug	Prior Authorization Criteria
	• **For Asthma:** Confirm patient has a documented indication from the criteria, is documented as clinically stable by a specialist in the past 6 months, meets all the medication trials in the criteria, and Dupixent is being used in combination with a high-dose (or maximally tolerated) ICS and at least one additional asthma controller medication such as a LAMA, LABA, or LRTA • **For COPD:** Confirm patient has a documented diagnosis of COPD with an eosinophilic phenotype, is documented as clinically stable by the specialist in the past 6 months, and Dupixent is being used in combination with a dual (LAMA/LABA) or triple (ICS/LABA/LAMA) maintenance therapy for COPD • **For all other specialties**: confirm patient is clinically stable by a specialist in the past 6 months AND meets all the medication trials in criteria for their respective indication. **For existing members who previously met the full criteria for their indication:** Confirm patient has clinically significant benefit documented during specialist follow-up within the last 12 months AND applicable criteria below. • **For Atopic Dermatitis**: Adult patients with clear or almost clear skin after at least 12 months of treatment with Dupixent should be prescribed 300mg SC every 3 to 4 weeks unless there is a special clinical situation documented (e.g. resistant disease, flare with previously attempted at dose extension) • **For Asthma:** Dupixent is being used in combination with a high-dose (or maximally tolerated) ICS and at least one additional asthma controller medication such as a LAMA, LABA, or LRTA • **For COPD:** Dupixent is being used in combination with a dual (LAMA/LABA) or triple (ICS/LABA/LAMA) maintenance therapy for COPD
Duvyzat (Givinostat)	*Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).* **Candidates for treatment with Duvyzat (givinostat) must meet ALL the following criteria:** • Prescribed by Pediatric Neurologist, Neurologist, Neuromuscular Specialists, or Medical Geneticists • Patient is male and age $\geq$ 6 years • Patient is ambulatory • Diagnosis of Duchenne muscular dystrophy (DMD) confirmed by genetic testing • Documentation of DMD characteristic clinical signs or symptoms present (e.g., proximal muscle weakness, Gowers' maneuver, elevated serum creatinine kinase level) • Patient is on a stable systemic steroid regimen (e.g., glucocorticoid, deflazacort, or vamorolone) before treatment initiation with Duvyzat (givinostat) Reasons for non-coverage: • Current use of any DMD therapies (exon-skipping therapies) excluding systemic steroid regimen (e.g., glucocorticoid, deflazacort, or vamorolone). ○ Note: patient should discontinue other therapies (excluding steroid regimen) prior to initiating givinostat • Prior receipt of gene therapy for DMD • Platelet count <150 x 10^9/L

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	• Elevated anti-adeno-associated virus serotype rh74 (AAVrh74) total binding antibody titers (≥1:400)
	• Hemoglobin level below the lower limit of normal
	  ○ For males: Hgb < 14 g/dl
	  ○ For females: Hgb <12 g/dl
	• Have a current or history of liver disease or impairment, including but not limited to a total bilirubin >1.5 x ULN, unless secondary to Gilbert disease or pattern consistent with Gilbert's
	• Inadequate renal function
	• Triglycerides >300 mg/dL in fasting condition
	• Positive test for hepatitis B surface antigen, hepatitis C antibody, or HIV
	• Have a baseline corrected QT interval, Fridericia's correction >450 msec (as the mean of 3 consecutive readings 5 minutes apart) or history of additional risk factors for torsades de pointes (e.g., heart failure, hypokalemia, or family history of long QT syndrome)
	• Have a sorbitol intolerance or sorbitol malabsorption, or have the hereditary form of fructose intolerance
	• Have exposure to another investigational drug within past three months
	
	<u>Initial Approval:</u> 12 months
	
	<u>Continued Approval:</u> 12 months if patient meets the following:
	• Patient meets all above coverage criteria without meeting criteria for discontinuation listed below.
	
	<u>Criteria for Discontinuation:</u>
	• Loss of ambulation
	• Intolerance to medication, including significant GI adverse events despite dosage modification
	• QTc interval is >500 ms or the change from baseline is >60 ms
	• Hematologic abnormalities that worsen despite dose modification
	• Elevated triglycerides despite adequate dietary intervention and dosage adjustment (i.e., fasting blood triglycerides >300 mg/gL)
	• Non-adherence to medication or follow-up labs and assessments
	• Other treatment for DMD therapy is initiated (excluding systemic steroid regimen)

Ebglyss
(Lebrikizumab-lbkz)
	Candidates for treatment with Ebglyss should meet ALL the following criteria:
	
	<u>Diagnosis of Atopic Dermatitis</u>:
	
	• Prescribed by a dermatologist
	• Age ≥ 12 years AND weighs at least 40 kg
	• Documented diagnosis of moderate-to-severe atopic dermatitis (such as BSA <u>≥</u> 10%, involvement of high-impact areas [e.g., face, hands, feet, genitals, skin folds], or documented major impact on quality of life)
	• Documented inadequate response, intolerance, or contraindication to ALL of the following therapies:
	  ○ One IL-13 inhibitor: Tralokinumab (Adbry)
	  ○ One IL-4/IL-13 inhibitor: Dupilumab (Dupixent)
	  ○ One IL-31 inhibitor: Nemolizumab (Nemluvio)

Drug	Prior Authorization Criteria

	• Ebglyss is not being used in combination with another biologic (e.g. tralokinumab, dupilumab, nemolizumab) or advanced small molecule (e.g., tofacitnib, upadacitinib, abrocitinib, ruxolitinib, apremilast) for the same indication
	
	Initial Approval: 6 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	
	Continued Approval: 12 months. Continue approval if the following criteria are met:
	
	For new members who were initiated on Ebglyss outside of KPGA:
	• Confirm patient meets the full criteria above and has a documented adequate response and tolerance to the medication during a specialist follow-up in the last 6 months.
	• For patients with an adequate clinical response after at least 16 weeks of Ebglyss:
	  ○ Maintenance dose is extended to 250mg every 4 weeks or every 8 weeks unless there is a special circumstance documented (e.g. resistant disease, flare with previous attempted dose extension).
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	
	For existing members who have previously met the full criteria above:
	• Documented adequate response and tolerance of medication during specialist follow up in the last 12 months.
	• For patients with an adequate clinical response after at least 16 weeks of Ebglyss:
	  ○ Maintenance dose is extended to 250mg every 4 weeks or every 8 weeks unless there is a special circumstance documented (e.g. resistant disease, flare with previous attempted dose extension).
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	• **Approve for member to fill via the outpatient pharmacy benefit only**

Eculizumab Products **Preferred:** **Epysqli** (Eculizumab-aagh) **Non-preferred:** **Bkemb** (Eculizumab-aeeb) **Soliris** (Eculizumab)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval for Soliris, but not for Epysqli (excluding Pharmacy Consult Service).** Soliris (eculizumab) or non-preferred eculizumab biosimilars will only be considered for use after trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction, etc) to Epysqli (eculizumab-aagh). **Candidates for treatment with Eculizumab must meet ALL the following criteria:** Criteria for Neuromyelitis Optica Spectrum Disorder (NMOSD) • Prescribed by a Multiple Sclerosis Specialist or Neurologist (if no regional subspecialist) • Age ≥18 years with confirmed diagnosis of NMOSD • Patient is AQP4 antibody seropositive

Drug	Prior Authorization Criteria
	• Patient has documentation of ONE of the following: a. Severe breakthrough relapse while on rituximab or rituximab biosimilar for at least 6 months not attributed to rapid steroid discontinuation (rituximab induction dose of 1,500 to 2,000 mg split in two IV infusions given 2 weeks apart followed by 500 mg IV infused every 6 months or adjusted as needed per prescriber). Examples of severe breakthrough relapse include, but are not limited to: i. hospitalization for neurological deficits from NMOSD relapse (e.g., quadriparesis or paraparesis) ii. optic neuritis severity (hand motion only or worse) confirmed by an ophthalmologist b. Recurrent moderate breakthrough relapses after 6-month trial of rituximab or rituximab biosimilar in combination with maximum tolerated doses of either mycophenolate mofetil or azathioprine. Maximum doses shown below: i. mycophenolate mofetil: 1,000 to 2,000 mg/day to target an absolute lymphocyte count of 1,000 to 1,500 cells/µL ii. azathioprine: 3 mg/kg/day • Documented baseline meningococcal vaccination status and complete blood count with differential • For requests for Soliris or non-preferred eculizumab biosimilar products: patient has a documented trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction, etc) to Epysqli (eculizumab-aagh), KP's preferred eculizumab biosimilar product. Criteria for Generalized Myasthenia Gravis: • Prescribed by or in consultation with a Neurologist with specialty in neuromuscular disorders • Diagnosis of generalized myasthenia gravis (gMG) • Confirmed anti-acetylcholine receptor (AChR) antibody positive • No history of thymoma or thymic neoplasm OR patient has history of thymoma and has had a thymectomy that was completed over 3 months ago • Patient has a Myasthenia Gravis Activities of Daily Living (MG-ADL) scale score of 5 or higher • Patient is currently taking pyridostigmine for symptomatic management as prescribed unless there is a severe intolerance or contraindication • Trial of corticosteroid for at least 3 months and patient experienced inadequate disease control or patient has an intolerance or contraindication to corticosteroid therapy • Trial of at least one non-steroidal immunosuppressive therapy for the indicated duration of therapeutic onset in gMG a. Azathioprine or mycophenolate for at least 12 months b. Rituximab or rituximab biosimilar for at least 12 months c. Other disease modifying therapy (e.g., cyclophosphamide, cyclosporine, tacrolimus, methotrexate) for at least 6 months • Patient has tried and failed or has a contraindication to chronic IV immune globulin (IVIG • Prescribing physician is enrolled in the appropriate eculizumab REMS program

Drug	Prior Authorization Criteria
	• For requests for non-preferred eculizumab biosimilar or Soliris: patient has a documented trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction, etc) to Epysqli (eculizumab-aagh), KP's preferred eculizumab biosimilar product. Criteria for Paroxysmal Nocturnal Hemoglobinuria: • Age ≥18 years and diagnosed with paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow cytometry • Prescribed by a specialist in the area of practice related to the patient's diagnosis (e.g., hematologist, oncologist, immunologist, or genetic specialist) • Documented baseline hemoglobin is ≤7 g/dl **OR** the patient has symptoms of anemia and the hemoglobin is ≤9 g/dl • Documented baseline value for serum lactate dehydrogenase (LDH) ≥1.5 times the upper limit of normal • Documented baseline meningococcal vaccine at least 2 weeks prior to start of therapy • Eculizumab product will be used as monotherapy and patient is not receiving treatment with another terminal complement inhibitor such as ravulizumab-vwvz (Ultomiris) • Prescribing physician is enrolled in the appropriate eculizumab REMS program • For requests for non-referred eculizumab biosimilar or Soliris: patient has a documented trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction, etc) to Epysqli (eculizumab-aagh), KP's preferred eculizumab biosimilar product. Criteria for Atypical Hemolytic Uremic Syndrome (aHUS): • Age ≥ 2 months AND weight ≥ 5 kg AND diagnosed with aHUS • Prescribed by a specialist in the area of practice related to the patient's diagnosis (e.g., hematologist, oncologist, immunologist, genetic specialist or nephrologist) • A diagnosis of Shiga toxin-related HUS has been ruled out • Documented baseline levels for platelet count, serum lactate dehydrogenase (LDH), plasma exchange/infusion requirement, and serum creatinine/eGFR • Documented baseline meningococcal vaccine at least 2 weeks prior to start of therapy • Eculizumab product will be used as monotherapy and patient is not receiving treatment with another terminal complement inhibitor such as ravulizumab-vwvz (Ultomiris) • Prescribing physician is enrolled in the appropriate eculizumab REMS program • For requests for non-preferred eculizumab biosimilar or Soliris: patient has a documented trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction, etc) to Epysqli (eculizumab-aagh), KP's preferred eculizumab biosimilar product. Reasons for non-coverage: • Patient is pregnant or woman of childbearing potential and not on a reliable birth control • Unresolved serious Neisseria meningitidis infection • Not vaccinated against Neisseria meningitidis, unless risk of treatment delay outweighs infection risk

Drug	Prior Authorization Criteria
	• For myasthenia gravis indication: patient is prescribed concomitant efgartigimod (Vyvgart) or monoclonal antibody therapy for myasthenia gravis such as Ultomiris or Rystiggo Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage or criteria for discontinuation listed below. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Continued Approval for indication of myasthenia gravis: 12 months if the following criteria are met: • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** For new members who were initiated on eculizumab (Soliris) or eculizumab biosimilar outside of KPGA, approve if ALL the following criteria are met: • Patient has had a visit with a Neurologist with specialty in neuromuscular disorder to discuss treatment options • Patient has tried and failed a corticosteroid AND at least one non-steroidal immunosuppressive therapy as listed above • Patient confirmed to be stable on therapy by Neurologist • For requests for non-preferred eculizumab biosimilar or Soliris: patient has a documented trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction, etc) to Epysqli (eculizumab-aagh), KP's preferred eculizumab biosimilar product. For first renewal of eculizumab or eculizumab biosimilar: documented improvement of at least 2-points on the Myasthenia Gravis-Activities of Daily Living scale (MG-ADL) For subsequent renewals after first renewal: documented maintenance of stable MG-ADL score or documented beneficial effect from therapy during Neurology follow up in the last 12 months Criteria for Discontinuation: • Patient is being treated for serious meningococcal infection • For NMOSD indication: Recurrent relapses or MRI changes 3-6 months after initiation of therapy • Patient has other serious untreated infection (e.g., viral) • Documented major intolerance to medication • Non-adherence to medication administration and/or follow-up assessments • Pregnancy Dosing and Administration: • Administer eculizumab by intravenous (IV) infusion over 35 minutes • Adults a. Loading (first five doses): 900 mg weekly for first 4 weeks, then 1200 mg for fifth dose 1 week later; Maintenance: 1200 mg every 2 weeks thereafter

Drug	Prior Authorization Criteria
	b. Supplemental dosing is required if patient is receiving plasmapheresis, plasma exchange or fresh frozen plasma infusion • Pediatrics (aHUS indication ONLY) a. 5 kg to <10 kg: IV: Induction: 300 mg weekly for 1 dose; Maintenance: 300 mg at week 2, then 300 mg every 3 weeks. b. 10 kg to <20 kg: IV: Induction: 600 mg weekly for 1 dose; Maintenance: 300 mg at week 2, then 300 mg every 2 weeks. c. 20 kg to <30 kg: IV: Induction: 600 mg weekly for 2 doses; Maintenance: 600 mg at week 3, then 600 mg every 2 weeks. d. 30 kg to <40 kg: IV: Induction: 600 mg weekly for 2 doses; Maintenance: 900 mg at week 3, then 900 mg every 2 weeks. e. ≥40 kg: Induction: IV: 900 mg weekly for 4 doses; Maintenance: 1,200 mg at week 5, then 1,200 mg every 2 weeks. **Supplemental dosing is required if patient is receiving plasmapheresis, plasma exchange or fresh frozen plasma infusion**
Egrifta SV **Egrifta WR** (Tesamorelin)	**Candidates for INITIAL treatment (current KP members newly starting treatment) should meet ALL of the following criteria:** • Age 18 to < 65 years • Prescribed by Infectious Disease or Endocrinology Specialist • Prescribed for the reduction of excess abdominal fat • Individual meets ONE of the following, o Men: waist circumference is ≥95 cm (37.4 in) and waist to hip ratio is ≥ 0.94 OR o Women: waist circumference is ≥94 cm (37.0 in) and waist to hip ratio is >0.88 • Stable on an anti-retroviral regimen (protease inhibitor-based regimen) for at least 8 weeks • Fasting blood glucose (FBG) < 150mg/dL Initial Approval: 6 months Continued Approval: 6 months. In addition, patient should have documented clinical improvement defined as a reduction in visceral adipose tissue (VAT) as measured by a waist circumference reduction of at least 2-3 cm from baseline after at least 90 days of therapy. Subsequent Continued Approval: 6 months. Confirm patient meets all above criteria without reasons for non-coverage. In addition, patient should have documented clinical improvement defined as a reduction and maintenance of visceral adipose tissue (VAT) waist circumference reduction of at least 2 cm from baseline. **For new members currently taking (defined as last prescription filled within 30 days) Egrifta:** Initial Approval: 3 months if the individual has responded per Endocrine or Infectious Disease Specialist evaluation or consultation, age 18 to < 65 years and does not have any reason for Non-coverage.

Drug	Prior Authorization Criteria
	Continued Approval: 6 months. Patient must have evaluation by endocrinology or infectious disease within initial coverage period to determine continuation of the medication and ensure no reasons for discontinuation. Reasons for Non-coverage: • Active malignancy or history of malignancy • Pregnancy • BMI ≤ 20 kg/m^2 • Fasting blood glucose >150 or know Type 1 or Type 2 diabetes • Hypopituitarism • Age > 65 years Ordering Information: • Egrifta is dispensed by the KP National Specialty Pharmacy.
Ekterly (Sebetralstat)	**Candidates for treatment with Ekterly should meet ALL the following criteria:** • Prescribed for acute treatment of hereditary angioedema (HAE) attacks • Prescriber must be an Allergist or Immunologist. • Age ≥ 12 years • Diagnosed with hereditary angioedema (HAE) confirmed by ONE of the following: a. C1 esterase inhibitor (C1-INH) antigenic level below the lower limit of normal; OR b. C1-INH functional level below the lower limit of normal; OR c. Normal C1-INH levels • Medication will NOT be used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Firazyr, Kalbitor, or Ruconest) Reasons for Non-coverage: • The patient had a trial of or contraindication to ONE of the following preferred agents: Kalbitor, Berinert, Ruconest, generic icatibant Initial Approval: 12 months Continued Approval: 12 months. Confirm patient meets all above criteria without reasons for Non-coverage. In addition, continue approval based on clinical documentation of functional improvement, a decrease in frequency of HAE attack, and an improvement in severity and duration of attacks.
Elfabrio (Pegunigalsidase Alfa)	**Please note: Reviewers must obtain approval from Physician Program Director of QRM or PCS prior to providing QRM PA approval.** **Candidates for treatment with Elfabrio should meet ALL the following criteria:**

Drug	Prior Authorization Criteria

	• Prescribed by or in consultation with a geneticist, nephrologist, cardiologist, or neurologist who specializes in the treatment of lysosomal disease.
	• Patient is 18 years of age or older
	• Documented diagnosis of Fabry disease confirmed by ONE of the following:
	  ○ Genetic testing indicating a pathogenic mutation of the GLA gene
	  ○ α-galactosidase activity level deficiency (males only)
	• Patient is experiencing signs or symptoms of Fabry disease (e.g., neuropathic pain, renal disease, cardiac disease, abdominal pain, etc.) **OR** there is evidence of injury to the heart, kidney, or central nervous system
	• Patient is not receiving Elfabrio in combination with Fabrazyme (agalsidase beta), Galafold (migalastat), or other enzyme replacement therapy.
	
	Initial Approval Period: 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or PCS prior to providing QRM PA approval.**
	
	Continued Approval Period: 24 months. Confirm patient has documentation of positive clinical response in an appointment with a specialist within 12 months.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or PCS prior to providing QRM PA approval.**

Elmiron (Pentosan Polysulfate Sodium)	**Candidates for treatment with Elmiron should meet ALL the following criteria:** • Prescribed by a Urology or Urogynecologist Specialist • Age > 18 years • Diagnosis of interstitial cystitis/bladder pain syndrome • Documented maximum tolerated dose of amitriptyline or another agent (hydroxyzine, cimetidine) for at least 3 months or documented allergy/intolerance or contraindication to amitriptyline. Reason for Non-coverage: History or current diagnosis of macular degeneration Initial Approval Period: 3 months Continued Approval: 12 months. Patient must meet all above coverage criteria without reasons for Non-coverage. In addition, patient must meet the following criteria: • Documented improvement in symptoms of interstitial cystitis • Documentation of FUNDUS or retinal exam within 12 months of initiation and within the past 365 days • Adherence to follow-up assessments and the medication Response to therapy: Discontinue medication if no improvement after 6 months of therapy in order to avoid unnecessary exposure to the drug and its possible risks.
Eloctate	**Candidates for treatment with Eloctate should meet ALL the following criteria:** • Documented diagnosis of Hemophilia A (<1% endogenous Factor VIII activity)

Drug	Prior Authorization Criteria

(Antihemophilic Factor [Recombinant], Fc Fusion Protein)	• Being used for one of the following:
	• Control and prevention of bleeding episodes
	• Perioperative management
	• Routine prophylaxis to prevent or reduce the frequency of bleeding episodes
	• Tried and failed or unable to tolerate **TWO** of the following:
	  ○ Advate
	  ○ Kogenate FS
	  ○ Xyntha
	
	Initial approval: 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM OR AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	Continued approval: 12 months. Patients continue to meet all criteria above and has shown clinical benefit compared to baseline with Eloctate therapy with documentation of improvement in bleeding rates.
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM OR AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**

Elevidys (Delandistrogene Moxeparvovec)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.**
	
	Candidates for treatment with Elevidys must meet ALL the following criteria:
	
	**Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).*
	
	• **MUST verify member's benefit information. If member's coverage is through Target, CLOSE the request.** Member must go through Aradigm for this therapy.
	• Patient is male
	• Patient is ambulatory defined as able to independently complete the 10-meter walk test (no walking assistance devices)
	• Age ≥ 4 years
	• Prescribed by a neurologist, pediatric neurologists, neuromuscular specialists, physical medicine & rehabilitation, geneticist
	• Documented diagnosis of Duchenne muscular dystrophy (DMD) with dystrophin gene mutation of DMD phenotype:
	  ○ Confirmed frameshift mutation or a premature stop codon mutation between exons 18 to 58 (inclusive) in the DMD gene AND
	  ○ No deletion in exon 8 and/or exon 9 in the DMD gene
	• Documented Anti-AAVrh74 total binding antibody titers <1:400
	
	Initial Approval: ONE-TIME TREATMENT

Drug	Prior Authorization Criteria
	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** Reasons for Non-coverage: • Serological evidence of HIV infection, Hepatitis B, or Hepatitis C infection • Abnormal laboratory values considered clinically significant (GGT >2 times upper limit of normal [ULN],total bilirubin > upper limit of normal mg/dL) • Recent vaccination within the past 4 weeks • Unwilling to be on a steroid regimen Ordering Information: • Elevidys is administered in select treatment centers nationwide. • If patient obtains QRM approval, providers should fax completed patient enrollment form to SareptAssist (Sarepta_Gene_Therapy_Enrollment_Form.pdf)

Elrexfio
(Elranatamab-bcmm)
	Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.
	
	Candidates for treatment with Elrexfio should meet all the following criteria:
	• Patient is 18 years of age or older
	• Prescribed by a Hematologist/Oncologist certified in the Elrexfio REMS program (registration available at ELREXFIO REMS)
	• Documented diagnosis of relapsed or refractory multiple myeloma.
	• Patient has received at least four prior lines of therapy, including at least ONE drug from each of the following categories:
	  ○ A proteasome inhibitor (e.g. bortezomib, ixazomib, carfilzomib, etc.) AND
	  ○ An immunomodulatory agent (e.g., lenalidomide, thalidomide, etc.) AND
	  ○ An anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc.).
	• Patient has not received prior treatment with any B-cell maturation antigen (BCMA) targeted therapy.
	
	• Elrexfio will be used as continuation therapy following inpatient administration of the step-up dose 1 and step-up dose 2 and patient had an absence of unacceptable toxicity while on therapy
	
	Initial approval: 12 months
	• Cycle 1 may be approved for administration at a KP-affiliated inpatient facility.
	• Subsequent cycles should be approved for back-office administration in a KP-infusion center ONLY.
	  ○ **NOTE:** If patient experiences a treatment delay >14 days, an additional cycle may be approved for administration at a KP-affiliated inpatient facility for therapy re-initiation.

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** Continued approval**:** 12 months. Confirm patient meets above criteria. In addition, patient should meet the following: • No evidence of disease progression or unacceptable toxicity. • **Approve for back-office administration in a KP-infusion center ONLY.** ○ **NOTE:** If patient experiences a treatment delay >14 days, an additional cycle may be approved for administration at a KP-affiliated inpatient facility for therapy re-initiation. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** Dosing and Administration: • For SUBQ administration only. • The recommended dosage of Elrexfio includes step-up doses of 12mg on Day 1 and 32mg on Day 4, followed by the first treatment dose of 76mg on Day 7. Elrexfio is administered once weekly thereafter, until disease progression or unacceptable toxicity. • Patients should be hospitalized for 48 hours after administration of the step-up dose 1 and 24 hours after administration of step-up dose 2. Pretreatment medication is given prior to each step-up dose and the first treatment dose. • Elrexfio should be given by a healthcare provider.
Emflaza (Deflazacort) **Preferred:** Deflazacort (generic Emflaza) **Non-Preferred:** Brand Emflaza	**Candidates for treatment with Emflaza should meet ALL the following criteria:** • Documented diagnosis of Duchenne muscular dystrophy (DMD) • Prescribed by a pediatric or adult neurologist with neuromuscular expertise • Age ≥ 2 years • Patient has tried prednisone for at least 12 months • Documented clinically significant weight gain, defined as crossing at least two stanines on the weight growth chart during the first 2 years of prednisone use (new weight gain after several years of prednisone use is likely due to multiple factors such as inactivity and persistence of appetite). • Documented ophthalmology evaluation to rule out presence of cataract Reasons for Non-coverage: • No prior history of prednisone use Initial Approval: 6 months Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continue approval if there is documented adherence to follow-up assessments (Weight, BMI, Blood pressure, HbA1c and Ophthalmology evaluation [every 12 months])

Drug	Prior Authorization Criteria
	Criteria for Discontinuation: • Non-adherence to follow-up assessments • Intolerance due to adverse effects • Development of cataract or optic nerve atrophy

Empaveli
(Pegcetacoplan)
	Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).
	
	Candidates for the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) should meet ALL the following criteria:
	
	• Age ≥ 18 years
	• Documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by flow cytometry demonstrating all the following:
	  ○ At least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
	  ○ PNH granulocyte clone size of 10% or greater
	• Prescribed by a hematologist or oncologist.
	• Patient is not using concurrent C5 complement inhibitor therapy (e.g., Epysqli (eculizumab-aagh), Ultomiris)
	  ○ Exception: patient may receive concurrent Empaveli and eculizumab or eculizumab biosimilar for 4 weeks when transitioning from eculizumab or eculizumab biosimilar to Empaveli per FDA approved dosing recommendations.
	• The patient has tried and failed Epysqli (eculizmab-aagh) or Ultomiris as evidenced by hemoglobin levels <10.5 g/dL directly following at least 3 months of stable dosing
	• Prescriber must be certified by the Empaveli REMS program (Empaveli REMS Website)
	
	Reasons for Non-coverage:
	• Patient is not currently vaccinated against certain encapsulated bacteria (including Streptococcus pneumoniae, Neisseria meningitidis types A, C, W, Y, and B, and Haemophilus influenzae type B (Hib)) unless documentation that risks of delaying Empaveli treatment outweigh the risks of developing a bacterial infection with the encapsulated organism.
	• Patients with unresolved serious infection caused by encapsulated bacteria including Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae.
	
	Initial Approval: 4 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Continued Approval: 1 year. Confirm patient meets all above coverage criteria without reasons for Non-coverage in addition to criteria below:

Drug	Prior Authorization Criteria
	• Patient demonstrates clinical benefit compared to baseline during treatment with Epysqli (eculizumab-aagh) or Ultomiris (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase, increased or stabilization of hemoglobin levels, less fatigue, improved health-related quality of life and fewer thrombotic events). • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** **Candidates for the diagnosis of C3 glomerulopathy (C3G) should meet all the following criteria:** • Age ≥ 12 years • Prescribed by nephrologist • Documented diagnosis of C3G confirmed by kidney biopsy • Urine protein-to-creatine ratio (UPCR) ≥1 g/g (labs in past 4 wks of request) • eGFR ≥30 mL/min/1.73 m2 (labs in past 4 wks of request) • Currently prescribed maximum tolerated dose of **one of the following** for at least 3 months or documented intolerance, contraindication ○ ACE I (e.g., lisinopril, benazepril) OR ARB (e.g., losartan, valsartan) • Currently prescribed SGLT2i (e.g., Jardiance, dapagliflozin) for at least 3 months or documented intolerance, contraindication • Prescriber must be certified by the Empaveli REMS program (Empaveli REMS Website) Reasons for Non-coverage: • Patient is not currently vaccinated against certain encapsulated bacteria (including Streptococcus pneumoniae, Neisseria meningitidis types A, C, W, Y, and B, and Haemophilus influenzae type B (Hib)) unless documentation that risks of delaying Empaveli treatment outweigh the risks of developing a bacterial infection with the encapsulated organism. • Patients with unresolved serious infection caused by encapsulated bacteria including Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae. Initial Approval: 6 months **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for non-coverage in addition to criteria below: • Physician attestation that patient has had a clinically significant reduction in proteinuria (e.g.,>50%) OR improved, stable kidney function compared to baseline. • No progression to kidney failure or need for dialysis/transplant • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**

Drug	Prior Authorization Criteria
	Dosing and Administration: • 1,080 mg SQ twice weekly • Pegcetacoplan may be self-administered or administered by a caregiver after proper training. • Administer SUBQ over ~30 minutes (if using 2 infusion sites) or ~60 minutes (if using 1 infusion site) via an infusion pump with a reservoir of at least 20 mL.
Emsam (Selegiline transdermal)	**Candidates for Emsam should meet ALL the following criteria:** • Documented diagnosis of major depressive disorder • Prescribed by Psychiatry • Age ≥ 18 years • Provider documents patient education re tyramine restricted diet in doses >6 mg/24 hours • Inadequate treatment response after documented adequate therapeutic trial (defined as minimum of 6 weeks) of the following: o Oral MAO inhibitor (e.g., phenelzine) and member is unable to continue treatment with an oral agent **AND** o 2 additional oral antidepressant medications from 2 different drug classes (SNRIs e.g., venlafaxine/duloxetine, SSRIs e.g., sertraline/escitalopram, atypical antidepressants e.g., bupropion/mirtazapine, TCAs e.g., nortriptyline, etc. this is not an all-inclusive list) or has a contraindication Initial Approval: 6 months Continued Approval: 12 months. Patient must meet all criteria above without reasons for Non-coverage and provider documents improvement in depression symptoms or stabilized on Emsam. Reasons for Non-coverage: • Pheochromocytoma • Concurrent therapy with serotonergic drugs including SSRIs, SNRIs, clomipramine and imipramine, meperidine, tramadol, methadone, pentazocine, and propoxyphene; and the antitussive agent dextromethorphan should not be used because of a risk of serotonin syndrome • Concurrent carbamazepine • Pregnancy
Enbrel (Etanercept)	**Candidates for treatment with Enbrel should meet ALL the following criteria PLUS the individual disease state criteria below:** • Prescribed by a Dermatologist or Rheumatologist • Patient has had a negative interferon-gamma release assay test for TB Infection within the past 24 months or is positive for latent TB and has completed treatment in the past or is currently on treatment.

Drug	Prior Authorization Criteria

	• Medication is not being used in combination with another biologic or advanced small molecule (e.g., tofacitinib, upadacitinib, apremilast) for the same indication
	• Then follow the disease state specific criteria below, based on diagnosis:
	
	<u>Diagnosis of Rheumatoid Arthritis:</u>
	
	• Age ≥ 18 years
	• Inadequate response (of at least a 3-month trial), intolerance, or contraindication to each of the following:
	  ○ 1 csDMARD:
	  ▪ Methotrexate, sulfasalazine, hydroxychloroquine, OR leflunomide
	  ○ 1 preferred TNF inhibitor:
	  ▪ Infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade)
	  ▪ Adalimumab product (Amjevita [preferred], Humira)
	  ○ 1 Janus Kinase (JAK) inhibitor
	  ▪ Tofacitinib [preferred]
	  ▪ Others: Baricitinib (Olumiant), Upadacitinib (Rinvoq)
	  ○ 1 IL-6 inhibitor
	  ▪ Tocilizumab product (Avtozma [preferred]), Tyenne)
	  ▪ Others: Kevzara (sarilumab)
	  ○ Abatacept (Orencia)
	
	<u>Diagnosis of Psoriatic Arthritis:</u>
	
	• Age ≥ 2 years
	• Inadequate response, intolerance, and/or contraindication to each of the following:
	  ○ 1 conventional synthetic DMARD (unless documented axial disease or severe disease (e.g. dactylitis, multiple (>=5) joint involvement, erosive disease, or functional limitation)):
	  ▪ methotrexate
	  ▪ sulfasalazine
	  ▪ leflunomide
	  ○ 1 preferred TNF Inhibitor:
	  ▪ Infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade)
	  ▪ Adalimumab product (Amjevita [preferred], Humira)
	  ○ 1 IL-17 Inhibitor:
	  ▪ Secukinumab (Cosentyx)
	  ▪ Others: Ixekizumab (Taltz)
	  ○ 1 IL-12/23 Inhibitor (unless documented axial disease):
	  ▪ Ustekinumab product (Yesintek [preferred], Stelara)
	  ○ 1 Janus Kinase (JAK) inhibitor:
	  ▪ Tofacitinib [preferred], Upadacitinib (Rinvoq)
	  ○ Abatacept (Orencia)

Drug	Prior Authorization Criteria

	Diagnosis of spondyloarthropathy/spondyloarthritis
	
	• Age ≥ 18 years
	• Inadequate response, intolerance, and/or contraindication to each of the following:
	  ○ 1 preferred TNF Inhibitor:
	  ▪ Infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade)
	  ▪ Adalimumab product (Amjevita [preferred], Humira)
	  ○ 1 IL-17 Inhibitor:
	  ▪ Secukinumab product (Cosentyx)
	  ▪ Others: Ixekizumab (Taltz)
	  ○ 1 Janus Kinase (JAK) inhibitor:
	  ▪ Tofacitinib [preferred], Upadacitinib (Rinvoq)
	
	Diagnosis of Juvenile Idiopathic Arthritis
	
	• Age ≥ 2 years
	• Inadequate response, intolerance, and/or contraindication to ALL of the following:
	  ○ Methotrexate
	  ○ Adalimumab product (Amjevita [preferred], Humira)
	  ○ Tocilizumab product (Avtozma [preferred]), Tyenne)
	• Patients with polyarticular JIA weighing more than 40kg must also have a documented contraindication, history of intolerance, or inadequate response to tofacitinib
	
	Diagnosis of Plaque Psoriasis:
	
	• Age ≥ 4 years
	• Adult criteria: Inadequate response (of at least a 3-month trial), intolerance and/or contraindication to ALL of the following:
	  ○ 1 preferred TNF inhibitor (e.g. adalimumab (Amjevita [preferred]) OR infliximab (Infliximab-dyyb/Inflectra [preferred])
	  ○ 1 Ustekinumab product (Yesintek [preferred], Stelara)
	  ○ Cosentyx
	• Pediatric (<18 years) criteria: inadequate response (of at least a 3-month trial), intolerance, and/or contraindication to ALL of the following:
	  ○ Ustekinumab product (Yesintek [preferred]) (if patient is age ≥ 6 years)
	  ○ Cosentyx (if patient is age ≥ 6 years)
	
	Initial Approval: 12 months
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Services).**
	• **For Prefilled Syringes, Prefilled SureClick Autoinjector and Mini Single-dose Cartridge: Approve for member to fill via the outpatient pharmacy benefit only**

Drug	Prior Authorization Criteria
	Continued Approval: 12 months. Continue approval if the following criteria are met: For new members who were initiated on Enbrel outside of KPGA: Confirm patient meets all above medication trials in the initial criteria AND has a documented clinically significant benefit from the medication during a Specialist follow up in the last 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Services).** • **For Prefilled Syringes, Prefilled SureClick Autoinjector and Mini Single-dose Cartridge: Approve for member to fill via the outpatient pharmacy benefit only** For existing members who have previously met the criteria: documented clinically significant benefit from the medication during Specialist follow up in the last 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Services).** • **For Prefilled Syringes, Prefilled SureClick Autoinjector and Mini Single-dose Cartridge: Approve for member to fill via the outpatient pharmacy benefit only**
Encelto (Revakinagene taroretcel)	**Candidates for treatment with Revakinagene taroretcel should meet ALL the following criteria:** • Documented diagnosis of macular telangiectasia type 2 (MacTel) • Prescribed by an Ophthalmologist • Age ≥ 18 years • Patient has not previously received an Encelto implant in the affected eye • Documented Inner segment/outer segment (IS/OS) photoreceptor (PR) break (loss) in ellipsoid zone (EZ) <0.5 mm as measured by spectral-domain optical coherence tomography (SD-OCT) • Best-corrected visual acuity (BCVA) score of 54 letters or better (20/80 Snellen equivalent) on Early Treatment Diabetic Retinopathy Study (ETDRS) chart • No evidence of neovascular MacTel type 2 • No evidence of foveal involvement Reasons for non-coverage: • Active or suspected ocular or periocular infections Approval: A single implant per eye per lifetime Dosing and Administration: • One implant surgically placed into affected eye

Drug	Prior Authorization Criteria
	• Revakinagene taroretcel implant insertion is a surgical procedure performed in an operating room under aseptic conditions by a qualified ophthalmologist.

Endari
(L-Glutamine)
	Candidates for treatment with Endari (l-glutamine) should meet ALL the following criteria:
	
	• Prescribed by Hematology/Oncology Specialist
	• Age ≥ 5 years
	• Diagnosed with sickle cell anemia or sickle beta-thalassemia (documented by hemoglobin electrophoresis)
	• Currently taking hydroxyurea, unless history of intolerance or contraindication
	• Documentation of One of the following:
	  ○ Two or more sickle cell pain crises within prior 12 months requiring intervention (home-managed, hospitalizations, emergency department or urgent care visits)
	  ○ History of acute chest syndrome (documented by pulmonary infiltrate on chest X-ray films)
	• Documentation of reason cannot take the OTC L-Glutamine Product
	
	Initial Approval: 6 months
	
	Continued Approval: 12 months. Confirm patient meets all above criteria. In addition, continue approval if the following criteria are met:
	• Reduction in frequency of sickle cell pain crises and/or acute chest syndrome events

Endothelin Receptor Antagonists for IgA Nephropathy
 	
Preferred:
Vanrafia
(Atrasentan)
 	
Non-Preferred:
Filspari
(Sparsentan)
	Candidates for treatment with Filspari or Vanrafia must meet ALL the following criteria:
	
	• Prescribed by a nephrologist
	• Age ≥ 18 years
	• Documented diagnosis of IgA nephropathy (IgAN) verified by renal biopsy
	• High risk of progression as defined by urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g and eGFR ≥ 30 mL/min/1.73 m^2
	• Proteinuria ≥ 1g/day
	• Blood pressure ≤ 150/100 mmHg
	• Currently prescribed **one of the following** for at least 3 months at the maximum tolerated dose or documented intolerance/contraindication:
	  ○ ACE inhibitor (e.g., lisinopril, benazepril) **OR**
	  ○ ARB (e.g., losartan, valsartan)
	• Currently prescribed **SGLT2i** (e.g., Jardiance, dapagliflozin) for at least 3 months or documented intolerance/contraindication
	• For female patients: confirmation of negative pregnancy test
	• **For Filspari (Sparsentan) non-preferred:**
	  ○ Prescriber and patient are enrolled in the FILSPARI REMS program
	  ○ Baseline aminotransferase levels (ALT AND AST) and total bilirubin
	  ○ Adequate therapeutic trial (defined as at least 3 months) or documented intolerance/contraindication to Vanrafia (atrasentan)
	
	Reasons for Non-Coverage:

Drug	Prior Authorization Criteria

	• eGFR < 30 mL/min
	• History of kidney transplant or currently undergoing dialysis
	• Secondary IgAN or rapidly progressive glomerulonephritis or IgA vasculitis
	• Pregnancy or lactation
	• Elevated serum transaminases (>3x Upper Limit of Normal)
	• Heart failure with BNP >200 pg/mL
	• **For Filspari (Sparsentan):**
	  ○ Concomitant use with angiotensin receptor blockers or alisikren
	  ○ Concurrent treatment with Vanrafia (atrasentan) and/or Fabhalta (iptacopan)
	  ○ Hepatic impairment (Child-Pugh Class A-C)
	• **For Vanrafia (Atrasentan):**
	  ○ Concurrent treatment with Filspari (sparsentan) and/or Fabhalta (iptacopan)
	  ○ Severe hepatic impairment (Child-Pugh Class C)
	
	Initial Approval: 12 months – **Vanrafia (Atrasentan)** will have a quantity limit of 30 tablets per 30 days
	
	Continued Approval: 12 months – **Vanrafia (Atrasentan)** will have a quantity limit of 30 tablets per 30 days. Continued approval for treatment with Filspari or Vanrafia should meet all above coverage criteria without reasons for non-coverage in addition to the following:
	• Documented clinically significant reduction in proteinuria (~30-50% from baseline)
	• The patient has improved, or stable kidney function compared to baseline
	
	Ordering Information:
	Pharmacies must be enrolled in FILSPARI REMS program to dispense Filspari

Ensacove (Ensartinib)	**Candidates for treatment with Ensacove (ensartinib) should meet ALL of the following criteria:** • Prescribed by an oncologist • Age ≥ 18 years • Diagnosed with anaplastic lymphoma kinase (ALK)-positive locally advanced or • metastatic non-small cell lung cancer (NSCLC) • Patient has not previously received an ALK-inhibitor [e.g., Alecensa (alectinib), Alunbrig (brigatinib), Lorbrena (lorlatinib), Xalkori (crizotinib), Zykadia (ceritinib) • Documented clinical rationale for why Alecensa cannot be utilized as first-line therapy Initial Approval: 12 months Continued Approval: 12 months. For continued approval for treatment, patient should meet ALL the following criteria: • No evidence of disease progression or unacceptable toxicity
Enspryng (Satralizumab-mwge)	**Candidates for treatment with Enspryng must meet ALL the following criteria:** • Prescribed by a Multiple Sclerosis Specialist or Neurologist if no regional subspecialist. • Age ≥18 years with confirmed diagnosis of NMOSD • Patient is AQP4 antibody seropositive

Drug	Prior Authorization Criteria

	• Patient has documentation of ONE of the following:
	  ○ Severe breakthrough relapse while on rituximab for at least 6 months not attributed to rapid steroid discontinuation (rituximab induction dose of 1,500 to 2,000 mg split in two IV infusions given 2 weeks apart followed by 500 mg IV infused every 6 months or adjusted as needed per prescriber). Examples of severe breakthrough relapse include, but are not limited to:
	  ▪ hospitalization for neurological deficits from NMOSD relapse (e.g., quadriparesis or paraparesis)
	  ▪ optic neuritis severity (hand motion only or worse) confirmed by an ophthalmologist
	  ○ Recurrent moderate breakthrough relapses after 6-month trial of rituximab in combination with maximum tolerated doses of either mycophenolate mofetil or azathioprine. Maximum doses shown below:
	  ▪ mycophenolate mofetil: 1,000 to 2,000 mg/day to target an absolute lymphocyte count of 1,000 to 1,500 cells/µL
	  ▪ azathioprine: 3 mg/kg/day
	• Documented baseline tuberculosis test, AQP4 antibody test, complete blood count with differential, liver function tests (AST, ALT, bilirubin), and HBV screening
	
	<u>Reasons for Non-coverage:</u>
	
	• No prior trial of mycophenolate mofetil or azathioprine for mild or moderate breakthrough relapse while on rituximab
	• Patient is pregnant or woman of childbearing potential and not on a reliable birth control
	• Documented contraindication to medication
	• Documented relapse with prior trial of tocilizumab
	• Known hypersensitivity to satralizumab or inactive ingredients
	• Active hepatitis B infection
	• Active or untreated latent TB
	
	<u>Initial approval:</u> 6 months
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	<u>Continued approval:</u> 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage or criteria for discontinuation listed below.
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	<u>Criteria for discontinuation:</u>
	
	• ALT or AST >5x upper limit of normal (ULN) with bilirubin elevation >ULN
	• Recurrent relapses or MRI changes 3-6 months after initiation of therapy
	• Patient has other serious untreated infection (e.g., viral)

Drug	Prior Authorization Criteria
	• Documented intolerance to medication • Non-adherence to medication administration and/or follow-up assessments • Pregnancy Dosing and Administration: • Administer satralizumab by subcutaneous injection; Outpatient for patient self-injection or administration by a caregiver • Loading (first three doses): 120 mg at Weeks 0, 2, and 4; Maintenance: 120 mg every 4 weeks

Enstilar Foam (Calcipotriene and Betamethasone Dipropionate)	**Candidates for treatment with Enstilar should meet ALL the following criteria:**
	
	• For topical treatment of plaque psoriasis in patients ≥ 12 years old
	• Prescribed by a dermatologist
	• History of inadequate response, contraindication, or intolerance to ALL of the following:
	  ○ A medium to high potency topical steroid (e.g., betamethasone dipropionate, augmented 0.05% (Diprolene) ointment, gel or cream) and a Vitamin D analog (e.g., calcitriol 3mcg/gm ointment or calcipotriene 0.005% solution, cream, ointment) used concurrently (as separate products)
	  ○ Tacrolimus 0.1% ointment AAA BID
	  ○ Tazarotene 0.1% topical cream AAA QHS **NF**
	  ○ A generic calcipotriene and betamethasone dipropionate combination product (e.g., calcipotriene 0.005% and betamethasone dipropionate 0.064% Suspension or Ointment) **NF**
	  ○ Phototherapy (of at least a 3-month trial)
	
	Initial Approval: Up to one month of total treatment
	
	Continued Approval: 6 months if the following:
	
	For new members who were initiated outside of KPGA: Patient must meet the full criteria above for approval of Enstilar.
	
	For existing members who have previously met the full criteria above: Documented beneficial effect from therapy on Dermatology follow-up

Preferred: **Entyvio** (Vedolizumab) 300mg intravenous infusion (IV) **Non-Preferred:** Entyvio (Vedolizumab)	**Adult candidates for treatment with Entyvio (vedolizumab) should meet ALL the following criteria:** • Patient has had negative interferon-gamma release assay test for TB Infection within the past 24 months or is positive for latent TB and has completed treatment in the past or is currently on treatment • Not prescribed in combination with another biologic agent [i.e., infliximab (Inflectra), adalimumab (Amjevita)] or advanced small molecule (e.g., tofacitinib, upadacitinib) for the same indication • Non-preferred Entyvio subcutaneous (SC) injection will only be considered for use if Entyvio SC criteria below are met.

Drug	Prior Authorization Criteria

108mg subcutaneous (SC)	**Criteria for ulcerative colitis:**
	• Prescribed by a gastroenterologist
	• Age ≥ 18 years
	• Documented moderately to severely active ulcerative colitis (UC)
	• Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL the following:
	  ○ Infliximab product (e.g., Inflectra [preferred])
	  ○ Ustekinumab product (e.g., Yesintek [preferred])
	
	Criteria for Crohn's Disease (CD):
	• Prescribed by a gastroenterologist
	• Age ≥ 18 years
	• Documented moderately to severely active Crohn's Disease (CD)
	• Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL the following:
	  ○ Infliximab product (e.g., Inflectra [preferred])*
	  ○ Adalimumab product (e.g., Amjevita [preferred])*
	  ○ Ustekinumab product (e.g., Yesintek [preferred])
	  ○ *Patient must try/fail all of the agents listed above unless provider documents rationale why additional anti-TNF agent is inappropriate (i.e., primary or secondary non-response despite therapeutic drug level +/- presence of anti-drug antibodies or adverse effect requiring a different mechanism of action, member temporarily located outside of our KP network and cannot receive infusions)
	
	Entyvio (vedolizumab) subcutaneous (SC) for ulcerative colitis (CD) or Crohn's Disease (CD):
	• Entyvio (vedolizumab) subcutaneous (SC) formulation requires documentation by a gastroenterologist that patient is unable to receive Entyvio IV infusions due to ONE of the following:
	  ○ Inadequate organizational resources (i.e., limited infusion appointment availability or staffing limitations)
	  ○ Temporarily located outside of the KP network where infusion services are not accessible
	  ○ Documented transportation or significant lifestyle-related barriers that prevent the patient from attending infusion appointments and impede access to medically necessary treatment
	  ○ For SC formulation: Patient must complete the first two doses of 300mg administered via IV infusion at week 0 and week 2 prior to approval for SC at home administration.
	
	Initial approval: 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	• **IV formulation: Approve for administration ONLY in KPGA infusion center, if patient resides in the Atlanta market**
	• **SC formulation: Approve for member to fill subcutaneous formulation via the outpatient**

Drug	Prior Authorization Criteria

	pharmacy benefit only
	
	Continued approval for new members and existing members: 12 months
	Documented clinical benefit (asymptomatic or in remission) from therapy, by a gastroenterology specialist within the past 12 months.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	• **IV formulation: Approve for administration ONLY in KPGA infusion center, if patient resides in the Atlanta market**
	• **SC formulation: Approve for member to fill subcutaneous formulation via the outpatient pharmacy benefit only**
	
	Continued approval for new members and existing members for Entyvio SC: 12 months, if patient meeting above criteria for Entyvio SC and has documented clinical benefit (asymptomatic or in remission), by a gastroenterology specialist within the past 12 months. **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Pediatric (age < 18 years) candidates for treatment with Entyvio (vedolizumab) IV or SC, should meet ALL the following criteria:
	
	*Not FDA-approved for pediatric IBD conditions
	• Prescribed by a Gastroenterologist
	• Documented moderate to severe Crohn's Disease or ulcerative colitis
	• Negative test for tuberculosis within the past 12 months
	• Documented inadequate response or loss of response, intolerance or contraindication to infliximab after at least 2 infusions. Provider should optimize dose, 5-10 mg/kg and consider dose interval change (q4 weeks).
	• Documented inadequate response (after at least a 3-month trial to each), intolerance or contraindication to ALL the following:
	  ○ An adalimumab product (Amjevita preferred) AND
	  ○ An ustekinumab product (Yesintek preferred)
	• **May approve for the SC formulation via outpatient pharmacy benefit only**
	  ○ For SC formulation: Patient must complete the first two doses of 300mg administered via IV infusion at week 0 and week 2 prior to approval for SC at home administration.
	
	Approval dose: As determined by provider
	
	Initial approval: 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	• **IV formulation: Approve for administration ONLY in a KPGA infusion center**
	• **SC formulation: Approve for member to fill via the outpatient pharmacy benefit only**

Drug	Prior Authorization Criteria
	Continued approval for new and existing pediatric members: 12 months Documented clinical benefit (asymptomatic or in remission) from therapy, by a gastroenterology specialist within the past 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **IV formulation: Approve for administration ONLY in a KPGA infusion center** • **SC formulation: Approve for member to fill via the outpatient pharmacy benefit only**
Enzyme replacement therapy **Preferred:** **Elelyso** (Taliglucerase alfa) **Non-Preferred:** **Cerezyme** (Imiglucerase) **Vpriv** (Velaglucerase alfa)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** **Candidates for treatment with Enzyme replacement therapy should meet ALL the following criteria:** • Documented diagnosis of Type 1 Gaucher's Disease and anemia • Patient is symptomatic (i.e., radiologic evidence of skeletal disease, platelet count <60,000 microL, liver >2.5 times normal size, OR spleen > 15 times normal size) • Patient has been evaluated by a Geneticist Initial approval period: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** (excluding Pharmacy Consult Service)**.** Continued approval: 24 months. Confirm patient meets all above criteria. In addition, continue approval if patient is responding to treatment (improving platelet count, decreased hepatomegaly and splenomegaly) • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Monitoring: • Disease monitoring: CBC, liver enzymes, IgG antibodies; MRI, CT, or US of liver and spleen; bone density studies; monitor antibodies in those patients who developed antibodies to other enzyme replacement therapies Dosing and Administration: *Elelyso* • Treatment-naïve adult and pediatric patients ≥ 4 years: 60 units/kg administered every other week as a 60 to 120 minute intravenous infusion • Patients switching from imiglucerase: Begin treatment with Elelyso at the same unit/kg dose as the patient's previous imiglucerase dose. Physicians can make dosage adjustments based on achievement and maintenance of each patient's therapeutic goals *Cerezyme* • Administered by intravenous infusion over 1-2 hours. • Dosage should be individualized to each patient. Initial dosages range from 2.5 U/kg of body weight 3 times a week to 60 U/kg once every 2 weeks.

Drug	Prior Authorization Criteria
	Vpriv • Patients Naïve to Enzyme Replacement Therapy: 60 Units/kg • Patients being treated with stable imiglucerase dosages for Gaucher disease: Can switch to VPRIV at previous imiglucerase dose two weeks after last imiglucerase dose

Eohilia
(Budesonide)
	Candidates for treatment with Eohilia should meet ALL the following criteria:
	
	• Prescribed by an allergy specialist, gastroenterologist, or otolaryngologist
	• Confirmed diagnosis of eosinophilic esophagitis (EoE) by upper endoscopy and biopsy with an eosinophil count of at least 15 eosinophils per high-power microscopy field
	• Two or more episodes of dysphagia per week
	• Age ≥ 11 years
	• Documented inadequate response, intolerance or contraindication to ALL of the following therapies:
	  ○ Proton pump inhibitor therapy with titrated dose to twice daily (8 week minimum) and continued therapy if response
	  ○ Topical glucocorticoid (8 week minimum)
	  ▪ Budesonide oral viscous slurry up to 2 mg twice daily for older children and adults. Take the budesonide slowly, over 5 to 10 minutes. Do not eat or drink for 30 minutes after taking budesonide suspension.
	  ▪ Fluticasone 220 mcg/spray, eight sprays daily swallowed (not inhaled) in 2 to 4 divided doses. Administer using a metered dose inhaler without a spacer. Spray into the mouth and then swallow. Do not inhale. Do not eat or drink for 30 minutes following administration.
	
	<u>Reasons for Non-Coverage:</u>
	• Patient has unresolved fungal infection, Strongyloides infestation, cerebral malaria, or ocular herpes simplex infection
	• Patient has severe hepatic impairment (Child-Pugh Class C)
	• Concomitant use of strong CYP3A4 inhibitors (e.g.,ketoconazole, ritonavir, erythromycin)
	
	<u>Approval Period</u>: 12 weeks

Epclusa (Sofosbuvir/velpatasvir) **KP Preferred:** Authorized generic for sofosbuvir/velpatasvir	**Candidates for treatment with sofosbuvir/velpatasvir (Epclusa) should meet ALL the following criteria PLUS the individual disease state criteria that follows:** • Do not approve coverage for brand Epclusa. Sofosbuvir/velpatasvir authorized generic (AG) is identical in composition of both active and inactive ingredients as brand Epclusa. **<u>Hepatitis C (HCV):</u>** • Prescribed by Gastroenterologist or Infectious Disease specialist • Documented hepatitis C virus (HCV) infection demonstrated by detectable quantitative HCV RNA level in previous 12 months

Drug	Prior Authorization Criteria
	Solid Organ Transplant (e.g., heart, lung, liver, and kidney): • Prescribed by a Transplant Specialist for solid organ transplant Initial Approval: • For patients without cirrhosis or compensated cirrhosis [Child-Turcotte-Pugh (CTP): class A], approve for 12 weeks • For patients with decompensated cirrhosis (CTP: class B or C), approve for 24 weeks Continued approval for new members who were initiated on Epclusa outside of KPGA: confirm diagnosed with hepatitis C and Epclusa initiation date. • For patients without cirrhosis or compensated cirrhosis (CTP: class A), approve **generic sofosbuvir/velpatasvir** for a total of 12 weeks • For patients with decompensated cirrhosis (CTP: class B or C), approve **generic sofosbuvir/velpatasvir** for a total of 24 weeks
Epidiolex (Cannabidiol)	**Candidates for treatment with Epidiolex should meet ALL the following criteria:** • Prescribed by Pediatric or Adult Neurology • Patient is ≥ 1 year old • Documented diagnosis of Lennox-Gastaut Syndrome (LGS), Dravet Syndrome (DS), tuberous sclerosis complex or other forms of refractory epilepsy • Documented treatment refractory to optimal dosing of **at least 2** antiepileptic drugs (e.g., for LGS- valproate, clobazam, clonazepam, felbamate, lamotrigine, rufinamide, topiramate, and levetiracetam; for DS-valproate, clobazam, topiramate, levetiracetam, clonazepam, zonisamide, and ethosuximide) • Any use of cannabis and its derivatives must be discontinued prior to initiation • Patient/Caregiver agrees to maintain a seizure diary and has at least 1 month of documentation prior to treatment initiation. • Patient does not have significant hepatic impairment (ALT or AST > 3x ULN AND total bilirubin > 2x ULN). Initial Approval: 12 months Continued Approval: 12 months. Approve Epidiolex if patient has completed a follow-up visit with a Neurologist in the last 12 months and is confirmed to be clinically stable on it. For new members who were initiated in Epidiolex outside of KPGA: Approve Epidiolex if patient is confirmed to be clinically stable on it by a specialist in the last 12 months. Ordering Information: • Epidiolex is available through the KP Specialty Pharmacy. Order via KP Healthconnect.

Drug	Prior Authorization Criteria

Epkinly
(Epcoritamab-bysp)
	Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.
	
	Candidates for treatment with Epkinly (epcoritamab-bysp) must meet ALL the following criteria:
	
	Criteria for follicular lymphoma (FL):
	
	• Prescribed by Hematology / Oncology Specialist
	• Patient is ≥ 18 years old
	• Patient has a diagnosis of relapsed or refractory FL
	• Patient meets ONE of the following:
	  ○ Patient has a documented adequate therapeutic trial or treatment failure after **ONE** line of systemic chemotherapy **AND** Epkinly will be used in combination with lenalidomide and rituximab **OR**
	  ○ Patient has a documented adequate therapeutic trial or treatment failure of mosunetuzumab (Lunsumio) **AND TWO** or more lines of systemic chemotherapy AND Epkinly will be used a monotherapy
	
	Criteria for diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell Lymphoma:
	• Prescribed by hematologist or oncologist
	• Patient is ≥ 18 years of age
	• Patient has a diagnosis of relapsed or refractory DLBCL, not otherwise specified (DLBCL, NOS) **OR** high-grade B-cell lymphoma
	• Patient has a documented adequate therapeutic trial or treatment failure of glofitamab (Columvi) **AND TWO** lines of systemic chemotherapy.
	
	Approval period: 12 months
	• Cycle 1 may be approved for administration at a KP-affiliated inpatient facility.
	• Subsequent cycles should be approved for back-office administration in a KP-infusion center ONLY.
	  ○ **NOTE:** If patient experiences a treatment delay >14 days, an additional cycle may be approved for administration at a KP-affiliated inpatient facility for therapy re-initiation.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.**
	
	Continued approval: 12 months. Confirm patient meets above criteria. In addition, patient should meet the following:
	• No evidence of disease progression or unacceptable toxicity.
	• **Approve for back-office administration in a KP-infusion center ONLY.**
	  ○ **NOTE:** If patient experiences a treatment delay >14 days, an additional cycle may be approved for administration at a KP-affiliated inpatient facility for therapy re-initiation.

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>
Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.
<u>Dosing and Administration:</u>
Epcoritamab DLBCL[a] and High-Grade B-cell Lymphoma Dosing Schedule[c] (28-day Treatment Cycles)
<table>
<tr><th>Cycle number</th><th>Day of treatment</th><th>Epcoritamab dose[c]</th></tr>
<tr><td rowspan="4">Cycle 1</td><td>Day 1</td><td>0.16 mg SUBQ (step-up dose 1)</td></tr>
<tr><td>Day 8</td><td>0.8 mg SUBQ (step-up dose 2)</td></tr>
<tr><td>Day 15[d]</td><td>48 mg SUBQ (first full dose)</td></tr>
<tr><td>Day 22</td><td>48 mg SUBQ</td></tr>
<tr><td>Cycles 2 and 3</td><td>Days 1, 8, 15, and 22</td><td>48 mg SUBQ</td></tr>
<tr><td>Cycles 4 to 9</td><td>Days 1 and 15</td><td>48 mg SUBQ</td></tr>
<tr><td>Cycles 10 and beyond[b]</td><td>Day 1</td><td>48 mg SUBQ</td></tr>
</table>
Epcoritamab Follicular Lymphoma Dosing Schedule[a] (Single-Agent Treatment; 28-day Treatment Cycles)
<table>
<tr><th>Cycle number</th><th>Day of treatment</th><th>Epcoritamab dose[b]</th></tr>
<tr><td rowspan="4">Cycle 1</td><td>Day 1</td><td>0.16 mg SUBQ (step-up dose 1)</td></tr>
<tr><td>Day 8</td><td>0.8 mg SUBQ (step-up dose 2)</td></tr>
<tr><td>Day 15</td><td>3 mg SUBQ (step-up dose 3)</td></tr>
<tr><td>Day 22[c]</td><td>48 mg SUBQ (first full dose)</td></tr>
<tr><td>Cycles 2 and 3</td><td>Days 1, 8, 15, and 22</td><td>48 mg SUBQ</td></tr>
<tr><td>Cycles 4 to 9</td><td>Days 1 and 15</td><td>48 mg SUBQ</td></tr>
<tr><td>Cycles 10 and beyond[b]</td><td>Day 1</td><td>48 mg SUBQ</td></tr>
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Epcoritamab Follicular Lymphoma Dosing Schedule[a] (In Combination with Lenalidomide[b] and Rituximab; 28-day Treatment Cycles)
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<tr><td>Cycles 2 and 3</td><td>Days 1, 8, 15, and 22</td><td>48 mg SUBQ</td></tr>
<tr><td>Cycles 4 to 12[c]</td><td>Day 1</td><td>48 mg SUBQ</td></tr>
</table>
</td></tr>
<tr><td>Erivedge
(Vismodegib)</td><td>Candidates for treatment with Erivedge must meet ALL the following criteria:

Prescribed by a dermatologist or oncologist.
Age ≥ 18 years
Patient has a diagnosis of ONE of the following:
Locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy OR patient is not a candidate for surgery or radiation therapy.

</td></tr>
</table>

Drug	Prior Authorization Criteria
	○ Metastatic basal cell carcinoma • Patient has a documented treatment failure, intolerance, or contraindication to sonidegib (Odomzo) Initial Approval: 12 months with quantity limit of 30 capsules per 30 days Continued Approval: 12 months with quantity limit of 30 capsules per 30 days. For continued approval for treatment with Erivedge, patient should meet ALL the following criteria: • Patient continues to meet the above criteria. • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. For new members who were initiated on Erivedge outside of KPGA: • Prescribed by a dermatologist or oncologist. • Age ≥ 18 years • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. • Quantity limit of 30 capsules per 30 days.
Erleada (Apalutamide)	**Candidates for treatment with Erleada must meet ALL the following criteria:** • Patient is male. • Prescribed by an oncologist or urologist. • Age ≥ 18 years • Diagnosis of prostate cancer that is; ○ Non-metastatic, castration resistant with documented treatment failure, intolerance, or contraindication to KP's preferred therapies Xtandi (enzalutamide) **AND** Nubeqa (darolutamide) ○ Metastatic, castration sensitive in patients with low volume disease **AND** ECOG PS 0-2 with documented intolerance, contraindication, or treatment failure to BOTH of the following: abiraterone + prednisone (KP's preferred 1st line) AND Xtandi (enzalutamide). • **Note:** Relative contraindication to abiraterone defined as: type 2 diabetes with A1c>7%, patient is on insulin, severe liver disease (Child-Pugh Class C), cardiovascular risk clearly documented by oncologist (e.g., heart failure with LVEF <50%; recent MI, or ventricular arrhythmia) ○ Metastatic, castration sensitive in patients with high volume disease and ECOG PS 2 with documented intolerance, contraindication or treatment failure to BOTH of the following: abiraterone + prednisone (KP's preferred 1st line) AND Xtandi (enzalutamide). • **Note:** Relative contraindication to abiraterone defined as: type 2 diabetes with A1c>7%, patient is on insulin, severe liver disease (Child-Pugh Class C), cardiovascular risk clearly documented by oncologist (e.g., heart failure with LVEF <50%; recent MI, or ventricular arrhythmia) • Prescribed in combination with: ○ Gonadotropin-releasing hormone (GnRH) agonist or antagonist (e.g., leuprolide (Lupron)) **OR** ○ Patient has had a bilateral orchiectomy

***Does not apply to Medicare Benefit**

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>Initial Approval: 12 months
The following quantity limits apply:
For 60 mg tablets, 120 tablets per 30 days.
For 240 mg tablets, 30 tablet per 30 days.
Continued Approval: 12 months. For continued approval for treatment with Erleada, patient should meet ALL the following criteria:
Patient continues to meet the above criteria
Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread
The following quantity limits apply:
For 60 mg tablets, 120 tablets per 30 days.
For 240 mg tablets, 30 tablet per 30 days.
For new members who were initiated on Erleada outside of KPGA: Patient should meet ALL the following criteria:
Patient is male
Prescribed by an oncologist
Patient is ≥18 years of age
Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread
The following quantity limits apply:
For 60 mg tablets, 120 tablets per 30 days.
For 240 mg tablets, 30 tablet per 30 days.</td></tr>
<tr><td>Eucrisa
(Crisaborole)</td><td>Candidates for treatment should meet ALL the following criteria:

Criteria for use for the diagnosis of atopic dermatitis:
Prescribed by a dermatologist
Age ≥ 3 months
Documented mild-to-moderate atopic dermatitis (BSA >5%)
Inadequate response, intolerance or contraindication to ALL of the following:
Phototherapy (unless documented that pediatric patient is developmentally unable to stand in light unit by him/herself)
For age >2 years: Topical calcineurin inhibitor [Pimecrolimus (Elidel) or tacrolimus (Protopic)] for a minimum of 2 weeks
Medium to very high potency topical steroid for a minimum of 2 weeks
<table>
<tr><th>Medium Potency</th><th>High and Very High Potency</th></tr>
<tr><td>Triamcinolone acet 0.1%, 0.025% O, C</td><td>Betameth diprop aug 0.05% C</td></tr>
<tr><td>Betamethasone val 0.1% C</td><td>Fluocinonide 0.05% O, C, G</td></tr>
<tr><td>Mometasone 0.1% O, C</td><td>Fluocinonoide-emollient 0.05% C</td></tr>
<tr><td>Triamcinolone acet 0.5% C</td><td>Desoximetasone 0.25% C</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>
<table>
<tr><td>Betamethasone diprop 0.05% C</td><td>Betamethasone diprop aug 0.05% O, G</td></tr>
<tr><td>Betamethasone val 0.1% L</td><td>Clobetasol 0.05% O, C</td></tr>
</table>
O = oint, C = cream, G = gel, L = lotion

Initial Approval: 12 months
• Quantity Limit: 60 grams per 30 days

Continued Approval: 12 months. Continue approval if the following are met:

For new members who were initiated on Eucrisa prior to joining KPGA: Confirm patient meets all medication trials in the initial criteria AND has a documented clinically significant benefit from the medication during Specialist follow-up in the past 12 months.
• Quantity Limit: 60 grams per 30 days

For existing members who have previously met the full criteria above: Documented clinically significant benefit from the medication during Specialist follow-up in the past 12 months.

Quantity Limit: 60 grams per 30 days</td></tr>
<tr><td>Evenity
(Romosozumab-aqqg)</td><td>Candidates for treatment with Evenity should meet ALL the following criteria:

• Documented diagnosis of postmenopausal osteoporosis as evidenced by BMD t-scores
  ○ T score is -2.5 or below in the lumbar spine, femoral neck, total proximal femur or 1/3 radius at any site
• One of the following:
  ○ History of recent osteoporotic fracture (past 12 months) OR
  ○ Very high risk for fracture (major osteoporosis fracture >30%, hip fracture >4.5%) OR
  ○ Multiple vertebral fractures (defined as two or more)
• Prescribed by endocrinologist or rheumatologist
• Documented inadequate response (trial of at least 12 months) or intolerance/contraindication to at least 1 oral bisphosphonates (i.e., alendronate, ibandronate, risedronate).
  ○ Example of inadequate response=fracture on bisphosphonate
• Documented inadequate response, intolerance/contraindication to an IV bisphosphonate (i.e., zoledronic acid) unless documented clinical reason for not trialing.
• Documented inadequate response (trial of at least 12 months), intolerance/contraindication to RANK-L inhibitor (e.g., denosumab).
• Documented inadequate response, intolerance/contraindication to preferred parathyroid hormone analog teriparatide (Forteo).</td></tr>
</table>

Drug	Prior Authorization Criteria
	• Calcium levels have been checked and any pre-existing hypocalcemia has been corrected. Reasons for Non-coverage: • Hypocalcemia • Patients with a history of MI or stroke within the preceding year • Non-FDA approved indications • Use combined with any of the following: denosumab, bisphosphonates, Evista (raloxifene), Miacalcin (calcitonin nasal spray), Reclast (zolendronic acid), Forteo (teriparatide), Tymlos (abaloparatide) • Individual has previously utilized Evenity (romosozumab-aqqg) for a total duration of 12 months or more in their lifetime. Initial Approval Duration: 12 months (12 doses) • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval Duration: None- limited duration of use is 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered. **For new members who were initiated on Evenity outside of KPGA: Approve Evenity if ALL the following are met:** • Endocrinologist or Rheumatologist visit and considered to be stable on current therapy • Provider has documented previous hx/failure of oral/IV bisphosphonates and/or fracture hx • Provider orders DEXA as clinically indicated. • Document start date and duration of therapy. Total duration of therapy cannot exceed 12 months. Dosage and Administration: • Evenity should be administered back-office by a healthcare professional • Two consecutive subcutaneous injections (105 mg each) for a total dose of 210 mg once monthly into the abdomen, thigh, or outer area of upper arm • 2 syringes should be removed from carton and allowed to sit at room temperature for at least 30 minutes before administration.
Evkeeza (Evinacumab)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** **Candidates for Evkeeza should meet ALL the following criteria**: • Documented clinical and/or laboratory determined diagnosis of homozygous familial hypercholesterolemia (HoFH) by one of the following:

Drug	Prior Authorization Criteria
	○ Genetic confirmation of two mutant alleles at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene locus OR ○ Treated LDL-C ≥ 300 mg/dL or untreated LDL-C ≥ 500 mg/dL with one of the following (i or ii): ▪ Tendinous or cutaneous xanthoma prior to age 10 years OR ▪ Evidence of heterozygous familial hypercholesterolemia in one/both parents (e.g., documented history of elevated LDL-C ≥ 190 mg/dL prior to lipid-lowering therapy) • Age ≥ 12 years • Prescribed by a cardiologist or endocrinologist • Patient has failed to achieve an LDL-C goal of less than 100 mg/dL (or 70 mg/dL with clinical ASCVD) despite optimal adherence to the following 3 therapies: ○ An adequate trial (of at least 3 months) of a high-intensity statin (atorvastatin 40 mg or 80 mg OR rosuvastatin 20 mg or 40 mg) OR statin therapy at the maximally tolerated dose with MRAR ≥ 80% for 3 months (If MRAR < 80%, reviewer can confirm adherence in the last 3 months based on medication sold dates found in Health Connect medication tab (e.g., 3 one month fills or one 90 day fill) UNLESS ▪ Documented trial and intolerance of at least 3 different statins (atorvastatin, rosuvastatin, and 1 additional statin), including an attempted alternative dosing regimen (e.g., every other day, once or twice weekly) OR ▪ Documented history of CPK >10x ULN or rhabdomyolysis attributed to a statin and not explained by drug interaction, fall, or prolonged immobility (Other causes of muscle symptoms must be ruled out (e.g., hypothyroidism, Vitamin D deficiency, recent exercise), drug-drug interactions that can increase systemic statin exposure should be considered) OR ▪ An absolute contraindication to statin therapy (e.g., active, decompensated liver disease, nursing female, pregnancy, or plans to become pregnant, or hypersensitivity reaction) ○ An adequate trial (of at least 3 months) of ezetimibe unless documented intolerance or contraindication to ezetimibe with MRAR ≥ 80% for 3 months (If MRAR < 80%, reviewer can confirm adherence in the last 3 months based on medication sold dates found in Health Connect medication tab (e.g., 3 one month fills or one 90 day fill) ○ An adequate trial (of at least 3 months) of a PCSK9 inhibitor (Repatha (evolocumab) or Praluent (alirocumab)) unless documented intolerance or contraindication to a PCSK9 inhibitor with MRAR ≥ 80% for 3 months (If MRAR < 80%, reviewer can confirm adherence in the last 3 months based on medication sold dates found in Health Connect medication tab (e.g., 3 one month fills or one 90 day fill)

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Reasons for Non-coverage: • Pregnancy or lactation Initial approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued approval**:** 12 months. Confirm patient meets all above coverage criteria without reasons for non-coverage. In addition, continued approval for treatment with Evkeeza should meet ALL the following criteria: • Documented compliance to Evkeeza from the provider's note • Patient continues to receive concomitant lipid-lowering therapy unless intolerant or contraindicated • Patient is responding positively to therapy as evidenced by lab results within the last 3 months showing an LDL-C reduction of at least 40% since initiation of Evkeeza therapy • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** For new members who were initiated on Evkeeza outside of KPGA: Approve Evkeeza if patient meets the full criteria above for approval without reasons for non-coverage and is confirmed to be clinically stable on Evkeeza by a Specialist in the last 6 months Dosing and Administration: • The recommended dose is 15 mg/kg administered by intravenous (IV) infusion once monthly (every 4 weeks)
Evrysdi (Risdiplam)	**Candidates for treatment with Evrysdi must meet ALL the following criteria:** **Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).* • Prescribed by a Pediatric Neurologist, Neurologist, or other physician specialist with expertise in managing spinal muscular atrophy (SMA) • Confirmed diagnosis of 5q-autosomal recessive SMA (biallelic deletions or mutations in the SMN1 gene) and • Patient has ≥2 *SMN2* gene copies and • Age 2 months to 25 years at treatment initiation. ○ Note: For age < 6 months, based on the strength of the current available data for onasemnogene abeparvovec-xioi (Zolgensma), KP consensus recommendation is to use onasemnogene abeparvovec as the preferred product for these patients. • Baseline labs completed: pregnancy test if female of childbearing potential. Reasons for Non-coverage:

Drug	Prior Authorization Criteria
	• Age > 25 years • Prior or planned treatment with onasemnogene abeparvovec or other gene therapy for SMA • Concurrent treatment with nusinersen (Spinraza) • Presymptomatic SMA • Permanent invasive ventilation or tracheostomy • Dependent on invasive or non-invasive ventilation during waking hours each day to control hypercarbia, or development of hypercarbia without ventilatory support Initial approval: 12 months Continued approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage or criteria for discontinuation listed below. Criteria for discontinuation: • Nusinersen or other gene treatment for SMA initiated • Permanent invasive ventilation or tracheostomy • Dependent on invasive or non-invasive ventilation during waking hours each day to control hypercarbia, or development of hypercarbia without ventilatory support • Intolerance to medication • Non-adherence to follow-up labs and assessments or medical treatment plan (e.g., nutrition, pulmonary, physical therapy) • Pregnancy occurs Ordering Information: EVRYSDI is OUTSOURCED to Accredo Specialty Pharmacy at 855-525-7995 or www.accredo.com. • Obtain the Evrysdi Therapy Referral Form from the Accredo Specialty Pharmacy website. • Fax page 4 and 5 directly to Accredo at 800-216-6938 instead of the number on the form.

Exdensur
(Depemokimab-ulaa)
	Candidates for treatment with Exdensur should meet ALL the following criteria:
	
	• Prescribed by a pulmonologist or allergy specialist
	• Age ≥ 12 years
	• Has a diagnosis of severe persistent asthma with an eosinophilic phenotype
	• Documented blood eosinophil count of:
	  ○ ≥ 150 cells/mm3 at therapy initiation OR
	  ○ ≥ 300 cells/mm3 in the previous 12 months
	• Uncontrolled asthma* despite an aggressive drug therapy regimen as demonstrated by BOTH of the following:
	  ○ High-dose inhaled corticosteroid (ICS), plus a long-acting beta-agonist (LABA) [e.g., wixela 500/50mcg (fluticasone/salmeterol)1 puff BID, Advair HFA 230/21mcg (fluticasone/salmeterol) 2 puffs BID, Breyna 160/4.5mcg (budesonide/formoterol) 2 puffs BID, Dulera 200/5mcg (mometasone/formoterol) 2 puffs BID] AND
	  ○ Currently receiving or history of systemic corticosteroids for > 3 days for frequent

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	or severe exacerbations in the past 12 months • Documented trial, intolerance or contraindication to all of the following: Fasenra (benralizumab), [KPGA's preferred interleukin-5 antagonist], Dupixent (dupilumab), Nucala (mepolizumab), • Exdensur will be used in combination with a high-dose or maximally tolerated dose of an ICS (e.g., fluticasone, budesonide, mometasone) AND at least ONE other maintenance medication such as a: o Long-acting beta agonist (LABA) (e.g., salmeterol, formoterol) o Long-acting muscarinic antagonist (LAMA) (e.g., tiotropium [Spiriva/Stiolto], glycopyrrolate [Breztri/Bevespi], revefenacin [Yupelri], aclidinium [Tudorza], umeclidinium [Incruse]) o Leukotriene receptor antagonist (LTRA) (e.g., montelukast, zafirlukast) OR o Theophylline • **NOT** be used concurrently with another systemic biologic (e.g., Fasenra, Dupixent, Nucala, Xolair, Tezspire for the treatment of eosinophilic asthma • **NOT** used for the relief of acute bronchospasm or status asthmaticus **Initial Approval:** 6 months • Approve for back-office administration by a healthcare provider ONLY • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** **Continued Approval:** 12 months. **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **For new members initiated on Exdensur outside of KPGA:** Confirm patient is clinically stable by a specialist in the past 6 months AND meets all the medication trials in criteria above • **For existing members who previously met the full criteria:** Confirm patient has clinically significant benefit documented during a specialist follow-up within the past 12 months AND meets applicable criteria below. o Exdensur is being used in combination with a high-dose or maximally tolerated dose of an ICS (e.g., fluticasone, budesonide, mometasone) AND at least ONE other maintenance medication such as a: ▪ Long-acting beta agonist (LABA) (e.g., salmeterol, formoterol) ▪ Long-acting muscarinic antagonist (LAMA) (e.g., tiotropium [Spiriva/Stiolto], glycopyrrolate [Breztri/Bevespi], revefenacin [Yupelri], aclidinium [Tudorza], umeclidinium [Incruse]) ▪ Leukotriene receptor antagonist [e.g., montelukast, zafirlukast] OR ▪ Theophylline
Exon Skipping Therapies:	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** **Candidates for treatment with Exon Skipping Therapies should meet ALL the following criteria:**

Drug	Prior Authorization Criteria
Amondys 45 (Casimersen) **Exondys 51** (Eteplirsen) **Viltepso** (Viltolarsen) **Vyondys 53** (Golodirsen)	• Must have a documented diagnosis of Duchenne muscular dystrophy (DMD) with confirmed deletion/mutation amenable to exon skipping required by the product selected. **(Confirmation of appropriate testing by a geneticist is required)** ○ Amondys 45: amenable to exon 45 skipping ○ Exondys 51: amenable to exon 51 skipping ○ Viltepso/Vyondys 53: amenable to exon 53 skipping • Prescribed by Pediatric Neurology or Adult Neurology with neuromuscular expertise. • Must be at least 4 years old • Must be ambulatory; cane or walker use acceptable, but no wheelchair dependency • Documentation in Medical Record: Minimum distance for unassisted 6- minute walk test (6MWT): 180 m • Must be on a stable dose of glucocorticoids for at least 6 months • %FVC ≥50% Predicted • Cardiac assessment: echocardiogram, electrocardiogram, and Holter monitor within 6 months prior to initiation. • Upper limb module (ULM) for patients age ≥ 8 years • Blood pressure assessment (for golodirsen and viltolarsen treated patients only) • Pulmonary assessment: ○ Age ≥ 6 years: spirometry, pulse oximetry, End-Tidal CO2 (ETCO2), lung volumes, maximal inspiratory pressure (MIP)/maximal expiratory pressure (MEP), and cough peak flows ○ Age < 6 years: pulse oximetry and ETCO2 Reasons for Non-coverage: • Non-ambulatory • Ambulatory with some level of wheelchair dependency • Requires nocturnal ventilation (includes BiPAP, excludes nocturnal CPAP) ○ Note: Excludes nocturnal CPAP for the treatment of obstructive sleep apnea • LVEF < 50% or QTc ≥ 450 msec • Average heart rate above normal for age as assessed via Holter monitor • Prior or planned treatment with gene therapy for DMD Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continue approval if determined by treating physician the need for continued therapy and follow-up function assessments performed. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.**

Drug	Prior Authorization Criteria
	Criteria for Discontinuation: If patient meets any of the following functional criteria: • Limited home level or below for ambulation test • Dependent level for sit to stand test • Ventilator support, including BiPAP, but excluding nocturnal CPAP • Has progressed to some level of wheelchair dependency • Intolerance to medication • Non-adherence to medication or follow-up assessments • For casimersen, golodirsen, and viltolarsen treated patients: If ≥10% reduction in GFR, new onset hematuria or proteinuria, or new onset hypertension, consider discontinuation or dosage reduction per consultation with a pediatric nephrologist. Dosing and Administration: • Amondys 45, Exondys 51 and Vyondys 53: 30 mg/kg weekly as a 35 to 60-minute intravenous infusion, diluted in 100-150 ml 0.9% sodium chloride injection, USP. • Viltepso: 80 mg/kg weekly as a 60-minute intravenous infusion, diluted in 100 ml 0.9% sodium chloride injection, USP.

Exxua
(Gepirone)
	Candidates for treatment with Exxua (gepirone) should meet ALL the following criteria:
	
	• Patient is ≥ 18 years of age
	• Prescribed by Psychiatry
	• Documented diagnosis of MDD (major depressive disorder) according to DSM-IV criteria
	• Baseline ECG with QTc <450 msec
	• Inadequate treatment response after documented adequate therapeutic trial (defined as minimum of ≥ 4 weeks) to **at least 4** agents from various drug classes at maximally indicated doses including the following unless contraindication:
	  ○ One to two selective serotonin inhibitors (SSRIs) (e.g., sertraline, escitalopram)
	  ○ One or two serotonin and norepinephrine reuptake inhibitors (SNRIs) (e.g., venlafaxine, duloxetine)
	  ○ One or two atypical antidepressants (e.g., bupropion, mirtazapine, buspirone)
	  ○ One or two serotonin modulators (e.g., vilazodone, Trintellix)
	
	Reasons for Non-coverage:
	
	• Prolonged QTc interval >450 msec at baseline or congenital long QT syndrome
	• Concomitant use of strong CYP3A4 inhibitors
	• Severe hepatic impairment (Child-Pugh Class C)
	• Pregnancy or lactating
	
	Initial approval: 3 months
	
	Continued Approval: 12 months

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• Provider attestation of clinical benefit (e.g., patient is now stable, improvement in depressive symptoms such as decrease in HAMD-17 score since initiation).

Fabhalta (Iptacopan)	**Candidates for Fabhalta (Iptacopan) should meet ALL the following criteria:**
	
	<u>Criteria for the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH):</u>
	
	• Age ≥ 18 years
	• Documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) by flow cytometry
	• Prescribed by a specialist in the area of practice related to the patient's diagnosis (e.g., hematologist, oncologist, immunologist, or genetic specialist)
	• Individual has tried and failed a C5 complement inhibitor (Epysqli (eculizumab-aagh) or Ultomiris) therapy with persistent anemia (Hb <10 g/dL)
	• Patient is not using concurrent C5 complement inhibitor therapy (e.g., Epysqli (eculizumab-aagh), Ultomiris)*
	• Documented failure, contraindication, or intolerance to Empaveli
	• Prescriber must be certified by the Fabhalta REMS program. (Fabhalta REMS Website)
	*See dosing and administration for additional information.
	
	<u>Reasons for Non-coverage:</u>
	
	• Patient has not completed or updated vaccination against certain encapsulated bacteria including streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B (Hib) at least two weeks prior to the first dose of Fabhalta.
	• Patients with unresolved serious infection caused by encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis, or Haemophilus influenzae type B.
	• Patients with severe renal impairment (i.e., eGFR < 30 mL/min/1.73 m^2) with or without hemodialysis.
	• Patients with severe hepatic impairment (i.e., Child-Pugh Class C).
	
	<u>Initial Approval:</u> 6 months
	
	<u>Continued Approval:</u> 1 year. Confirm patient meets all above coverage criteria without reasons for non-coverage in addition to criteria below:
	
	• Patient demonstrates clinical benefit compared to baseline (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase, increased or stabilization of hemoglobin levels, less fatigue)
	
	<u>Criteria for the diagnosis of IgA nephropathy (IgAN):</u>
	
	• Age ≥ 18 years
	• Prescribed by nephrologist
	• Documented diagnosis of IgA nephropathy (IgAN) verified by renal biopsy
	• Currently prescribed maximum tolerated dose of one of the following for at least 3 months or documented intolerance, contraindication
	  ○ ACE I (e.g., lisinopril, benazepril) OR
	  ○ ARB (e.g., losartan, valsartan)

Drug	Prior Authorization Criteria
	• Currently prescribed SGLT2i (e.g., Jardiance, dapagliflozin) for at least 3 months or documented intolerance, contraindication • High risk of progression as defined by urine protein-to-creatine ratio (UPCR) >1.5 • eGFR ≥ 30 mL/min • Adequate therapeutic trial or contraindication to one generic system corticosteroid therapy (e.g., oral prednisone, methylprednisolone) • Trial of both Tarpeyo and Filspari or contraindication, documented intolerance *NOTE: As of 8/7/2024, it has not been established whether Fabhalta slows kidney function decline in patients with IgAN. Tarpeyo, Filspari are associated with sustained and clinically relevant reduction in kidney function loss. Reasons for Non-coverage: • Hx of kidney transplant or currently undergoing dialysis • Concurrent treatment with Tarpeyo or Filspari • Severe hepatic impairment (Child-Pugh class C) • Patient with unresolved serious infection caused by encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis, or Haemophilus influenza type B. • Patient has not completed or updated vaccination against certain encapsulated bacteria including streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenza type B (HiB) at least two weeks prior to the first dose of Fabhalta. Initial Approval: 6 months Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for non-coverage in addition to criteria below: • Documented clinically significant reduction in proteinuria (~30-40% from baseline) **Criteria for the diagnosis of C3 glomerulopathy (C3G):** • Age ≥18 years old • Prescribed by nephrology who is enrolled in Fabhalta REMS program • Documented diagnosis of C3G confirmed by biopsy • Urine protein-to-creatine ratio (UPCR) ≥1 g/g • eGFR ≥30 mL/min/1.73 m2 • Currently prescribed maximum tolerated dose of one of the following for at least 3 months or documented intolerance, contraindication o ACE I (e.g., lisinopril, benazepril) OR o ARB (e.g., losartan, valsartan) • Currently prescribed SGLT2i (e.g., Jardiance, dapagliflozin) for at least 3 months or documented intolerance, contraindication Reasons for Non-coverage: • Rapidly progressive crescentic glomerulonephritis • Renal biopsy showing interstitial fibrosis/tubular atrophy >50% • History of solid organ or cell transplant

Drug	Prior Authorization Criteria
	Initial approval: 6 months Continued approval: 12 months. Confirm patient meets all above coverage criteria without reasons for non-coverage in addition to criteria below: • Documented clinically significant reduction in proteinuria as evidence by UPCR Ordering Information: • FABHALTA is available only through a restricted program under a REMS called FABHALTA REMS, because of the risk of serious infections caused by encapsulated bacteria. • Fabhalta is only available through Specialty Pharmacies – Biologics by McKesson or Onco360 Oncology Pharmacy.

Fabrazyme
(Agalsidase beta)
	Please note: Reviewers must obtain approval from the Physician Program Director of QRM or PCS prior to providing QRM PA approval
	
	Candidates for treatment with Fabrazyme should meet ALL the following criteria:
	• Prescribed by or in consultation with a geneticist, nephrologist, cardiologist, or neurologist who specializes in the treatment of lysosomal disease
	• Patient age ≥ 2 years old
	• Documented diagnosis of Fabry disease confirmed by ONE of the following:
	  ○ Genetic testing indicating a pathogenic mutation of the GLA gene
	  ○ α-galactosidase activity level deficiency (males only)
	• Patient is experiencing signs or symptoms of Fabry disease (e.g. neuropathic pain, renal disease, cardiac disease, abdominal pain, etc.) **OR** there is evidence of injury to the heart, kidney, or central nervous system
	• Patient is not receiving Fabrazyme in combination with Elfabrio (pegunigalsidase alfa), Galafold (migalastat), or other enzyme replacement therapy.
	
	Initial approval period: 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or PCS prior to providing QRM PA approval**
	
	Continued approval: 24 months. Confirm patient has documented positive response in an appointment with a specialist within 12 months.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or PCS prior to providing QRM PA approval**

Fasenra (Benralizumab)	**Candidates for treatment with Fasenra should meet ALL of the following criteria PLUS the individual disease state criteria below:** • Prescribed by an allergist or pulmonologist • Patient is NOT currently receiving Fasenra in combination with any other biologic for the same indication (e.g., Dupixent, Xolair, Nucala, Cinqair, Tezspire).

Drug	Prior Authorization Criteria

	Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)
	• Age ≥ 18 years
	• Documented diagnosis of severe eosinophilic granulomatosis with polyangiitis (EGPA)
	• Documented inadequate response, intolerance, or contraindication to standard therapy with systemic corticosteroids (e.g., prednisone, methylprednisolone) with or without immunosuppressive therapy (e.g., cyclophosphamide, rituximab)
	
	Diagnosis of severe eosinophilic asthma
	• Age ≥ 6 years
	• Eosinophilic phenotype indicated by one of the following:
	  ○ Non-OCS dependent: blood eosinophil count of ≥ 300 cells/mm^3 within the previous 12 months
	  ○ OCS dependent: blood eosinophil count of ≥ 150 cells/mm^3 within the previous 12 months
	  ○ Current or recent (prior 6 months) biologic use: current blood eosinophil count is not required. Confirm patient has a diagnosis of an eosinophilic asthma phenotype.
	• Documented uncontrolled asthma defined as ONE of the following:
	  ○ Two or more asthma exacerbations in the past 12 months requiring systemic corticosteroids for ≥ 3 days OR at least one serious exacerbation requiring hospitalization or ER visit in the past 12 months
	  ○ Asthma Control Test (ACT) consistently < 20 over the past 12 months
	  ○ Dependence on oral corticosteroid (OCS) for asthma control
	• Receiving high-dose or maximally tolerated inhaled corticosteroid plus long-acting beta-agonist (ICS/LABA)‡ for ≥ 3 consecutive months with or without OCS
	‡For age ≥ 12 years: fluticasone/salmeterol 500/50 mcg 1 puff twice daily or budesonide/formoterol 160/4.5 mcg 2 puffs BID
	For ages 6 to < 12 years: fluticasone/salmeterol 100/50 mcg 1 puff twice daily or budesonide/formoterol 80/4.5 mcg 2 puffs BID
	• Fasenra (benralizumab) is used as add-on therapy to a high-dose, or maximally tolerated, ICS/LABA.
	
	Initial Approval: 12 months
	• **Approve for member to fill autoinjector via the outpatient pharmacy benefit only.** There is not an elevated risk for anaphylaxis with patient self-administration that warrants observed injection
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Continued Approval: 12 months for the autoinjector if the patient has experienced any of the following:
	
	For new members who were initiated on Fasenra outside of KPGA: confirm patient has diagnosis of eosinophilic asthma phenotype and is documented as clinically stable by a specialist in the past 12 months and Fasenra is being used in combination with a high-dose or maximally tolerated ICS and at least one additional asthma controller medication such as a LAMA, LABA, or LRTA.
	• **Approve for member to fill autoinjector via the outpatient pharmacy benefit only.** There is not an elevated risk for anaphylaxis with patient self-administration that warrants

Drug	Prior Authorization Criteria
	observed injection • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** **For existing members who previously met the full criteria for their indication:** Confirm patient has clinically significant benefit documented during specialist follow-up within the last 12 months AND Fasenra is being used in combination with a high-dose or maximally tolerated ICS and at least one additional asthma controller medication such as a LAMA, LABA, or LRTA • **Approve for member to fill autoinjector via the outpatient pharmacy benefit only.** There is not an elevated risk for anaphylaxis with patient self-administration that warrants observed injection • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Dosage and administration: • **Prefilled Syringe:** For administration by a healthcare provider only • **Autoinjector:** For administration by patient or caregiver

Ferriprox
 	
Preferred: Deferiprone (generic Ferriprox) (NOTE: non-formulary, must be approved by PCS prior to coverage)
 	
Non-preferred: Ferriprox (Deferiprone)
 	
Ferriprox Twice-A-Day (Deferiprone)
	Candidate for treatment with BRAND Ferriprox should meet ALL the following criteria:
	
	Treatment of chronic transfusion-related iron overload:
	• Prescribed be a hematologist or oncologist.
	• Patient is ≥3 years of age.
	• Patient has a diagnosis of transfusional iron overload with thalassemia syndromes, sickle cell disease, or other anemias.
	• Patient has a documented adequate therapeutic trial, intolerance, or concentration to BOTH deferasirox (generic Jadenu) tablets/granules AND deferasirox (generic Exjade) tablets for oral suspension.
	• Patient has a tried deferiprone (generic Ferriprox) and experienced a clinical reaction that cannot be explained by other clinical or lifestyle factors and maybe due to the **inactive** components of the generic products.
	  ○ If request for coverage of brand Ferriprox is based on side effects due to the active ingredients (e.g., nausea, vomiting, stomach-area (abdominal pain), joint pain, abnormal liver function, fever, bone pain, headache, vomiting, back pain, change in urine color to reddish brown, etc.) the request will be denied.
	  ○ If the physician's request for coverage of brand Ferriprox is based upon the physician's and/or member's unwillingness to change to a preferred alternative, the request will be denied until the member meets the full criteria.
	
	Reasons for non-coverage:
	• Pregnancy
	
	Initial Approval: 12 months with quantity limit of 30-day supply

Drug	Prior Authorization Criteria
	• Note: generic deferiprone can be dispended from KP pharmacies. BRAND Ferriprox formulations must be ordered from KP Specialty Pharmacy. Continued Approval: 12 months with quantity limit of 30-day supply. For continued approval for treatment, patient should meet ALL the following criteria: • Patient continues to meet the above criteria. • Note: generic deferiprone can be dispended from KP pharmacies. BRAND Ferriprox formulations must be ordered from KP Specialty Pharmacy. For new members who were initiated on treatment outside of KPGA: Patient should meet ALL the following criteria: • Patient is responding positively to therapy based on stabilization of disease. • Patient has a documented adequate therapeutic trial, intolerance, or concentration to BOTH deferasirox (generic Jadenu) tablets/granules AND deferasirox (generic Exjade) tablets for oral suspension. • Patient has tried deferiprone (generic Ferriprox) and experienced a clinical reaction that cannot be explained by other clinical or lifestyle factors and maybe due to the inactive components of the generic products. ○ If request for coverage of brand Ferriprox is based on side effects due to the active ingredients (e.g., nausea, vomiting, stomach-area (abdominal pain), joint pain, abnormal liver function, fever, bone pain, headache, vomiting, back pain, change in urine color to reddish brown, etc.) the request will be denied. ○ If the physician's request for coverage of brand Ferriprox is based upon the physician's and/or member's unwillingness to change to a preferred alternative, the request will be denied until the member meets the full criteria. • Note: generic deferiprone can be dispended from KP pharmacies. BRAND Ferriprox formulations must be ordered from KP Specialty Pharmacy.
Filspari (sparsentan)	**Candidates for treatment with Filspari should meet ALL the following criteria:** Diagnosis of focal segmental glomerulosclerosis (FSGS) documented by biopsy or genetic testing: • Prescribed by nephrology • Age ≥ 8 years • High risk of progression as defined by the following in the past 3 months: ○ Urine protein-to-creatine ratio (UPCR) ≥ 1.5 g/g AND ○ eGFR ≥ 30 ml/min/1.73 m2 in the past 3 months AND ○ Proteinuria ≥ 1 g/day • Currently prescribed the following or documented inadequate response, intolerance or contraindication ▪ ACE inhibitor (e.g. lisinopril) OR ARB (e.g. losartan) • Prescriber and patient are enrolled in the FILSPARI REMS program AND baseline ALT, AST, total bilirubin in the past 3 months • NOT used in combination with RAS inhibitors (d/c ACE I or ARB prior to initiating Filspari) • NOT currently in nephrotic syndrome (NS). Defined as the following: proteinuria >3.5 g/24h in adults or UPCR >2.0 g/g in pediatric patients <18 years of age, serum albumin <3.0 g/dL, and edema

Drug	Prior Authorization Criteria
	Initial Approval: 12 months • **Approve for member to fill via the outpatient pharmacy benefit only** • **Quantity Limit for FSGS: (2 400 mg tabs × 30-count bottles/30 days)** Continued Approval: 12 months. Continue approval if the following criteria are met: • Documented clinically significant reduction in proteinuria (~30-50% from baseline) • NOT currently in nephrotic syndrome defined by concurrent proteinuria >3.5 g/24h in adults or UPCR >2.0 g/g in pediatric patients <18 years of age, serum albumin <3.0 g/dL, and edema For new members who were initiated on Filspari outside of KPGA: Confirm patient meets all above coverage criteria and has a documented clinically significant benefit from the medication during Nephrology follow-up in the last 12 months. • **Approve for member to fill via the outpatient pharmacy benefit only**
Filsuvez (Birch triterpenes)	**Candidates for Filsuvez (birch triterpenes) should meet ALL the following criteria:** • Documented diagnosis of junctional epidermolysis bullosa (JEB) or dystrophic epidermolysis bullosa (DEB) • Prescribed by a dermatologist or pediatric dermatologist • Age ≥ 6 months • Confirmation of JEB or DEB by skin biopsy or genetic testing including LAMA3, LAMB3, LAMC2, or COL7A1 • Presence of wounds that have not healed despite three months of standard wound care, or have recurrent ulceration of wound. If wound pain is causing significant functional impairment, a two-month trial of standard wound care is adequate • Presence of partial thickness wound of 10-50 cm^2 in surface area Reasons for Non-coverage: • Current or history of squamous cell carcinoma in the area that will undergo treatment • Actively receiving chemotherapy or immunotherapy • Prior allergic reaction to any component of birch triterpenes Initial Approval: 3 months Continued Approval: 3 months. Continue approval if wound reopens. Confirm patient meets all above coverage criteria without reasons for Non-coverage or criteria for discontinuation listed below. Criteria for Discontinuation: • Lack of clinically significant signs of improvement after three months of treatment • Lack of wound closure after six months of treatment • Discontinue after wound closure • Intolerance to medication

Drug	Prior Authorization Criteria

Fintepla (Fenfluramine)	**Candidates for treatment with Fintepla should meet all the following criteria:**
	• Prescribed by a Neurologist
	• Age ≥ 2 years
	• Diagnosis of Dravet Syndrome (DS) OR Lennox-Gastaut syndrome (LGS) with documentation of ongoing convulsive seizures despite stable antiepileptic medication regimen
	• Documentation of inadequate treatment response to 2 antiepileptic drugs (AEDs) that are appropriate for the diagnosis (DS- valproate, clozabam, levetiracetam, topiramate, clonazepam, zonisamide or ethosuximide; LGS- valproate, clobazam, clonazepam, felbamate, lamotrigine, rufinamide, topiramate, and levetiracetam)
	• Patient is currently established on treatment with fenfluramine (Fintepla) OR
	  ○ For Dravet syndrome: Inadequate response, intolerance or contraindication to cannabidiol (Epidiolex) AND stiripentol (Diacomit)
	  ○ For Lennox-Gastaut syndrome: inadequate response, intolerance or contraindication to cannabidiol (Epidiolex)
	
	Reasons for Non-coverage:
	• Initiation of therapy within 14 days of the administration of a monoamine oxidase inhibitor (MAOI) (i.e phenelzine, selegiline, tranylcypromine, isocarboxazid)
	• Concomitant therapy with cannabidiol
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. Confirm patient meets all above coverage criteria. In addition, confirm patient meets the following:
	• Documentation that patient has achieved and maintains a reduction in the frequency of convulsive seizures OR longer interval between convulsive seizures over baseline
	• Patient has not developed any significant adverse drug effects (i.e serotonin syndrome, valvular heart disease, pulmonary arterial hypertension, acute decreases in visual acuity/ocular pain, suicidal thoughts/behaviors)
	
	Ordering information:
	
	Fintelpla is available through AnovoRx Specialty Pharmacy (Contact information: Phone 844-288-5007, Fax: 855-813-2039, Website: anovorx.com)

Preferred: **Icatibant** (generic Firazyr) **Non-Preferred:** **Firazyr** (Icatibant)	**Candidates for treatment with Firazyr should meet ALL the following criteria:** • Prescribed for acute treatment of hereditary angioedema (HAE) attacks • Prescriber must be an Allergist or Immunologist. • Age ≥ 18 years • Medication will NOT be used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Kalbitor, or Ruconest) • For brand name Firazyr, patient has tried generic icatibant and had a documented

Drug	Prior Authorization Criteria
Unavailable through KP channels: **Sajazir** (branded generic Icatibant)	allergy/intolerance that is likely due to the **inactive** components of generic icatibant (generic Firazyr) and cannot be explained by other clinical or lifestyle factors. a. NOTE: if the physician's request for coverage of brand Firazyr is based upon the physician's and/or member's unwillingness to change to a preferred alternative, the request will be denied unless the member meets the full criteria. • Do not approve Sajazir (branded generic icatibant) as it is only available through a limited distribution program with Cycle Pharma and cannot be ordered / dispensed through KP internal pharmacies. Reasons for Non-coverage: • Routine **prophylaxis** against angioedema attacks in adolescent and adult patients with HAE Initial Approval: 12 months Continued Approval: 12 months. Confirm patient meets all above criteria without reasons for Non-coverage. In addition, continue approval based on clinical documentation of functional improvement, a decrease in frequency of HAE attack, and an improvement in severity and duration of attacks.
Firdapse (Amifampridine Phosphate)	**Candidates for treatment with Firdapse should meet ALL the following criteria:** • Documented diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) based on clinical, serologic, and electrodiagnostic exam. • Age ≥ 6 years • Forced vital capacity (%FVC) ≥ 60% • Prescribed by a neurologist or pediatric neurologist • Approval for use obtained from Neurology Department Chair Reasons for Non-coverage: • Non-Ambulatory • Seizure disorder, history of seizures, or active brain metastasis • Pregnancy or pregnancy potential without use of effective contraception • End-Stage renal disease Initial Approval**:** 3 months Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continued approval will be based on documented improvement with therapy Do not continue therapy if: • No improvement after a 3- month trial with therapy • Patient becomes non-ambulatory

Drug	Prior Authorization Criteria
	• Significant clinical decline (such as assisted ventilation or hospice care) • Patient develops epileptic seizures • Non-adherence or intolerance to therapy
Fotivda (Tivozanib)	**Candidates for treatment with Fotivda (tivozanib) should meet ALL the following criteria**: • Age ≥ 18 years • Prescribed by an Oncologist • Documented diagnosis of advanced or metastatic renal cell carcinoma that is relapsed or refractory to at least 2 prior systemic therapies (i.e axitinib, ipilimumab, nivolumab, everolimus) AND • Documentation that at least 1 prior therapy is an anti-VEGFR TKI (i.e axitinib, lenvatinib, pazopanib, sunitinib, cabozantinib) Reasons for Non-coverage: • Documentation of severe hepatic impairment (i.e total bilirubin greater than 3-10 times ULN with any AST) • Pregnancy or lactation Initial approval period: 12 months Continued approval: 12 months. Continued approval for treatment with Fotivda should meet ALL criteria above in addition to the criteria below: • Documentation of disease response to treatment (i.e stabilization of disease or decrease in tumor size or tumor spread)
Fruzaqla (Fruquintinib)	**Candidates for treatment with Fruquintinib must meet ALL the following criteria:** • Age ≥ 18 years • Prescribed by an oncologist • Documented diagnosis of metastatic colorectal cancer • The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (i.e., FOLFOX, FOLFIRI, CapeOx) • The patient has received previous treatment with an anti-VEGF therapy (e.g., Bevacizumab, Zaltrap [ziv-aflibercept], Cyramza [ramucirumab]) • If patient has *RAS* wild-type mCRC, documentation of disease progression following treatment with anti-EGFR therapy (e.g., cetuximab, panitumumab) Initial Approval: 3 months Reasons for Non-coverage: • Pregnancy or breastfeeding

Drug	Prior Authorization Criteria
	• GI perforation or fistula • Suspected or confirmed Posterior Reversible Encephalopathy Syndrome (PRES) • Artery thrombosis or DVT within 6 months prior to treatment Or If patient develops Arterial thromboembolism while on the treatment • Severe hepatic impairment (total bilirubin greater than 3 times upper limit of normal and any AST) Continued Approval: 12 months • Patient must meet all criteria above without reasons for non-coverage in addition to the following: • The patient has not experienced major adverse events or unacceptable toxicity (i.e., severe bleeding, gastrointestinal perforations, arterial thromboembolism, elevated liver enzymes) • No evidence of disease progression

Galafold (Migalastat)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM or PCS prior to providing QRM PA approval**
	
	Candidates for treatment with Galafold should meet ALL the following criteria:
	• Prescribed by or in consultation with a geneticist, nephrologist, cardiologist, or neurologist who specializes in the treatment of lysosomal disease.
	• Patient is 18 years of age or older
	• Documented diagnosis of Fabry disease confirmed by **ONE** of the following:
	  ○ Genetic testing indicating a pathogenic mutation of the GLA gene (males only)
	  ○ α-galactosidase activity level deficiency
	• Patient is experiencing signs or symptoms of Fabry disease (e.g. neuropathic pain, renal disease, cardiac disease, abdominal pain, etc.) **OR** there is evidence of injury to the heart, kidney, or central nervous system
	• Patient has an amenable galactosidase alpha gene (GLA) variant for Galafold treatment based on in vitro assay
	• Baseline eGFR ≥ 30 mL/min/1.73 m^2 and patient does not require dialysis
	• Patient is not receiving Galafold in combination with Fabrazyme (agalsidase beta), Elfabrio (pegunigalsidase alfa), or other enzyme replacement therapy.
	
	Initial approval period: 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	
	Continued approval: 24 months. Confirm patient has documentation of a positive response in an appointment with a specialist within 12 months.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	
	Ordering Information:
	• Galafold is only available through Accredo Specialty Pharmacy.

Gattex (Teduglutide)	**Candidates for treatment with Gattex should meet ALL the following criteria:**

Drug	Prior Authorization Criteria
	• Diagnosis of short bowel syndrome (SBS) • Dependent on parenteral nutrition (PN) and/or intravenous (IV) fluids continuously for at least 12 months • Prescribed by a gastroenterologist who is a certified REMS provider *__NOTE:__ For more information and to enroll, please go to the following site: http://www.gattexrems.com/ • Age ≥18 years • Colonoscopy performed within the last 6 months • Serum bilirubin, alkaline phosphatase, lipase and amylase levels drawn within the last 6 months Initial approval period**:** 1 year Continued approval**:** 1 year. Confirm patient meets all above criteria. In addition, continue approval based on review of compliance to therapy and documented beneficial effect from therapy. Patient must also have documented colonoscopy 1 year after therapy with Gattex**.** Ordering information • Gattex is available through the KP Specialty Pharmacy. • Prescribers must: (1) Complete the Prescriber Education and Post-Training Knowledge Assessment Questions on the Gattex REMS website (http://www.gattexrems.com) (2) Report completion of the training to the REMS Program via the REMS Website or fax to the REMS Program Call Center (855-359-3393) and (3) Submit the Gattex prescription directly to KP National Specialty Pharmacy (KPNSP) via ePrescribing in KP HealthConnect.
Gazyva (Obinutuzmab)	**Candidates for treatment with Gazyva should meet ALL the following criteria:** Diagnosis of Lupus Nephritis (LN) Class III, IV, or V: • Prescribed by a Rheumatologist or Nephrologist • Age ≥ 18 years • Documentation of confirmed LN class III (focal), IV (diffuse) or V (membranous) • Prescribed concomitant standard-of care with hydroxychloroquine unless contraindicated or intolerant. • Prescribed concomitant standard immunosuppressive regimen consisting of one or more of the following: cyclophosphamide, mycophenolate, azathioprine, calcineurin inhibitor (e.g., tacrolimus or cyclosporine) • Not used in combination with other biologics for Lupus Nephritis (e.g., belimumab or rituximab). Initial Approval: 12 months • Approve for administration at a KP facility ONLY unless the member is seeing an external rheumatologist

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: 12 months For existing members who previously met the full criteria above: Approve if confirmed adequate tolerance and response to medication during specialist follow up in the last 12 months. • Approve for administration at a KP facility ONLY unless the member is seeing an external rheumatologist • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** For new members who were initiated on Gazyva outside of KPGA: Approve if confirmed adequate tolerance and response to medication during specialist follow up in the last 12 months. • Approve for administration at a KP facility ONLY unless the member is seeing an external rheumatologist • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**

Gilenya (Fingolimod)
 	
Preferred:
Fingolimod (generic Gilenya) capsules (NOTE: available on the formulary)
	Candidates for treatment with Gilenya should meet ALL the following criteria:
	
	Gilenya should be reserved for treatment of patients with relapsing forms of multiple sclerosis exhibiting high-disease activity or prognostic factors for early progression to secondary progressive multiple sclerosis.
	
	• Documented diagnosis of relapsing-remitting multiple sclerosis (RRMS) or active secondary progressive multiple sclerosis (active SPMS)
	• Prescribed by a neurologist
	• Documented baseline CBC with differential, ophthalmologic exam, LFT, serum bilirubin and EKG
	• For females of childbearing age (12-50 years of age), a baseline negative pregnancy test within the past month AND either a prescription for birth control (IUD or other contraceptive) or documentation of the patient declining contraception and being counseled of the potential risk of pregnancy
	• Patient has tried generic fingolimod and had an intolerance or allergic reaction that is likely due to the **inactive** components of the generic medication and cannot be explained by other clinical or lifestyle factors
	  ○ Note: If the request for coverage of brand Gilenya is based upon disease progression or side effects due to the active ingredient fingolimod (e.g., bradycardia, LFT abnormalities, lymphopenia) the request will be denied unless the member meets the full criteria
	  ○ Note: If the physician's request for coverage of brand Gilenya is based upon the

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>
physician's and/or member's unwillingness to change to a preferred alternative, the request will be denied unless the member meets the full criteria
• Documented clinical barrier, therapeutic failure or intolerance to rituximab product (Riabni is the preferred product if rituximab has never been tried) AND one of the following:
  ○ Documented inadequate response to ONE or more moderately effective DMT (interferon beta, glatiramer acetate, dimethyl fumarate or teriflunomide) OR
  ○ Documented evidence of at least one high-risk feature for early progression to secondary-progressive MS (see Table 1)

Table 1: High-risk features for early progression

<table>
<tr><td colspan="2">History of MS relapse with</td><td rowspan="2">Lesion load</td></tr>
<tr><td>Duration/Symptom</td><td>Frequency/Treatment</td></tr>
<tr><td>- ≥ 30 days and significant functional limitations besides ongoing sensory symptoms
- Sphincter OR
- Ambulatory OR
- Cerebellar (ataxia or tremor) impairment
- Visual acuity of 20/200 or worse
- Brain stem (dysarthria, dysphagia)</td><td>- ≥ 1 relapse/year average over 2 to 3 years OR
- Requiring plasma exchange</td><td>- High T2 load (> 20 lesions on brain MRI) OR
- ≥ 2 Gad+ lesions OR
- ≥ 1 cord lesion OR
- Posterior fossa lesions OR
≥ 4 lesions over 2 years on DMT OR
- Tumefactive lesions OR</td></tr>
</table>

Reasons for Non-coverage:

Gilenya should NOT be used in patients with ANY of the following:

• Unstable angina within the last 6 months
• Concomitant Class Ia or Class III anti-arrhythmic drugs (beta-blockers, diltiazem, verapamil, quinidine, disopyramide, procainamide, amiodarone, dofetilide, ibutilide, dronedarone, sotalol)
• Heart failure, class III/IV within the last 6 months
• Decompensated heart failure requiring hospitalization within the last 6 months
• Mobitz type II second-degree or third-degree atrioventricular block (history or current), unless the patient has a functional pacemaker
• Myocardial infarction within the last 6 months
• QTc interval at baseline 500 milliseconds or greater
• Sick-sinus syndrome (history or current), unless the patient has a functional pacemaker
</td></tr>
</table>

Drug	Prior Authorization Criteria
	• Heart rate less than 55 bpm • Irregular heartbeat • Stroke within the last 6 months • TIA within the last 6 months • Opportunistic infection • Macular edema or significant risk factors for macular edema (diabetes or uveitis), unless documentation that benefit of Gilenya outweighs risk • Pregnancy or lactation • Patients on beta-blockers • Patients with uncontrolled hypertension Initial approval period: 1 year Continued approval: 1 year. Continued approval for treatment with Gilenya should meet ALL the following criteria: For new members who were initiated on Gilenya or other S1P modulator therapy outside of KPGA: patient must meet the full criteria above for approval without reasons for non-coverage. For existing members who have previously met the full criteria above: • Documented beneficial effect from therapy during neurology follow up • Confirmed trial and failure of generic fingolimod and rituximab as described above

Gilotrif
(Afatinib)
	Candidates for Gilotrif should meet ALL the following criteria:
	
	Diagnosis of non-small cell lung cancer (NSCLC) – epidermal growth factor receptor (EGFR) mutation-positive:
	• Prescribed by an oncologist.
	• Age ≥ 18 years
	• Patient has advanced or metastatic disease.
	• Patient has sensitizing EGFR mutation-positive NSCLC and ONE of the following:
	  ○ For common mutations Exon19del or Exon 21 L858R, patient as a documented treatment failure, intolerance, or contraindication to KP's preferred therapy, osimertinib (Tagrisso).
	  ○ For Exon 20 insertion, patient as a documented treatment failure, intolerance, or contraindication to an amivantamab (Rybrevant)-based treatment regimen
	  ○ For uncommon EGFR mutations (S768I, L861Q, and G719X), afatinib (Gilotrif) is preferred.
	
	Diagnosis of NSCLC – squamous cell carcinoma:
	• Prescribed by an oncologist.
	• Age ≥ 18 years
	• Patient has metastatic squamous cell carcinoma.

Drug	Prior Authorization Criteria
	• Patient has disease progression after treatment with platinum-based chemotherapy. Diagnosis of head and neck cancer: • Prescribed by an oncologist. • Age ≥ 18 years • Patient has a diagnosis of recurrent, unresectable, or metastatic non-nasopharyngeal cancers (lip, oral cavity, oropharynx, hypopharynx, glottis, larynx, supraglottic, larynx, ethmoid sinus, maxillary sinus, occult primary). • Patient has disease progression after treatment with platinum-based chemotherapy. Reasons for non-coverage: • Patient whose tumor have resistant EGFR mutations. • Patient with confirmed interstitial lung disease. Initial Approval: 12 months with quantity limit of 30 tablets per 30 days. Continued Approval: 12 months with quantity limit of 30 tablets per 30 days. For continued approval for treatment with Gilotrif, patient should meet ALL the following criteria: • Patient continues to meet the above criteria. • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. For new members who were initiated on Gilotrif outside of KPGA: Patient should meet ALL the following criteria: • Prescribed by an oncologist. • Age ≥ 18 years • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. • Quantity limit of 30 tablets per 30 days.
Givlaari (Givosiran)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** **Candidates for treatment with Givlaari should meet ALL the following criteria:** • Prescribed by hematology specialists with experience in treating porphyrias. • Age ≥ 18 years. • Documented clinical symptoms consistent with active acute hepatic porphyria (AHP) • Two or more documented porphyria attacks within the last 6 months leading to hospitalization, emergency department (ED) visit, or intravenous hemin administration. • Patient has documented elevated urinary (24-urine collection) porphobilinogen (PBG) or aminolevulinic acid (ALA) within the past year. • Documented baseline liver function tests (LFTs), serum creatinine (SCr), eGFR and pregnancy test if child-bearing potential.

Drug	Prior Authorization Criteria
	Reasons for Non-coverage: Givlaari should NOT be used in patients with any of the following: • Active HIV, hepatitis C virus, or hepatitis B virus infection(s) • Planned liver transplantation • History of recurrent pancreatitis • Alanine aminotransferase (ALT) >2x upper limit of normal (ULN) • Total bilirubin >1.5x ULN (or < 2x ULN if due to Gilbert's syndrome) • Estimated Glomerular Filtration Rate (eGFR) <30 mL/min/1.73 m2 Initial approval period: 6 months ***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Criteria for discontinuation: • No improvement in the number of attacks leading to hospitalizations, ED visits, clinic visits, or hemin requirement after 6 months of treatment (i.e., status stable or worse from baseline) • Clinically significant changes in LFTs, SCr, or eGFR • Intolerance to medication • Non-adherence to medication or follow-up labs and assessments Continued approval period: 6 months. Patient should not meet any criteria for discontinuation above. ***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Dosage and Administration: • 2.5 mg/kg (actual body weight) once monthly by subcutaneous injection • Givosiran should be administered by a healthcare professional only
Gleevec (Imatinib)	**Candidates for treatment with Brand Gleevec for hematologic/oncologic indications should meet ALL the following criteria:** • Prescribed by a hematologist/oncologist • Requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines AND • Patient has a diagnosis of ONE of the following: ○ Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) ▪ Age ≥ 1 year ▪ Confirmed by molecular testing by the detection of the Ph chromosome or BCR-ABL gene prior to initiation of therapy ▪ If the patient has had prior therapy with a TKI then ONE of the following requirements must be met: ○ Resistance to prior therapy with TKI

Drug	Prior Authorization Criteria
	a. T315I mutation negative ○ Toxicity or intolerance to prior therapy with a TKI ○ Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) ▪ Age ≥ 1 year ▪ Confirmed by molecular testing by the detection of the Ph chromosome or BCR-ABL gene prior to initiation of therapy ▪ If the patient has had prior therapy with a TKI then <u>ONE</u> of the following requirements must be met: ○ Resistance to prior therapy with TKI a. T315I mutation negative ○ Toxicity or intolerance to prior therapy with a TKI ○ Myelodysplastic/myeloproliferative diseases (MDS/MPD) ▪ Age ≥ 18 years ▪ Confirmed with PDGFR (platelet-derived growth factor receptor) gene re-arrangement ○ Aggressive systemic mastocytosis (ASM) with ONE of the following mutations: ▪ Age ≥ 18 years ▪ Confirmed without the D816V c-Kit mutation by genetic test ▪ Confirmed with c-Kit mutational status unknown ○ Gastrointestinal stromal tumors (GIST) ▪ Age ≥ 18 years ○ Chordoma (progressive, advanced, or metastatic) ▪ Age ≥ 18 years ▪ PDGFRB or PDGFB positive ○ Desmoid tumors (unresectable or progressive) ▪ Age ≥ 18 years ○ Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT) ▪ Age ≥ 18 years ○ Dermatofibrosarcoma protuberans (DFSP) ▪ Age ≥ 18 years ○ Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) ▪ Age ≥ 18 years ○ Melanoma ▪ Age ≥ 18 years ▪ Confirmed c-Kit mutation-positive • Patient has tried generic imatinib and experienced a clinical reaction that cannot be explained by other clinical or lifestyle factors and may be due to the **inactive** components of the generic imatinib product. ○ **Note:** if the physician's request for coverage of brand Gleevec is based upon the physician's and/or member's unwillingness to change to generic imatinib, the request will be denied. <u>Approval period:</u> 1 year

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Reasons for Non-coverage: • T315I mutation positive Continued Approval: 1 year if ALL the following are met: • Member continues to meet the above criteria • Continues to be seen by a hematologist/oncologist • Member is responding positively to therapy as defined by stabilization of disease/lack of disease progression or decrease in size of tumor or tumor spread • Absence of unacceptable toxicity from the drug • NO dual therapy with another tyrosine kinase inhibitor

Glimepiride 3 mg
 	
Preferred
Glimepiride
1 mg, 2 mg or 4 mg
Available on the COM formulary
 	
Non-Preferred:
Glimepiride 3 mg
	Candidates for treatment with glimepiride 3 mg for Type 2 Diabetes Mellitus should meet ALL the following criteria:
	
	• Documented diagnosis of T2DM
	• Prescribed by endocrinologist
	• Documented contraindication or inadequate A1C control after documented adequate therapeutic trial (defined as minimum of 6 wks unless intolerance) of the following:
	  ○ Glimepiride 1 mg, 2 mg or 4 mg (preferred formulary tablet formulations)
	  ○ Glipizide
	  ○ Metformin
	  ○ Dapagliflozin
	• Provide clinical rationale why preferred glimepiride formulations are not appropriate
	
	Initial Approval: 6 months
	
	Continued Approval: 12 months
	
	• Patient is tolerating the glimepiride 3 mg formulation
	• Documented disease improvement (A1C lowering by 0.5% since initiation) and stable or at goal

GLP-1 Receptor Agonists (GLP-1RAs, Cardiovascular Indication) **Preferred:** **Wegovy Subcutaneous Formulation** (Semaglutide) **Wegovy Oral Formulation** (Semaglutide)	**Candidates for treatment with the preferred Semaglutide Subcutaneous Formulation (Wegovy) should meet ALL the following criteria**: **GLP-1 RAs must be tried in order list in left side of document.** Wegovy oral formulation may also be approved for patients who are unable to master subcutaneous semaglutide self-injection technique. **For current KP members:** • Prescribed by a Kaiser Permanente affiliated Cardiologist, Adult Medicine or Family Medicine clinician • Age 55 to 74 years • Does NOT have diabetes (defined as A1C < 6.5%) or NYHA Class IV heart failure. ○ If A1C ≥ 6.5%, follow diabetes pathway for GLP-1 RA.

Drug	Prior Authorization Criteria

Non-Preferred:
Any other GLP-1 RA
	• Body mass index (BMI) of ≥ 27 kg/m^2 using documented **in office** body weight taken within the past 1 month
	• History of myocardial infarction (MI)
	• Currently receiving all standard of care treatments of CVD listed below or documented trial/intolerance/or documented rationale why treatment is inappropriate
	  ○ Moderate to high-intensity statin therapy or alternative lipid-lowering drug
	  ○ Antiplatelet agent
	  ○ Antihypertensive (beta-blocker, ACE-I, ARB)
	• Not currently using another GLP-1 RA agents (i.e., Victoza, Ozempic, Rybelsus), GLP-1 RA/GIP agents (i.e. Mounjaro), or DPP-4 inhibitors (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
	
	Initial approval: 6 months
	
	Continued approval: 12 months. Ensure patient meets the following:
	• Patient has not developed NYHA Class IV heart failure
	• Not currently using another GLP-1 RA agents (i.e., Victoza, Ozempic, Rybelsus), GLP-1 RA/GIP agents (i.e. Mounjaro), or DPP-4 inhibitors (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
	• For patients who are currently approved and receiving Ozempic subcutaneous formulation, reviewer may approve continuation of Ozempic subcutaneous formulation without requiring a trial of preferred Wegovy, as long as the patient continues to meet other PA coverage criteria.
	
	For new members who were initiated on semaglutide outside of KPGA: Patients should continue to meet all above coverage criteria and may be continued on Ozempic or switched to preferred Wegovy subcutaneous formulation. Wegovy oral formulation is reserved for use in patients who are unable to master subcutaneous semaglutide self-injection technique.

GLP-1 Receptor Agonists [GLP-1 RAs, Metabolic or Nonalcoholic Steatohepatitis (MASH or NASH)]
 	
Preferred:
Wegovy Subcutaneous Formulation (Semaglutide)
 	
Non-Preferred:
Any other GLP-1 RA
	Candidates for treatment with the preferred Semaglutide Subcutaneous Formulation (Wegovy) should meet ALL the following criteria:
	
	• Prescribed by a Kaiser Permanente affiliated Hepatologist or Gastroenterologist
	• Age ≥ 18 years
	• Patient diagnosed with noncirrhotic metabolic or nonalcoholic steatohepatitis (MASH or NASH), confirmed by one of the following:
	  ○ History of a liver biopsy in the past 2 years if no change in body weight of > 5% post biopsy*
	  ○ Transient elastography (e.g. Fibroscan) in the past 12 months if no change in body weight of > 5%*
	*Note: If change in body weight of > 5% then re-evaluation to grade and stage MASH is required
	• Diagnosis is consistent with advanced liver fibrosis consistent with stages F2 or F3
	• For patients with a BMI ≥ 27kg/m^2, inability to achieve the target weight-loss goal of ≥ 10% from baseline after lifestyle interventions and a 3-month trial of at least **TWO** of the following oral medications, unless documented contraindication or intolerance. *This requirement is not applicable if BMI < 27 kg/m²*:
	  ○ Phentermine**

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ Qsymia (phentermine/topiramate ER)** or separate prescriptions taken concomitantly ○ Contrave (naltrexone/bupropion) or separate prescriptions taken concomitantly ○ Orlistat (common formulation include Alli, Xenical) ○ If patient achieves a weight reduction of ≥ 5%, then re-evaluation to grade and stage MASH is required **Note: Maintained on a stimulant medication for **ADHD** is a contraindication to phentermine use. Phentermine contraindicated with uncontrolled HTN (blood pressure >140/90 mmHg on 2 or more appropriately dose adjusted HTN meds), hx of ASCVD, hyperthyroidism, glaucoma, agitated states, hx of drug abuse. If phentermine/Qsymia is contraindicated, patients aged 18 or older must trial Contrave (or separate prescriptions) and Orlistat unless contraindication or intolerance. • Prescriber documentation and patient agrees to alcohol avoidance. Peth lab test (POPETH) completed with baseline labs and is < 20. • If concurrent diagnosis of Type 2 Diabetes Mellitus, all the following are also required: ○ A1C at goal in the past 3 months (see below): ▪ Documented A1C < 7% OR ▪ Documented A1C < 8% if age > 65 years OR age 18-64 years with dementia, blindness, lower extremity amputation, CKD 4/5, ESRD, cardiomyopathy/CHF, cardiovascular disease (acute coronary syndromes, history of MI, stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, TIA, carotid stenosis ≥ 50%, or symptomatic peripheral arterial disease presumed to be of atherosclerotic origin) ○ Currently receiving statin unless documented contraindication or intolerance <u>Reasons for non-coverage</u>: • Concomitant use with GLP-1 RA agents (i.e., Victoza, Ozempic, Rybelsus), GLP-1 RA/GIP agents (i.e. Mounjaro), or DPP-4 inhibitors (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin) • Documented Child-Pugh Class B or C • Regular use of drugs historically associated with metabolic dysfunction-associated fatty liver disease (MAFLD) due to concern for drug-induced fatty liver (e.g. amiodarone, methotrexate, systemic glucocorticoids at ≥ 5 mg/day, tamoxifen, estrogens at doses greater than those used for hormone replacement or contraception, anabolic steroids (except testosterone replacement), valproic acid and known hepatotoxins) <u>Initial Approval</u>: 12 months <u>First Continued Approval</u>: 12 months <u>For existing members who previously met the full criteria for initial approval above</u>: • Has patient completed a repeat elastography (i.e. Fibroscan) ○ If yes, go to next question ○ If no, patient does NOT meet criteria. GI follow up required.

Drug	Prior Authorization Criteria

	• Does Fibroscan show an improvement in liver stiffness measure (LSM): kPA has decreased from baseline
	  ○ If yes, go to next question
	  ○ If no, patient does NOT meet criteria
	• Does Fibroscan show an improvement in controlled attenuation parameter (CAP): CAP has decreased from baseline
	  ○ If yes, go to next question
	  ○ If no, patient does not meet criteria
	• Patient meets all of the following criteria:
	  ○ No fibrosis stage F4 or liver cirrhosis
	  ○ If diagnosis of T2DM, current A1C shows documented lowering of 0.5% from initial A1C or A1C now at goal.
	  ○ Provider documentation of continued abstinence from alcohol
	  ○ For patients who are currently approved and receiving Ozempic subcutaneous formulation, reviewer may approve continuation of Ozempic subcutaneous formulation without requiring a trial of preferred Wegovy, as long as the patient continues to meet other PA coverage criteria.
	  ○ Ensure there are no reasons for non-coverage
	  ○ If yes, continue to approval for 12 months
	
	<u>Continued Approval</u>: 12 months (after first 12-month continued approval)
	
	• Ensure there are no reasons for non-coverage
	• NAFLD Activity Score (NAS) has decreased by at least 2 points from baseline
	• Reduction in fibrosis stage
	• NAFLD Activity Score (NAS) of > 3
	• Liver fibrosis stage ≥ 2
	• For patients who are currently approved and receiving Ozempic subcutaneous formulation, reviewer may approve continuation of Ozempic subcutaneous formulation without requiring a trial of preferred Wegovy, as long as the patient continues to meet other PA coverage criteria.
	
	For new members who were initiated on semaglutide outside of KPGA: Patients should continue to meet all above coverage criteria except baseline BMI without reasons for non-coverage and continued on Ozempic or Wegovy subcutaneous formulation.

GLP-1 Receptor Agonists (GLP-1 RAs, Weight Loss Treatments) **<u>Preferred</u>:**	**Candidates for treatment with the preferred Semaglutide Subcutaneous Formulation (Wegovy) should meet ALL the following criteria:** **GLP-1 RAs must be tried in order list in left side of document.** Wegovy oral formulation may also be approved for patients who are unable to master subcutaneous semaglutide self-injection technique. **<u>For current KP members:</u>**

Drug	Prior Authorization Criteria

Wegovy Subcutaneous Formulation (Semaglutide)
 	
Wegovy Oral Formulation (Semaglutide)
 	
<u>Non-Preferred</u>: Foundayo (Orforglipron)
 	
Saxenda (Liraglutide)
 	
Any other GLP-1 RA
	• Must verify the Member's Benefits to <u>confirm</u> in a Plan with the Class III (formerly "Morbid Obesity") Rider AND documented **in office** baseline body weight taken within the past 1 month. A patient reported weight documented/added to vitals in a video/telephone/secure message is **NOT** acceptable.
	• Prescribed by a Kaiser Permanente affiliated Endocrinologist, Weight Management Specialist, Adult Medicine or Family Medicine clinician
	• Age requirements:
	  ○ Patients ≥ 18 years for Wegovy oral formulation OR
	  ○ Patients ≥ 12 years for Wegovy subq/Saxenda subq formulation
	• For adults, whose current baseline body weight recorded **in office** meets or exceeds calculated body mass index (BMI) of:
	  ○ BMI ≥ 40 kg/m^2 with or without comorbid conditions OR
	  ○ BMI ≥ 35 kg/m^2 with at least one weight-related comorbid condition, such as Type 2 diabetes, hypertension, ASCVD defined as acute coronary syndromes, MI, stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, TIA, carotid stenosis ≥50%, or symptomatic peripheral arterial disease presumed to be of atherosclerotic origin, congestive heart failure, chronic kidney disease stage 3 or higher and / or severe obstructive sleep apnea (using standard hypopnea scoring rules, with apnea-hypopnea index [AHI-4%] ≥ 30) on valid sleep study within the past 5 years AND current weight within 5% of weight at time of study
	• For adolescents aged 12 to < 18 years, baseline BMI is at or above 140% of the 95th percentile for age and sex or BMI ≥ 40 kg/m^2
	• Documented contraindication,* intolerance or failure to lose and maintain ≥ 5% body weight after a 3-month trial to:
	  ○ At least 2 of the following for age ≥ 18 years:
	  a. Phentermine* or diethylpropion
	  b. Qsymia* (phentermine/topiramate ER) or separate prescriptions
	  c. Contrave (naltrexone/bupropion) or separate prescriptions
	  d. Orlistat (common formulations include Alli, Xenical)
	  ○ At least 1 of the following for age 12 to 17 years:
	  a. Phentermine* (only age ≥ 17 years)
	  b. Qsymia* (phentermine/topiramate ER)
	• Patients with pre-diabetes (A1C 5.7 to 6.4%) or diagnosis of type 2 diabetes must be currently prescribed metformin at maximally tolerated dose for ≥ 3 months with MRAR ≥ 80%** unless documented intolerance or contraindication IN ADDITION to the criteria above
	  ○ If GI intolerance with metformin IR, must document trial of metformin SR titrated to maximally tolerated dose
	• Not currently using another GLP-1 RA agents (i.e., Victoza, Ozempic, Rybelsus), GLP-1 RA/GIP agents (i.e. Mounjaro), or DPP-4 inhibitors (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Initial Approval: 6 months First Continued Approval: 6 months Continued Approval: 12 months (after 1st 6-month continued approval) Continued Approvals: Ensure patient has achieved ≥ 5% weight loss from baseline weight by 6 months or ≥ 10% weight loss from baseline weight by 12 months as documented **in an office** visit encounter. A patient reported weight documented/added to vitals in a video/telephone/secure message is **NOT** acceptable. Do not consider baseline BMI. • For patients who are currently approved and receiving Ozempic subcutaneous formulation, reviewer may approve continuation of Ozempic subcutaneous formulation without requiring a trial of preferred Wegovy, as long as the patient continues to meet other PA coverage criteria. • For patients who have not met weight loss requirement taking Ozempic 2 mg or Wegovy 2.4 mg subcutaneously weekly, reviewer may approve for 6 months if titrating to Wegovy HD 7.2 mg subcutaneously weekly. For new members who were initiated on semaglutide or liraglutide outside of KPGA: Patients should continue to meet all above coverage criteria except for baseline BMI and continued on Ozempic or Wegovy or switched to preferred Wegovy subcutaneous formulation. NOTES: *Maintained on a stimulant medication for **ADHD** is a contraindication to phentermine use. Phentermine contraindicated with uncontrolled HTN (blood pressure >140/90 mmHg on 2 or more appropriately dose adjusted HTN meds), hx of ASCVD, hyperthyroidism, glaucoma, agitated states, hx of drug abuse. If phentermine/Qsymia is contraindicated, patients aged 18 or older must trial Contrave (or separate prescriptions) and Orlistat unless contraindication or intolerance. **If MRAR < 80%, reviewer can confirm adherence in the last 90 days based on medication sold dates found in Health Connect medication tab (e.g., 3 one-month fills or one 90-day fill).
GLP-1 Receptor Agonists (GLP-1 RAs requiring QRM review, Diabetes Indication) **Preferred:** **Ozempic Subcutaneous Formulation** (Semaglutide) **Ozempic Oral Formulation** (Semaglutide) **Rybelsus** (Semaglutide)	**Candidates for treatment with GLP-1 Receptor Agonists requiring QRM review should meet ALL the following criteria**: **Liraglutide (generic Victoza) is the preferred GLP-1 RA for type 2 diabetes mellitus and does not require PA.** **GLP-1 RAs must be tried in order list in left side of document.** • Ozempic oral may also be approved for patients who are unable to master liraglutide and Ozempic self-injection techniques. • Non-preferred GLP-1 RAs**:** Only to be used when patient has documented contraindication, intolerance or failure to achieve ≥ 0.8% A1C lowering or A1C goal after at least a 3-month trial (with MRAR ≥ 80%*) to preferred GLP-1 RAs at maximally tolerated doses. **For current KP members:** • Documented diagnosis of type 2 diabetes mellitus • Age requirements: ○ Patient age ≥ 18 years for Ozempic/Rybelsus/Soliqua/Xultophy OR

Drug	Prior Authorization Criteria
<u>Non-Preferred</u>: **Brand Victoza** (Liraglutide) **Trulicity** (Dulaglutide) **Soliqua** (Insulin glargine/lix-esenatide) **Xultophy** (Insulin degludec/liraglutide)	○ Patients age ≥ 10 years for Victoza/Trulicity only • A1C within 2% of designated goal after completion of required 3-month medication trials and within the past 3 months or on concurrent insulin ○ A1C goal < 7% OR ○ A1C goal < 8% if: age ≥ 65 years OR age 18-64 years with: dementia, blindness, lower extremity amputation, CKD 4/5, ESRD, cardiomyopathy/CHF, cardiovascular disease (acute coronary syndromes, history of MI, stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, TIA, carotid stenosis ≥ 50%, or symptomatic peripheral arterial disease presumed to be of atherosclerotic origin) • Currently prescribed metformin at maximally tolerated dose (optimal dose 1500 to 2000 mg daily) for ≥ 3 months with MRAR ≥ 80%* unless documented intolerance or contraindication: ○ If GI intolerance with metformin IR, must document trial of metformin SR titrated to maximally tolerated dose. • Documented contraindication, intolerance or failure to achieve ≥ 0.8% A1C lowering or A1C goal after at least a 3-month trial to liraglutide 1.8 mg daily or maximally tolerated dose • Not currently using another GLP-1 RA agents (i.e., Victoza, Ozempic, Rybelsus), GLP-1 RA/GIP agents (i.e. Mounjaro), or DPP-4 inhibitors (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin) <u>Initial approval period:</u> DM: 6 months. Patient must obtain A1C after initiating therapy. DM + CKD stage 3 or higher: Continue approval indefinitely <u>Continued approval of current preferred QRM GLP-1 RA (i.e. Ozempic) for DM</u>: 12 months. Ensure patient meets one the following: • Current A1C shows documented lowering of ≥ 0.8% from initial A1C or A1C now at designated goal** • If approved with A1C > 2% of goal, current A1C shows documented A1C lowering of 0.5% from initial A1C** **<u>New and current KP members with DM + ASCVD:</u>** • Documented diagnosis of type 2 diabetes mellitus • Documented diagnosis of ASCVD defined as acute coronary syndromes, history of MI, stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, TIA, carotid stenosis ≥ 50%, or symptomatic peripheral arterial disease presumed to be of atherosclerotic origin • A1C ≥ 7% unless currently on GLP-1 RA or GLP-1 RA/GIP • Patient MUST be on the current medications: ○ Moderate to high-intensity statin therapy. If not on a statin, there must be a documented trial and intolerance of at least 3 different statins. ○ Aspirin or another antiplatelet. If not prescribed, prescriber should document rationale. ○ ACE inhibitor or angiotensin receptor blocker (ARB) therapy. If not prescribed, prescriber should document rationale.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	• Currently prescribed metformin at maximally tolerated dose (optimal dose 1500 to 2000 mg daily) for ≥ 3 months with MRAR ≥ 80%* unless documented intolerance or contraindication (not required if on GLP-1 RA or GLP-1 RA/GIP and A1C within 2% of goal within the past 3 months [e.g., new member]):
	  ○ If GI intolerance with metformin IR, must document trial of metformin SR titrated to maximally tolerated dose
	• Documented contraindication, intolerance or failure to achieve ≥ 0.8% A1C lowering or A1C goal after at least a 3-month trial to liraglutide (Victoza) 1.8 mg daily or maximally tolerated dose (not required if on GLP-1 RA or GLP-1 RA/GIP and A1C within 2% of goal within the past 3 months [e.g., new member])
	• For new members currently on Trulicity, Soliqua, or Xultophy approve for preferred Ozempic subcutaneous formulation. For new members currently on Rybelsus, approve for preferred Ozempic oral formulation.
	• Not currently using another GLP-1 RA agents (i.e., Victoza, Ozempic, Rybelsus), GLP-1 RA/GIP agents (i.e. Mounjaro), or DPP-4 inhibitors (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
	
	<u>Initial approval period</u>: Continue approval indefinitely for patients with DM + ASCVD
	
	<u>The preferred QRM GLP-1 RA coverage criteria for new members. Must meet ALL the following</u>:
	• Documented diagnosis of type 2 diabetes mellitus
	• A1C within 2% of goal, at goal or on concurrent insulin**
	• Currently prescribed metformin at maximum tolerated dose unless A1C within 2% of goal (optimal dose 1500 to 2000 mg daily) or documented intolerance or contraindication
	  ○ If GI intolerance with metformin IR, must document trial of metformin SR titrated to maximally tolerated dose
	• For new members currently on Ozempic, Trulicity, Soliqua, or Xultophy, approve for preferred Ozempic subcutaneous formulation. For new members currently on Rybelsus, approve for preferred Ozempic oral formulation.
	• Not currently using another GLP-1 RA agents (i.e., Victoza, Ozempic, Rybelsus), GLP-1 RA/GIP agents (i.e. Mounjaro), or DPP-4 inhibitors (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
	
	<u>Continued approval</u>: 12 months. Ensure A1C remains at goal or within 2% of goal.
	
	NOTES:
	*If MRAR < 80%, reviewer can confirm adherence in the last 90 days based on medication sold dates found in Health Connect medication tab (e.g., 3 one month fills or one 90-day fill).
	
	**Provider may document medical justification for preferred GLP-1 RA in the event of an extraordinary temporary life event resulting in short term nonadherence/non control, if A1C control was attained within the past 6 months while stable on the requested drug prior to the event. Such events include gap in insurance coverage, steroid course, drug interaction raising A1C, traumatic life event, etc. To be eligible for consideration the physician documents the event, the patient meets other outlined criteria for drug class coverage and preferred therapy is prescribed. Physician states rationale: re-prescribing drug class presumes reattaining previous level of individual A1C goal control.

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td></td></tr>
<tr><td>Gomekli
(Mirdametinib)</td><td>Candidates for treatment with Gomekli (mirdametinib) should meet ALL of the following criteria:

• Prescribed by an oncologist or neuro-oncologist
• Age ≥ 2 years
• Diagnosed with neurofibromatosis type 1
• Documentation of symptomatic plexiform neurofibromas (PN) that cannot be completely resected without risk for substantial morbidity due to: encasement of or close proximity to vital structures, invasiveness, or high vascularity of the PN

<u>Reasons for Non-coverage:</u>

• Pregnancy and lactation

<u>Initial Approval:</u> 6 months

<u>Continued Approval:</u> 12 months. For continued approval for treatment, patient should meet ALL the following criteria:
• No documented disease progression
• No documented unacceptable toxicity (e.g., ocular toxicity, left ventricular
• dysfunction, severe dermatologic adverse reactions)</td></tr>
<tr><td>Growth Hormones
(somatropin):

<u>Preferred (all ages):</u>
Omnitrope cartridges for use in pen

Genotropin
Norditropin
Humatrope
Nutropin AQ
Serostim

<u>Non-preferred:</u>
Ngenla (Somatrogon-ghla)*

Sogroya
(Somapacitan-beco)

Skytrofa
(Lonapegsomatropin)</td><td>Candidates for treatment with growth hormone (GH) should meet ALL the following criteria:

<u>Criteria for use of GH in children (age < 18 years):</u>

• Prescribed by pediatric endocrinologist OR nephrologist
• Documented diagnosis of an approved indication appropriate for GH product:
FDA Approved Indications for Growth Hormone Products
<table><tr><th rowspan="2">Brand</th><th colspan="2">GHD</th><th>TS</th><th>ISS</th><th>SGA</th><th>PWS</th><th>CKD</th><th>NS</th><th>SHOX</th><th>HIV</th><th>SBS</th></tr><tr><th>Pediatric</th><th>Adult</th></tr><tr><td>Genotropin</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Humatrope</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td></td><td></td><td>X</td><td></td><td></td></tr><tr><td>Norditropin</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td></td><td>X</td><td></td><td></td><td></td></tr><tr><td>Nutropin AQ</td><td>X</td><td>X</td><td>X</td><td>X</td><td></td><td>X</td><td>X</td><td></td><td></td><td></td><td></td></tr><tr><td>Omnitrope</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Zomacton</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td></td><td></td><td></td><td>X</td><td></td><td></td></tr><tr><td>Serostim</td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td></td><td></td><td>X</td><td></td></tr><tr><td>Zorbtive</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td></tr><tr><td>Ngenla</td><td>X</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Skytrofa</td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Sogroya</td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>
Key:</td></tr>
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Drug	Prior Authorization Criteria
*These agents have specific age considerations	○ GHD = growth hormone deficiency ○ TS = Turner syndrome ○ ISS = idiopathic short stature ○ SGA = growth failure in children born small for gestational age ○ PWS = Prader-Willi syndrome in children ○ CKD = growth failure due to chronic kidney disease ○ NS = Noonan syndrome ○ SHOX = short stature homeobox-containing gene deficiency ○ HIV = human immunodeficiency virus-associated wasting or cachexia ○ SBS = short bowel syndrome • Documentation of open epiphyses (defined as bone age ≤ 16 years for males and ≤ 14 years for females) • **For Prader-Willi Syndrome (PWS)**, approve GH treatment based on confirmed diagnosis and epiphyses criteria above regardless of annual growth velocity. • **For growth failure due to chronic kidney disease (CKD) indication only**, patient has documented renal insufficiency (creatinine clearance ≤ 75 ml/min per 1.73 m^2 or serum creatinine > 3.0 mg/dl, or dialysis dependent) • **For idiopathic short stature (ISS) indication only**, patient must meet 3 of the following: ○ Height > 2.25 SD below the mean for age or > 2 SD below the midparental height percentile ○ Growth velocity <25th percentile for bone age ○ Bone age >2 SD below the mean for age ○ Low serum insulin-like growth factor 1 (IGF-I) and/or insulin-like growth factor binding protein 3 (IGFBP3) • Bone age predicts a final adult height > 2.25 SD below the mean for gender. For all first-time approvals, Omnitrope is the first-line agent when above criteria is met. Must try in order of preference: Documented inadequate response of at least a 4-month trial, intolerance, or no FDA-approved indication to Omnitrope → Genotropin → Norditropin → Humatrope prior to any other GH product approval. • Documentation of contraindication to somatropin, then may proceed with below in the order of preference listed • **For Skytrofa only,** age ≥ 1 year AND weight ≥ 11.5 kg • **For Nglena only**, age 3 to 17 years AND ONE of the following: ○ The patient's height is at least 2 standard deviations (SD) below the mean height for normal children of the same age and gender ○ The patient has a height velocity that is less than 25th percentile for age ○ The patient has a low peak growth hormone (less than 10 ng/mL) on two growth hormone stimulation tests, OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for same age and gender • **For Sogroya only,** age ≥ 2.5 years <u>Criteria for use of GH in transitional care after childhood GH treatment:</u> *When patients with persistent GHD reach adult height, continuation of GH therapy is critically important to ensure the development of optimal bone mass • Patients with documented persistent GHD, including those with multiple (≥ 3) pituitary hormone deficiencies regardless of etiology, or GHD with a documented causal genetic mutation or specific pituitary/hypothalamic structural defect except posterior pituitary.

Drug	Prior Authorization Criteria

	Initial Approval: 12 months
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**.
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	
	Continued Approval: 12 months. Confirm patient meets all above criteria and ONE of the following below:
	• The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year AND epiphyses are open (defined as bone age ≤ 16 years for males and ≤ 14 years for females).
	• The patient is near the terminal phase of puberty and has an annual growth velocity of at least 2.5 cm compared with what was observed from the previous year AND epiphyses are open (defined as bone age ≤ 16 years for males and ≤ 14 years for females).
	• For PWS only: approve if epiphyses are open per specifications above regardless of growth velocity.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**.
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	
	Criteria for use of GH in adults (18 + years of age):
	• Must be prescribed by an Endocrinologist or Reproductive Medicine Specialist
	• Documented adult- OR childhood-onset GHD syndrome, with biochemical diagnosis of GHD confirmed via two GH stimulation tests OR IVF indication
	  ○ **Adult Onset GHD (AOGHD):** Patients who have GHD, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma
	  ▪ Patients with irreversible hypothalamic-pituitary structural lesions and those with evidence of panhypopituitarism (at least 3 pituitary hormone deficiencies) and serum IGF-I levels below the age and sex appropriate reference range when off GH therapy are deemed to be GH deficient and DO NOT require further GH stimulation testing.
	  ○ **Childhood Onset GHD (COGHD):** Patients with a prior diagnosis of COGHD confirmed as an adult before GH therapy is started.
	  ▪ Patients with COGHD previously treated with GH replacement in childhood should be retested after final height is achieved and GH therapy discontinued for at least 1 month to ascertain their GH status before considering restarting GH therapy.
	• No retesting is required for those with known mutations, those with embryopathic/congenital defects, those with irreversible hypothalamic-pituitary structural lesions, and those with evidence of panhypopituitarism (at least 3 pituitary hormone deficiencies) and serum IGF-I levels below the age- and sex-appropriate reference range off GH therapy.
	• For all first-time approvals, Omnitrope is the first-line agent when above criteria is met. Must try in order of preference: Documented inadequate response (of at least a 4-month

Drug	Prior Authorization Criteria
	trial), intolerance, or no FDA-approved indication to Omnitrope → Genotropin → Norditropin → Humatrope prior to any other GH product approval. • Documentation of contraindication to somatropin, may approve **Sogroya** for adults • For IVF indication and prescribed by a Reproductive Medicine Specialist: ○ Request change to Omnitrope or document why the preferred therapy cannot be utilized. Then approve for FEHB members with Infertility Rider Coverage ONLY. No additional review required. Initial Approval Period**:** 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**. • **Approve for member to fill via the outpatient pharmacy benefit only** Continued Approval Period: 12 Months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. Documented positive response to therapy (improved body composition, reduced body fat, and increased lean body mass). • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**. • **Approve for member to fill via the outpatient pharmacy benefit only**
Harvoni (Ledipasvir/ sofosbuvir) **KP Preferred:** Authorized generic for Ledipasvir/Sofosbuvir	**Candidates for treatment with ledipasvir/sofosbuvir (Harvoni) should meet ALL the following criteria:** • Prescribed by Gastroenterologist or Infectious Disease specialist • Documented Hepatitis C virus (HCV) infection demonstrated by detectable quantitative HCV RNA level in previous 12 months • Documented HCV genotype is 1, 4, 5 or 6 • Documented intolerance or contraindication to sofosbuvir/velpatasvir (Epclusa authorized generic), such as clinically significant drug interactions or hypersensitivity • Do not approve coverage for brand Harvoni. Ledipasvir/sofosbuvir authorized generic (AG) is identical in composition of both active and inactive ingredients as brand Harvoni. Initial Approval: • For patients without cirrhosis or compensated [Child-Turcotte-Pugh (CTP): class A] cirrhosis, approve for 12 weeks • For patients with decompensated cirrhosis (CTP: class B or C), approve for 24 weeks Continued approval for new members who were initiated on Harvoni outside of KPGA: confirm diagnosed with hepatitis C and Harvoni initiation date. • For patients without cirrhosis or compensated cirrhosis (CTP: class A), approve **generic ledipasvir/sofosbuvir** for a total of 12 weeks

Drug	Prior Authorization Criteria
	• For patients with decompensated cirrhosis (CTP: class B or C), approve **generic ledipasvir/sofosbuvir** for a total of 24 weeks
Hemgenix (Etranacogene dezaparvovec-drlb)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** *Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).* **Candidates for treatment with Hemgenix should meet ALL the following criteria:** • **MUST verify member's benefit information. If member's coverage is through Target, CLOSE the request.** Member must go through Aradigm for this therapy. • Male patient, age ≥18 years • Prescribed by a Hematologist with expertise in hemophilia • Documented diagnosis of congenital hemophilia B, classified as severe or moderately severe, and are currently on Factor IX prophylaxis • Documentation of current or historical life-threatening hemorrhage • Documented that patient has repeated, serious spontaneous bleeding episodes • Patient has greater than 150 previous exposure days of treatment with factor IX protein <u>Reasons for Non-coverage:</u> • Known high titer of neutralizing anti-AAV serotype 5 antibodies. a. Note: In the clinical trial, majority of patients had a titer of <1:700. The sub-group with detectable preexisting neutralizing anti-AAV5 antibodies up to titers of 1:678 showed mean Factor IX activity that was numerically lower compared to the sub-group without detectable preexisting neutralizing anti-AAV5 antibodies. One subject with a titer of 1:3,212 had no human Factor IX expression observed. It is unknown at this time how various high titer levels may affect human Factor IX expression. • History of factor IX inhibitors • Positive factor IX inhibitor test a. Note: If the initial results for human Factor IX inhibitors test is positive, a re-test should be performed within approximately two weeks. If both the initial test and re-test results are positive, do not administer etranacogene dezaparvovec to this patient. • Creatinine >2 times upper limit of normal (ULN) • Positive human immunodeficiency virus (HIV) test, not controlled with anti-viral therapy as shown by CD4+ counts ≤200/µL • Previous treatment with any gene therapy, AAV vector, or other gene transfer agent • Thrombocytopenia, defined as a platelet count <50 × 10^9/L • Known severe infection or any other significant concurrent, uncontrolled medical condition including, but not limited to, renal, hepatic, cardiovascular, hematological, gastrointestinal, endocrine, pulmonary, neurological, cerebral or psychiatric disease, alcoholism, drug dependency or any other psychological disorder • Known significant medical condition that may significantly impact the intended transduction of the vector and/or expression and activity of the protein, including but not

Drug	Prior Authorization Criteria
	limited to disseminated intravascular coagulation, accelerated fibrinolysis, or advanced liver fibrosis (suggestive of or equal to METAVIR Stage 3 disease; e.g., FibroScan score of ≥9 kPa is considered equivalent) • Known history of an allergic reaction or anaphylaxis to factor IX products • Known uncontrolled allergic conditions or allergy/hypersensitivity to any component of the excipients • Known medical condition that would require chronic administration of steroids • Active infection with hepatitis B or C with the following criteria present: a. Currently receiving antiviral therapy for these infections AND/OR b. Positive for any of the following (based on central laboratory results) i. Hepatitis B surface antigen (HBsAg), except due to a previous Hepatitis B vaccination rather than active Hepatitis B infection ii. Hepatitis B virus deoxyribonucleic acid (HBV DNA) iii. Hepatitis C virus ribonucleic acid (HCV RNA) OR c. On treatment for active hepatitis B * Please note: For all patients who have a history of hepatitis B or C, radiological liver abnormalities, and/or sustained liver enzyme elevations, consult Hepatologists to determine appropriateness of initiating treatment. Approval Period: ONE-TIME, SINGLE-DOSE INFUSION. Approve ONLY for administration by a healthcare provider. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** Continued Approval: None Dosing and Administration: • The recommended dose of HEMGENIX is 2 x 10^{13} genome copies (gc) per kg of body weight (or 2 mL/kg body weight) administered as an intravenous infusion after dilution with 0.9% sodium chloride solution (normal saline) • Must be administered in an infusion clinic or inpatient setting.
Hemlibra (Emicizumab-kxwh)	**Candidates for treatment with Hemlibra should meet ALL the following criteria:** • Diagnosis of hemophilia A (congenital factor VIII deficiency) • Phenotypically severe hemophilia A requiring prophylaxis (frequent bleeding or higher risk for frequent bleeding, regardless of factor VIII level) with or without FVIII inhibitors • For patients with documented history of clinically significant factor VIII inhibitor: ○ Nonresponsive to first-line therapy of immune tolerance induction (ITI), or is not a candidate for ITI (e.g., cannot undergo central line placement), or requires prophylaxis while on ITI therapy. ▪ ITI is frequent, continuing exposure to factor VIII in order to achieve tolerance by antigen overload. • Prescribed by a Hematologist/Oncologist

Drug	Prior Authorization Criteria

	Reasons for Non-coverage:
	• Inherited or acquired bleeding disorder other than hemophilia A
	• Previous current treatment of thromboembolic disease or signs of thromboembolic disease
	• Conditions that may increase risk of bleeding or thrombosis
	
	Initial Approval: 3 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Continued Approval: 6 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continue approval if **ALL** the following are met:
	• Adherence to follow-up assessments and the medication
	• No reports of severe adverse events
	• Documentation of improvement in bleeding rates.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Criteria for Discontinuation:
	• Non-adherence with follow-up assessments and/or medication
	• Intolerance to Hemlibra
	• Discontinuation or temporary discontinuation may be considered if:
	  ○ Patient successfully completes ITI therapy
	  ○ Bleed rates do not improve while on Hemlibra
	  ○ Patient is being evaluated and treated for bleeds
	  ○ Patient is undergoing a surgery
	
	Dosage and Administration
	• 3 mg/kg by subcutaneous injection once weekly for the first 4 weeks, followed by 1.5 mg/kg once weekly

Hepcludex (Bulevirtide-gmod)	**Candidates for treatment with Hepcludex should meet ALL the following criteria** • Prescribed by Hepatologist, Gastroenterologist, or Infectious Disease Specialist • Age ≥ 18 years • Diagnosed with chronic hepatitis delta virus infection without cirrhosis or with compensated cirrhosis • Documented positive HDV antibody test or HDV RNA PCR in previous 6 months • Documented current positive HDV RNA PCR result • Documented ALT >1 but <10 × upper limit of normal • Patient does not have history of decompensated liver disease, including but not limited coagulopathy, hepatic encephalopathy, ascites or esophageal varices hemorrhage Initial Approval: 6 months • **Approve for member to fill via the outpatient pharmacy benefit only** • **Quantity Limit: 30 vials/30 days**

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: 12 months. Continue approval if the following criteria are met: For new members who were initiated Hepcludex outside of KPGA: Confirm patient has a documented clinically significant benefit from the medication during Hepatologist, Gastroenterologist, or Infectious Disease Specialist follow-up in the last 12 months. • **Approve for member to fill via the outpatient pharmacy benefit only** • **Quantity Limit: 30 vials/30 days** • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** For existing members who have previously met the full criteria above: Documented clinically significant benefit from the medication during Hepatologist, Gastroenterologist, or Infectious Disease Specialist follow up in the last 12 months • **Approve for member to fill via the outpatient pharmacy benefit only** • **Quantity Limit: 30 vials/30 days** **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
Hereditary Transthyretin-Mediated Amyloidosis – Polyneuropathy (hATTR-PN) Therapies* **Preferred:** **Amvuttra** (Vutrisiran) Subcutaneous **Non-Preferred:** **Onpattro** (Patisiran) Intravenous **Wainua** (Eplontersen) Subcutaneous	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** **Candidates for treatment should meet ALL of the following criteria:** • Documented diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) • Prescribed by a neurologist and/or neuromuscular specialist • Age ≥ 18 years • Documented confirmed TTR mutation from genetic testing • Karnofsky performance status score ≥ 50 • Objective weakness in motor strength exam consistent with diagnosis and with confirmation via electrodiagnostic studies (i.e., electromyogram, nerve conduction study) • Signs of large fiber neuropathy on exam and/or clinically significant autonomic findings (orthostatic hypotension, tachycardia, bradycardia, etc.) • **Onpattro and Wainua only:** documented treatment failure or intolerance to preferred agent Amvuttra for at least 6 months Reasons for Non-coverage: • Severe hepatic impairment and/or cirrhosis • End-stage renal disease (CKD Stage 5) • Neuropathic pain without large fiber neuropathy or clinically significant autonomic findings.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	• Pregnant, lactating, or pregnancy potential without adequate contraception.
	• Active untreated infection (HIV, HCV, etc.) or active malignancy
	• Prior Liver transplant
	
	Initial Approval: 6 months
	
	Continued Approval: Confirm patient meets all coverage criteria without reason for Non-coverage, in addition to 6 months with documented clinical response to therapy and none of the following below.
	
	Treatment should be **discontinued** for any of the following:
	• Non-adherence to follow-up assessments
	• Significant clinical decline with life expectancy of less than one year
	• Karnofsky performance status score of less than 30
	• Development of cardiogenic shock requiring inotropic support
	• Severe renal or hepatic impairment
	• Patient is requiring hospice care
	• Pregnancy
	• Hypersensitivity reaction
	
	Dosing and Administration:
	• **Amvuttra:**
	  ○ 25 mg administered by subcutaneous injection once every 3 months
	  ○ Clinic-administered injection
	• **Onpattro**:
	  ○ 0.3 mg/kg if < 100 kg by intravenous infusion; 30 mg if ≥ 100 kg.
	  ○ Infusion clinic administration
	• **Wainua**
	  ○ 45 mg subcutaneously once monthly
	  ○ Outpatient for self-administration

Hernexeos (Zongertinib)	**Candidates for treatment with Hernexeos (zongertinib) should meet ALL of the following criteria:** • Prescribed by a hematologist or oncologist • Age ≥ 18 years • Diagnosed with unresectable or metastatic non-squamous non-small cell lung cancer with HER2 (ERBB2) tyrosine kinase domain activating mutations Reasons for Non-coverage: • Pregnancy or breastfeeding Initial Approval: 6 months Continued Approval: 12 months. Patient continues to meet above criteria AND • Documented beneficial effect from therapy with NO evidence of progressive disease or unacceptable toxicity.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
Hetlioz (Tasimelteon) **Preferred:** Tasimelteon **Non-preferred:** Hetlioz	**Candidates for treatment with Hetlioz should meet ALL the following criteria:** • Prescribed by a specialist trained in sleep disorders • Patient has documented diagnosis of Non-24-Hour Sleep-Wake Disorder • Must have a log of when the patient sleeps and is awake that supports the diagnosis of Non-24-Hour Sleep-Wake Disorder • Patient must be totally blind and have no light perception • Patient must have no other concomitant sleep disorder (i.e., sleep apnea, insomnia) • The patient has received at least 6 months of continuous therapy (i.e., 6 consecutive months of daily treatment) with melatonin under the guidance of a physician who specializes in the treatment of sleep disorders • The patient did not achieve adequate results with melatonin therapy according to the prescribing physician (e.g., entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep) • Documented inadequate response or unable to tolerate Rozerem Reasons for Non-coverage: • Patient has severe hepatic impairment Initial Approval: 2 months Continued Approval: • Hetlioz should be discontinued if after 2 months of initiated treatment the patient has not significantly improved from response received during melatonin 6 month trial. • If after 2 months of initiated treatment, confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continue approval if the patient has documented positive clinical response to Hetlioz therapy (e.g., entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep), then 12 months of continued approval.

Human C1 Esterase Inhibitors
 	
Preferred:
Haegarda (Human C1 Esterase Inhibitor) subcutaneous
 	
Non-Preferred:
Cinryze (Human C1 esterase Inhibitor) Intravenous
	Candidates for treatment with Cinryze or Haegarda should meet ALL the following criteria:
	
	Non-preferred Human C1 Esterase Inhibitors: Only to be used when the preferred Human C1 Esterase Inhibitor (Haegarda) has failed, unless ages 6 to < 12 years.
	
	• Prescribed by allergist or immunologist
	• Age ≥ 6 years
	• A diagnosis of **one** of the following:
	  ○ Type I hereditary angioedema (HAE) with documented C4 level below the lower limit of normal as defined by the laboratory performing the test AND C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test
	  ○ Type II HAE with documented C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test with documentation

Drug	Prior Authorization Criteria
	provided ○ For Cinryze: Cinryze can be used off label for treatment of HAE attack • Documented use for long term HAE prophylaxis to minimize the frequency and/or severity of recurrent attacks • Patient has experienced HAE attacks of high severity and/or frequency (e.g., airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, or painful facial distortion) with baseline HAE attack rate of ≥ 2 attacks per 4 weeks • Documented intolerance, trial, failure, or contraindication to Takhzyro for HAE prophylaxis if patient is 12 years or older. Approve Cinryze for patient if aged 6 to < 12 years • Haegarda or Cinryze is NOT being used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Takhzyro, Orladeyo) Reasons for Non-coverage: • For Haegarda only: Treatment of angioedema acute attacks in adult and adolescent patients with HAE Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Haegarda: Approve for member to fill via the outpatient pharmacy benefit only** • **Cinryze may be approved for administration at a KP Facility or via the outpatient benefit if approved by prescriber (i.e., patient has been trained on self-administration).** Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for non-coverage. In addition, continue approval based on clinical documentation of functional improvement, a decrease in frequency of HAE attack, and an improvement in severity and duration of attacks. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Haegarda: Approve for member to fill via the outpatient pharmacy benefit only** • **Cinryze may be approved for administration at a KP Facility or via the outpatient benefit if approved by prescriber (i.e., patient has been trained on self-administration)**
Hyaluronic Acid Injection: **Preferred:** **Durolane (P)** **Non-Preferred:** **Supartz (2nd Line)** **Gelsyn-3 (2nd Line)**	**Candidates for treatment with Hyaluronic Acid Injection should meet ALL the following criteria:** • Patient has clinically documented osteoarthritis of the knees (American College of Rheumatology criteria) confirmed by history, exam, x-ray, and synovial fluid analysis, and requested for use in knee • Failed or intolerant to nonpharmacological therapies (physical therapy, ice, weight loss, etc.) • Documented inadequate control of pain or intolerance to an adequate trial (at least 3 months) of ONE of the following: acetaminophen (4 grams/day), NSAIDs, and other non-narcotic or narcotic analgesics • Documented inadequate trial with intra-articular corticosteroid injection (i.e., efficacy lasting less than 6-8 weeks)

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
Euflexxa (N) **Gel-One (N)** **Hyalgan (N)** **Orthovisc (N)** **Synvisc (N)** **Synvisc-One (N)** **Synojoynt (N)** **Visco-3 (N)** **Trivisc (N)** **Triluron (N)** **Hymovis (N)** **Hymovis-One (N)** **NOTE**: Durolane is the preferred medication.	Initial Approval: • For Durolane, approve for a maximum of 1 injection per knee within 6 months. Criteria for Continuation of Therapy: There are no data on repeated courses of therapy for Euflexxa and Supartz; there is no evidence of increased adverse drug events in repeated courses of therapy for Durolane, Gelsyn-3, Hyalgan, Synvisc, and Orthovisc when separated by at least six months. **Requests for repeated courses of therapy should be approved by the Chief of Service.** ****NOTE:** Durolane is now the preferred medication
Hyftor (Sirolimus)	**Candidates for Hyftor should meet ALL of the following criteria:** • Prescribed by or in consultation with an oncologist or dermatologist • Age ≥ 6 years • Documented diagnosis of facial angiofibroma associated with tuberous sclerosis • Patient has 3 or more facial angiofibromas (≥ 2 mm in diameter with redness in each) present • Patient is not a candidate for laser therapy or surgery Reasons for Non-coverage: • Breastfeeding Initial Approval Period: 3 months Continued Approval Period: 12 months. Patient must continue to meet criteria above and have positive response to therapy evidenced by a reduction in the size and/or redness of facial angiofibroma.

Hympavzi
(Marstacimab-hncq)
	Candidates for treatment with Hympavzi (marstacimab-hncq) should meet ALL the following criteria:
	
	• Prescribed by a hematologist
	• Age ≥ 6 years
	• Patient has a diagnosis of ONE of the following:
	  ○ Hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors
	  ○ Hemophilia B (congenital factor IX deficiency) with or without factor IX inhibitors.
	• Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
	• **If diagnosed with hemophilia A**:

Drug	Prior Authorization Criteria
	○ Patient has tried and failed, unable to tolerate, or has contraindication to at least 1 long-acting factor 8 replacement product **AND** ○ Examples of long-acting factor 8 replacement products: Adynovate, Altuviiio, Eloctate, Espercot, Jivi, etc ○ Patient has tried and failed, unable to tolerate or has a contraindication to Hemlibra (emicizumab) • **If diagnosed with hemophilia B:** patient has tried and failed, unable to tolerate, or has contraindication to at least 1 long-acting factor 9 replacement product ○ Examples of long-acting factor 9 replacement products: Alprolix, Idelvion, and Rebinyn • Hympazi will not be used in combination with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab]). Initial Approval: 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Continued Approval: 12 months. Patient continues to meet all criteria above and has shown clinical benefit compared to baseline with Hympavzi therapy with documentation of improvement in bleeding rates. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Dosing and Administration for Adults and Pediatric Patients 12 Years of Age and Older: • Loading dose: SUBQ: 300 mg single loading dose (as two 150 mg injections) • Maintenance dose (begin 1 week after the loading dose): SUBQ: 150 mg once weekly (on the same day each week at any time of the day). • For SUBQ administration only. Administer on the same day each week; however, may administer at any time of the day on that day. If more than 1 injection is required to deliver a complete dose, administer each injection at a different injection site. • Intended for use under the guidance of a healthcare provider. • After proper training in subcutaneous injection technique, a patient may self-inject or the patient's caregiver may administer Hympavzi, if a healthcare provider determines that it is appropriate. • Please see package insert for recommendations on dose adjustments during treatment or for missed doses. Dosing and Administration for Pediatric Patients 6 to less than 12 Years of Age • Loading dose: 150 mg (one 150 mg subcutaneous injection or two 75 mg subcutaneous injections) • Maintenance dose (begin 1 week after the loading dose): SUBQ: 75 mg once weekly (on the same day each week at any time of the day). • For SUBQ administration only. Administer on the same day each week; however, may administer at any time of the day on that day. If more than 1 injection is required to deliver a complete dose, administer each injection at a different injection site. • Intended for use under the guidance of a healthcare provider.

Drug	Prior Authorization Criteria
	• Please see package insert for recommendations on dose adjustments during treatment or for missed doses.

Ibrance
(Palbociclib)
	Candidates for Ibrance should meet ALL the following criteria:
	
	<u>Diagnosis of HER2-negative or HER2-low without visceral crisis breast cancer:</u>
	• Prescribed by an oncologist
	• Age ≥ 18 years
	• Patient has a diagnosis of advanced, recurrent, or metastatic breast cancer
	• Disease is hormone-receptor positive (e.g., ER+ and/or PR+)
	• Disease HER2-negative OR HER2 low without visceral crisis disease.
	• Ibrance will be prescribed in combination with ONE of the following:
	  ○ An aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)
	  ○ Fulvestrant (Faslodex)
	  ○ Tamoxifen
	• Patient meets ONE of the following:
	  ○ Previous trial of ribociclib 200 mg to 400 mg dose with documented toxicity
	  ○ Patient has a relative contraindication to ribociclib (Kisqali) defined as <u>one</u> of the following:
	  • Long QT syndrome
	  • Baseline QTc ≥450 ms
	  • Use of drugs that are known to prolong the QT interval
	  • Use of tamoxifen
	  • Use of strong CYP3A4 inhibitors
	  • Uncontrolled or significant cardiac disease (use as myocardial infarction or arrhythmias within the past 12 months, congestive heart failure NYHA class III-IV or with LVEF <50%, unstable angina, or bradycardia)
	  ○ Patient has a PIK3CA mutation AND Ibrance will be used in combination with Itovebi (inavolisib) and fulvestrant
	• For Female patients, patient meets ONE of the following:
	  ○ Patient is post-menopausal.
	  ○ Patient is pre/perimenopausal and is receiving ovarian suppression or ablation with a gonadotropin-releasing hormone (GnRH) agonist (e.g., leuprolide acetate (Lupron), goserelin (Zoladex)) **OR** patient has had surgical bilateral oophorectomy or ovarian irradiation.
	
	<u>Diagnosis of HER2-positive breast cancer:</u>
	• Prescribed by an oncologist.
	• Age ≥ 18 years
	• Patient has a diagnosis of advanced, recurrent, or metastatic breast cancer.
	• Disease is hormone-receptor positive (e.g., ER+ and/or PR+)
	• Disease is HER2 positive
	• Ibrance will be prescribed in combination with trastuzumab with or without pertuzumab
	• Ibrance with be prescribed in combination with ONE of the following:

Drug	Prior Authorization Criteria
	○ An aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) ○ Fulvestrant (Faslodex) ○ Tamoxifen • For Female patients, patient meets ONE of the following: ○ Patient is post-menopausal. ○ Patient is pre/perimenopausal and is receiving ovarian suppression or ablation with a gonadotropin-releasing hormone (GnRH) agonist (e.g., leuprolide acetate (Lupron), goserelin (Zoladex)) **OR** patient has had surgical bilateral oophorectomy or ovarian irradiation. <u>Diagnosis of well-differentiated/dedifferentiated liposarcoma (WD-DDLS):</u> • Prescribed by an oncologist. • Age ≥ 18 years • Patient has diagnosis of unresectable retroperitoneal WD-DDLS. <u>Initial Approval:</u> 12 months with quantity limit 30 capsules or tablets per 30 days. <u>Continued Approval:</u> 12 months with quantity limit of 30 capsules or tablets per 30 days. For continued approval for treatment with Ibrance, patient should meet ALL the following criteria: • Patient continues to meet the above criteria. • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. <u>For new members who were initiated on Ibrance outside of KPGA:</u> Patient should meet ALL the following criteria: • Prescribed by an oncologist. • Age ≥ 18 years • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. • Quantity limit of 30 capsules or tablets per 30 days
Ibsrela (Tenapanor)	**Candidates for treatment with Ibsrela should meet ALL the following criteria:** • Member is ≥ 18 years of age • Diagnosis of irritable bowel syndrome with constipation • History of failure, contraindication or intolerance to ALL OTC medications used for the treatment of constipation listed below: ○ Psyllium powder 15 gm Daily OR Calcium polycarbophil capsules or equivalent 2 caps Daily to QID ○ Polyethylene glycol 17 gm Daily to BID OR Lactulose 10 gm/15 mL solution 15-30 mL Daily • History of failure, contraindication, or intolerance to ALL the following: ○ Lubiprostone 8mcg-24mcg twice daily ○ Prucalopride (generic Motegrity®) 1-2mg daily ○ Plecanatide (Trulance®) 3mg daily ○ Linaclotide (Linzess®) 72-290mcg daily

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Reasons for Non-coverage: • Known or suspected mechanical gastrointestinal obstruction Initial Approval: 12 months Continued Approval: 12 months. For continued approval for treatment with tenapanor , patient should meet ALL the following criteria: For new members who were initiated on Ibsrela outside of KPGA: • Member must meet all criteria listed above and documentation of positive clinical response to therapy For existing members who previously met the full criteria above: • Member must continue to meet all criteria listed above and documentation of positive clinical response to therapy
Ibtrozi (Taletrectinib)	**Candidates for treatment with Ibtrozi (taletrectinib) should meet ALL the following criteria:** • Prescribed by an oncologist • Age ≥ 18 years • Diagnosis of locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) Initial Approval: 12 months with a quantity limit of 90 tablets per 30 days Continued Approval: 12 months with a quantity limit of 90 tablets per 30 days. Continue approval if the following criteria are met: • Patient continues to meet the above criteria • No evidence of unacceptable toxicity or disease progression
Iclusig (Ponatinib)	**Ponatinib will only be considered for use after a trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction) to KP's preferred therapies, imatinib or dasatinib (OR when there is a medical contraindication to the preferred product, imatinib or dasatinib) UNLESS patient is T315I mutation positive.** **Candidates for treatment with Iclusig for hematologic/oncologic indications should meet all the following:** 1. Prescribed by a hematologist/oncologist 2. Age ≥ 18 years 3. Requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines 4. Patient has a diagnosis of ONE of the following: a. Acute lymphoblastic leukemia (ALL) i. Philadelphia chromosome-positive ii. Newly diagnosed Ph+ ALL in combination with chemotherapy if no cardiovascular risk OR

Drug	Prior Authorization Criteria
	iii. As monotherapy for whom no other tyrosine kinase inhibitor therapy indicated **OR** T315I-positive 1. Ponatinib will only be considered for use as monotherapy after a trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction) to KP's preferred therapies, imatinib or dasatinib (OR when there is a medical contraindication to the preferred product, imatinib or dasatinib) UNLESS patient is T315I mutation positive. a. NOTE: Do not apply criteria **4.a.iii.1** if patient is T315I mutation positive b. Chronic myeloid leukemia (CML) i. No other tyrosine kinase inhibitor therapy indicated **OR** T315I-positive ii. Chronic phase (CP) CML with resistance or intolerance to at least two prior kinase inhibitors. iii. Ponatinib will only be considered for use after a trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction) to KP's preferred therapies, imatinib or dasatinib (OR when there is a medical contraindication to the preferred product, imatinib or dasatinib) 1. NOTE: Do not apply criteria **4.b.iii** if patient is T315I mutation positive Reasons for Non-coverage: • Treatment of newly diagnosed chronic phase CML • Patients with clinically significant, uncontrolled, or active cardiovascular disease, including any history of myocardial infarction, peripheral vascular infarction, revascularization procedure, venous thromboembolism, clinically significant atrial/ventricular tachyarrhythmias, unstable angina, or congestive heart failure. Approval period: 1 year Continued Approval: 1 year. Patient must meet all the following: • Member continues to meet the above criteria AND • Continues to be seen by a hematologist/oncologist AND • Member is responding positively to therapy as defined by stabilization of disease/lack of disease progression or decrease in size of tumor or tumor spread AND • Absence of unacceptable toxicity from the drug AND • NO dual therapy with another tyrosine kinase inhibitor
Icotyde (Icotrokinra)	**Candidates for treatment with Icotyde should meet ALL of the following criteria:** Diagnosis of plaque psoriasis: • Prescribed by a dermatologist • Age ≥ 12 years and weight ≥ 40 kg

Drug	Prior Authorization Criteria

	• Inadequate response (of at least a 3-month trial), intolerance and/or contraindication to each of the following:
	  ○ At least 1 preferred TNF inhibitor (e.g., infliximab (Infliximab-dyyb/Inflectra [preferred]), adalimumab (Amjevita [preferred], Humira)
	  ○ Ustekinumab product (Yesintek [ustekinumab-kfce]
	  ○ Cosentyx (secukinumab)
	  ○ Tremfya (guselkumab)
	  ○ Skyrizi
	  ○ Taltz
	
	Initial Approval: 12 months
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Continued Approval: 12 months.
	
	• For new members who were initiated outside of KPGA: Approve if patient meets all above coverage criteria and is confirmed to be clinically stable by a specialist during the last 6 months.
	• For existing members who have previously met the criteria: Documented clinically significant benefit (adequate response or optimizing therapy to achieve adequate response) from the medication during specialist follow up in the last 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**

Idhifa
(Enasidenib)
	Candidates for treatment with Idhifa should meet ALL the following criteria:
	
	• Diagnosis of acute myeloid leukemia (AML) with an IDH2 mutation.
	• Prescribed by hematology/oncology.
	• Age ≥ 18 years
	• Medication will be used as monotherapy.
	• Patient has ONE of the following:
	  ○ Disease is relapsed or refractory OR
	  ○ Prescribing clinician documents patient is NOT a candidate for more intensive remission induction therapy.
	
	Reasons for Non-coverage:
	• Pregnancy and/or breastfeeding
	• Unable to swallow whole tablets
	
	Initial Approval: 12 months

Drug	Prior Authorization Criteria
	Continued Approval: 12 months. Continued approval for treatment with Idhifa should meet ALL of the criteria above in addition to the criteria below: • Patient does not show evidence of progressive disease while on Idhifa therapy. • Absence of significant toxicity from the medication • Continued monitoring by Hematology/Oncology

Idvynso (Doravirine and Islatravir)	**Candidates for treatment with Idvynso (doravirine and islatravir) should meet ALL the following criteria:**
	• Prescribed by an Infectious Disease Specialist or HIV Specialist
	• Age ≥ 18 years
	• Diagnosis of HIV-1 infection
	• Diagnosis of virologically-suppressed HIV-1 defined by an **HIV-1 RNA level ≤ 20 copies/mL for at least 6 months UNLESS** trial, failure, contraindication, intolerance, or documented resistance to ALL the following:
	  ○ Dovato (dolutegravir/lamivudine)
	  ○ Biktarvy (bictegravir/tenofovir AF/emtricitabine)
	  ○ Genvoya (elvitegravir/cobicistat/tenofovir AF/emtricitabine)
	  ○ Odefsey (rilpivirine/tenofovir AF/emtricitabine)
	  ○ Generic Atripla (efavirenz/tenofovir DF/emtricitabine)
	  ○ Generic Complera (rilpivirine/emtricitabine/tenofovir DF)
	• No baseline resistance to either doravirine or islatravir.
	• Not prescribed any other HIV antiretroviral medications (e.g. lamivudine or emtricitabine or rilpivirine or efavirenz or etravirine)
	Reasons for Non-coverage:
	• Diagnosis of hepatitis B OR are not immune to hepatitis B.
	• Pregnancy
	• Diagnosis of hepatitis C with cirrhosis
	Initial Approval: 6 months
	Continued Approval: 12 months. Continue approval if the following criteria are met:
	• Documented maintenance of virologic suppression defined by an **HIV-1 RNA level ≤ 20 copies/mL**

Ilaris (Canakinumab)	**Candidates for treatment with Ilaris should meet ALL the following criteria:** Criteria for cryopyrin-associated periodic syndromes (CAPS): • Documented diagnosis of cryopyrin-associated periodic syndromes (CAPS) • Documented laboratory evidence of a genetic mutation in the Cold-Induced Auto-inflammatory Syndrome 1 (CIAS1- sometimes referred to as the NLRP3).

Drug	Prior Authorization Criteria

	• Clinical documentation that the patient is experiencing classic symptoms of CAPS in either criteria below:
	  ○ Familial Cold Auto-Inflammatory Syndrome (FCAS): recurrent episodes of rash, fever/chills, and joint pain following exposure to mild cold environment. (e.g., cool breeze, air conditioning) Symptoms generally last for up to 24 hours.
	  ○ Muckle-Wells Syndrome (MWS): chronic fever and rash sometimes exacerbated by generalized cold exposure. Episodes can last up to 2-3 days.
	• Clinical documentation of significant functional impairment leading to limitations of activities of daily living (ADLs).
	• Documented inadequate response or inability to tolerate either of the following:
	  ○ Prednisone
	  ○ Anakinra (Kineret) injection
	
	Criteria for systemic juvenile idiopathic arthritis (SJIA) aka Still's disease
	• Diagnosis of moderate to severe systemic juvenile idiopathic arthritis
	• Prescribed by a rheumatologist
	• Documented inadequate response or inability to tolerate to at least one of the following:
	  ○ Tocilizumab (Avtozma [preferred], Actemra) Anakinra (Kineret))
	
	Criteria for Acute Gout
	• Patient is experiencing an acute flare of gout
	• Prescribed by a rheumatologist
	Documented inadequate response or inability to tolerate ALL of the following preferred alternatives: one NSAID, prednisone or other corticosteroid, colchicine and anakinra (Kineret).
	
	Reasons for Non-coverage:
	• Chronic, active, or recurrent infections
	• Untreated latent tuberculosis
	
	Initial approval period: 2 months for acute gout, 12 months for other indications
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	• **Approve for subcutaneous administration at a KPGA facility only**
	
	Continued approval: 2 months for acute gout per flare episode, 24 months for other indications. Confirm patient meets all above coverage criteria without reasons for Non-coverage and patient has had a follow up appointment with the Specialist in the last 6 months.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	• **Approve for subcutaneous administration at a KPGA facility only**
	
	Caution:
	• Concurrent use with live vaccines not recommended

Drug	Prior Authorization Criteria
	• Increased risk of malignancies may occur • Infections, serious (mostly upper respiratory tract) have been reported; discontinue if serious infection develops Monitoring: • Serum C reactive protein and serum amyloid A levels periodically • Improvement in signs and symptoms of cryopyrin-associated periodic syndromes (i.e., fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis) or systemic juvenile idiopathic arthritis (SJIA) • Latent tuberculosis test prior to initiating therapy Dosing: *Cryopyrin-associated periodic syndromes (CAPS)* • The recommended dose of Ilaris is 150 mg for CAPS patients with body weight greater than 40kg. • For CAPS patients with body weight between 15 kg and 40 kg, the recommended dose is 2mg/kg. • For children 15 to 40 kg with an inadequate response, the dose can be increased to 3mg/kg. • Ilaris is administered every 8 weeks as a single dose via subcutaneous injection. *Systemic juvenile idiopathic arthritis (SJIA)* • The recommended dose for patients with body weight ≥ 7.5 kg is 4 mg/kg • Administered every 4 weeks via subcutaneous injection • Maximum: 300 mg/dose
Ilumya (Tidrakizumab)	**Candidates for treatment with Ilumya should meet ALL the following criteria:** Diagnosis of plaque psoriasis: • Prescribed by a dermatologist • Age ≥ 18 years • Inadequate response (of at least a 3-month trial), intolerance and/or contraindication to ALL of the following: a. ≥ 1 preferred TNF inhibitor (e.g., adalimumab (Amjevita [preferred], Humira) OR infliximab (Inflectra [preferred], Remicade)) b. Ustekinumab product (Yesintek [preferred], Stelara) c. Cosentyx (secukinumab) d. Tremfya e. Skyrizi • Prescribed the maintenance dose (Ilumya 100mg every 12 weeks) when transitioning to Ilumya from another biologic agent. If loading dose is ordered, documented clinical rationale must be provided (e.g., actively flaring, BSA >50%, prior ER visit for psoriasis).

Drug	Prior Authorization Criteria
	Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for administration at a KP facility only (e.g., back office, Complex Nurse Center)** Continued Approval: 12 months. Continue approval if the following criteria are met: For new members who were initiated on Ilumya outside of KPGA: Confirm patient meets all above coverage criteria AND has a documented clinically significant benefit from the medication during a Specialist follow up in the last 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for administration at a KP facility only (e.g., back office, Complex Nurse Center)** For existing members who have previously met the full criteria above: Documented clinically significant benefit from the medication during Specialist follow up in the last 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for administration at a KP facility only (e.g., back office, Complex Nurse Center)**
Imbruvica (Ibrutinib)	**Candidates for treatment with Imbruvica should meet all the following criteria:** • Prescribed by, or in consultation with an Oncology Specialist • Age ≥1 years • For the treatment of chronic lymphocytic leukemia (CLL) as monotherapy if intolerant to KP preferred agent Zanubritinib or alternative agent acalabrutinib • For the treatment of relapsed refractory diffuse large B-cell lymphoma (DLBCL) if non germinal B cell (GCB) as 3rd line therapy or greater • For the treatment of Waldenstrom's macroglobulinemia (WM) who are symptomatic (e.g., hyperviscosity, neuropathy, symptomatic adenopathy or organomegaly, amyloidosis, cryoglobulinemia, cold agglutinin disease, and presence of cytopenia) and intolerant to KP preferred agent zanubrutinib or alternative agent acalabrutinib • For the treatment of chronic graft versus host disease (cGVHD) after failure of one or more systemic therapy. • Patient has documented trial and failure (e.g., intolerance, allergic reaction, disease progression) to KP's preferred therapy Brukinsa (zanubrutinib) OR Calquence (acalabrutinib) if other agents listed are indicated • In the following clinical situation Ibrutinib will be preferred: Primary CNS lymphoma (PCNL) for all new and existing patients. ○ Note: Failure of acalabrutinib or zanubrutinib is NOT required Reasons for Non-coverage: • Documented treatment-naïve chronic lymphocytic leukemia (CLL)

Drug	Prior Authorization Criteria

	• Treatment of small lymphocytic leukemia (SLL) as combination therapy with obinutuzumab.
	
	Initial Approval: 12 months with the following strength / formulation specific criteria:
	• For 70 mg daily, approve ONLY 70 mg **capsules.**
	• For 140 mg daily, approve ONLY 140 mg **capsules.**
	• For 280 mg daily, approve ONLY 140 mg **capsules, 2 capsules daily.**
	• For 420 mg daily, approve ONLY 420 mg **tablets.**
	• For 560 mg daily, approve ONLY 560 mg **tablets.**
	• Do NOT approve 140 mg tablets OR 280 mg tablets, please utilize capsules for these daily doses.
	• Please reach out to MD to request prescription with preferred formulation prior to approval.
	
	Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for non-coverage. In addition, must meet criteria below:
	• Patient does not show evidence of progressive disease while on Imbruvica therapy
	• Absence of significant toxicity (e.g., hemorrhage, infections, cytopenias, second primary malignancies, cardiac arrhythmias)
	• Continued monitoring by Hematology/Oncology
	• Please approve on the following strength / formulations:
	  ○ For 70 mg daily, approve ONLY 70 mg **capsules.**
	  ○ For 140 mg daily, approve ONLY 140 mg **capsules.**
	  ○ For 280 mg daily, approve ONLY 140 mg **capsules, 2 capsules daily.**
	  ○ For 420 mg daily, approve ONLY 420 mg **tablets.**
	  ○ For 560 mg daily, approve ONLY 560 mg **tablets.**
	  ○ Do NOT approve 140 mg tablets OR 280 mg tablets, please utilize capsules for these daily doses.
	  ○ Please reach out to MD to request prescription with preferred formulation prior to approval

Imcivree
(Setmelanotide)
	*Please note: Reviewers must obtain approval from the Physician Program Director of QRM or PCS prior to providing QRM PA approval.
	
	Candidates for Imcivree should meet ALL of the following criteria:
	• Prescribed by an Endocrinologist or Pediatric Endocrinologist
	• Diagnosis of **one** of the following:
	  ○ Age ≥ 2 years with documented obesity due to POMC, PCSK1, or LEPR deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic or likely pathogenic. If variant of uncertain significance (VUS) detected, test results are deemed to be highly suspicious by a medical geneticist.
	  ○ Age ≥ 2 years with clinical diagnosis of Bardet-Biedl Syndrome (BBS) confirmed by genetic testing or highly suspected BBS based on review and evaluation by a medical geneticist
	  ○ Age ≥ 4 years with clinical diagnosis of acquired hypothalamic obesity (HO)
	• Documented **in office baseline weight** within the past 1 month that corresponds to **one** of the following age and BMI requirements:

Drug	Prior Authorization Criteria
	○ Age 2 to 17 years with BMI ≥ 95th percentile for age and gender for POMC/ PCSK1/LEPR deficiency, or BBS ○ Age 4 to 17 years with BMI ≥ 95th percentile for age and gender for acquired hypothalamic obesity (HO) ○ Age ≥ 18 years with BMI ≥ 30 • Patient is not using concurrent GLP-1 RA or GLP-1 RA/GIP agent (e.g., Wegovy, Ozempic, Zepbound, Mounjaro) Reasons for Non-coverage: • End stage renal disease (estimated glomerular filtration rate (eGFR) < 15 mL/min/1.73m^2 • Severe renal impairment (eGFR 15-29 mL/min/1.73m^2) for pediatric patients aged 6 years to less than 12 years • Bariatric surgery with > 10% weight loss • Significant liver disease [alanine aminotransferase (ALT), aspartate aminotransferase (AST), or total bilirubin > 2x upper limit of normal (ULN)] Initial Approval: 4 months via the outpatient pharmacy benefit only Continued Approval: 6 months via the outpatient pharmacy benefit only if the following criteria are met: • Patient continues to meet the above criteria • Patient is responding positively to therapy as evidence by one of the following per **in office weight** with documented change from baseline in prescriber note: ○ Age < 18 years: Patient has lost ≥ 5% of baseline BMI ○ Age ≥ 18 years: Patient has lost ≥ 5% of baseline body weight Ordering Information: Imcivree is only available through PANTHERx Rare Pharmacy (Form and Contact information)
Imdelltra (Tarlatamab-dlle)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** **Candidates for treatment with Imdelltra should meet ALL the following criteria:** • Patient is ≥18 years of age • Prescribed by a hematologist or oncologist • Documented diagnosis of relapsed or refractory extensive stage small cell lung cancer (ES-SCLC) • Documented disease progression on or after treatment with platinum-based chemotherapy (e.g., cisplatin, carboplatin, etc.) AND at least one other line of prior systemic therapy Initial Approval: 12 months. • Cycle 1 may be approved for administration at a KP-affiliated inpatient facility. • Subsequent cycles should be approved for back-office administration in a KP-infusion center ONLY.

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>

NOTE: If patient experiences a treatment delay >14 days, an additional cycle may be approved for administration at a KP-affiliated inpatient facility for therapy re-initiation.

Please note: Reviewers must obtain approval from the Physician Program Director or QRM or AAMD prior to providing QRM PA approval.

<u>Continued Approval:</u> 12 months.
Patient should meet ALL the following:

Patient continues to meet the above criteria.
No evidence of disease progression or unacceptable toxicity.
Approve for back-office administration in a KP-infusion center ONLY.

NOTE: If patient experiences a treatment delay >14 days, an additional cycle may be approved for administration at a KP-affiliated inpatient facility for therapy re-initiation.

Please note: Reviewers must obtain approval from the Physician Program Director or QRM or AAMD prior to providing QRM PA approval.

<u>Dosing and Administration:</u>
Recommended Tarlatamab IV Dosing Schedule[a,c]
<table>
<tr><th>Dosing schedule</th><th>Day</th><th>Tarlatamab dose[a,c]</th></tr>
<tr><td rowspan="3">Step-up dosing schedule cycle 1[a]</td><td>Day 1</td><td>1 mg[b]</td></tr>
<tr><td>Day 8</td><td>10 mg[b]</td></tr>
<tr><td>Day 15</td><td>10 mg</td></tr>
<tr><td>Cycle 2 and beyond[a]</td><td>Day 1 and 15</td><td>10 mg</td></tr>
</table>

Patients should be monitored in an appropriate health care setting during infusion and for 22 to 24 hours after cycle 1, day 1 and cycle 1, day 8 infusions. Patients should remain within 1 hour of an appropriate facility and be accompanied by a care giver for a total of 48 hours from the beginning of cycle 1, day 1 and cycle 1, day 8 infusions.

</td></tr>
<tr><td>Immune globulin (Subcutaneous):

<u>Preferred</u> <u>(no PA required)</u>

Gammagard (Immune globulin) with subcutaneous pump

<u>Non-preferred</u> <u>(PA required):</u>

Gamunex-C (Immune globulin)</td><td>Intravenous immune globulin (IVIG) does not require PA and is preferred to subcutaneous immune globulin for all indications.

Candidates for treatment with SC Immune Globulin should meet ALL the following criteria:

<u>Criteria for diagnosis of primary immunodeficiency</u>

Diagnosis of primary immunodeficiency (including but not limited to congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies) in patients 2 years and older AND

Documented barrier to IVIG including any one of the following: Documented systemic adverse reaction during or after an IV infusion OR
Documented limited venous access OR
Prescriber documents intolerability to IV dose due to volume OR
Documented suboptimal clinical conditions resulting from low immune globulin serum trough level OR

</td></tr>
</table>

Drug	Prior Authorization Criteria
Hizentra (Immune globulin subcutaneous) **Cutaquig** (Immune globulin, subcutaneous) **Cuvitru** (Immune globulin subcutaneous) **Hyqvia** (Immune globulin Infusion with Recombinant Human hyaluronidase) **Xembify** (Immune globulin subcutaneous)	○ Documented risk for thromboembolic events or hemolysis. • Documentation of ALL the following: ○ Appropriate training provided to patient for self-administration or caregiver. ○ Patient or caregiver is able to perform self-administration and adhere to prescribed dosing • Inadequate response, intolerance, and/or contraindication to preferred Gammagard (Immune globulin) with subcutaneous pump. Hizentra approval is preferred and recommended before any other non-preferred subcutaneous products. ***NOTE**: Subcutaneous Immune Globulin is NOT administered in infusion centers. It may be administered back office or by the patient or caregiver after appropriate training. Gammagard may be administered subcutaneously using a subcutaneous pump. Initial Approval: • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • 3-month approval in a monitored setting (i.e., KP Complex Nurse Clinic [CNC], back office) to monitor effectiveness and safety. First Continued Approval: 9-months (after first 3-month approval) to be dispensed via the outpatient pharmacy benefit or via administration in the KP CNC**.** Continued Approval: 12 months to be dispensed via the outpatient pharmacy benefit or via administration in the KP CNC if the patient has documented clinical benefit on SC Immune Globulin • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Members new to KP on SC Immune Globulin: • Initial approval: 12 months to be dispensed via the outpatient pharmacy benefit or via administration in the KP CNC if patient has documented clinical benefit on SC Immune Globulin • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Criteria for diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) or myasthenia gravis • Prescribed by or in consultation with a Neurology Neuromuscular Specialist • Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) or myasthenia gravis • Documented barrier to IVIG including any one of the following: ○ Systemic adverse reaction during or after an IV infusion OR ○ Documented limited venous access ORc. Prescriber documents intolerance to IV dose due to volume ORd. Documented risk for thromboembolic events or hemolysis • Documentation of ALL the following: ○ Appropriate training provided to patient for self-administration or caregiver. ○ Patient or caregiver is able to perform self-administration and adhere to prescribed dosing • Inadequate response, intolerance, and/or contraindication to preferred Gammagard

Drug	Prior Authorization Criteria
	(Immune globulin) with subcutaneous pump. Hizentra is preferred and recommended before any other non-preferred subcutaneous products. ***NOTE**: Subcutaneous Immune Globulin is NOT administered in Infusion centers. It may be administered in the KP CNC or by the patient or caregiver after appropriate training. Gammagard may be administered subcutaneously using a subcutaneous pump. Initial Approval: • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • 3-month approval in a monitored setting (i.e., KP Complex Nurse Clinic [CNC], back office) to monitor effectiveness and safety. First Continued Approval: 9-months (after first 3-month approval) to be dispensed via the outpatient pharmacy benefit or via administration in the KP CNC**.** Continued Approval: 12 months to be dispensed via the outpatient pharmacy benefit or via administration in the KP CNC. Confirm patient meets all above criteria. In addition, confirm documented adequate response to treatment by Specialist. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Members new to KP on SC Immune Globulin for CIDP or myasthenia gravis: • 12 months to be dispensed via the outpatient pharmacy benefit or via administration in the KP CNC. Confirm patient meets ALL above criteria. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
Impavido (Miltefosine)	**Candidates for treatment with Impavido should meet ALL the following criteria:** *If Member contracted Leishmaniasis during active military duty, please contact Veteran's Affairs for Coverage. • Prescribed by Infectious Disease • Documented diagnosis of visceral, cutaneous, or mucosal leishmaniasis • Age $\geq$ 12 years • Documented negative pregnancy test (urine or serum) in females of reproductive potential prior to prescribing Impavido. • Females of reproductive potential should use effective contraception during Impavido therapy and for 5 months after therapy. Reasons for Non-coverage: • Known or suspected pregnancy • Sjogren-Larsson-Syndrome

Drug	Prior Authorization Criteria
	Approval period: 28 days

Inbrija (Levodopa Inhalation Powder)	**Candidates for treatment with Inbrija (levodopa inhalation powder) should meet ALL the following criteria:**
	• Patient is at least 18 years of age
	• Documented diagnosis of Parkinson's disease
	• Prescribed by, or in consultation with a neurologist or specialist in the treatment of Parkinson's disease
	• Patient continuing to experience ≥ 2 hours of "off" time per day despite optimal management of carbidopa-levodopa oral therapy including documentation of the following:
	  ○ Dose and dosing interval optimization including taking at least 3 daily doses of levodopa totaling 1600 mg or less
	• Patient will continue to receive maintenance daily treatment with oral carbidopa/levodopa-containing medication
	• Documented inadequate response to, contraindication, or intolerance to at least TWO different classes of adjunctive medications for the treatment of Parkinson's disease:
	  ○ Monoamine oxidase (MAO) type B inhibitors (e.g., selegiline, rasagiline)
	  ○ Dopamine agonists, (e.g., pramipexole, ropinirole)
	  ○ Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
	  ○ Amantadine
	
	Reasons for Non-coverage:
	Inbrija should NOT be used in patients with ANY of the following:
	• Chronic underlying lung disease (e.g., asthma, COPD, etc.)
	• Active psychosis or active psychotic disorder unless psychiatrist has been consulted.
	• Currently taking or within the last 2 weeks have taken a non-selective monoamine oxidase inhibitor (MAOI) (e.g., phenelzine, isocarboxazid, tranylcypromine)
	
	Initial Approval Period: 12 months
	Continued approval: 24 months. Continue approval based on the following:
	• Documentation of continued positive clinical response to Inbrija therapy
	• Documented continued adherence to maintenance oral carbidopa/levodopa regimen
	Dosage and Administration:
	• Oral inhalation: 84 mg up to 5 times daily as needed when symptoms of an OFF-period return; maximum: 84 mg/dose and 420 mg/day
	• Inbrija capsules should ONLY be administered via oral inhalation with the Inbrija inhaler device. Inbrija should not be swallowed orally.

Drug	Prior Authorization Criteria

Infliximab Products
 	
<u>Preferred:</u> Inflectra (infliximab-dyyb) – **Formulary / No PA required**
 	
<u>Preferred – PA required</u>: Infliximab (Unbranded)
 	
<u>Non-Preferred– PA required:</u>
 	
Avsola (Infliximab-axxq)
 	
Renflexis (Infliximab-abda)
 	
Remicade (Branded)
	Candidates for treatment with Infliximab (branded/unbranded)/Avsola/Renflexis should meet all the following criteria.
	
	<u>For plaque psoriasis, rheumatoid arthritis, psoriatic arthritis, or axial spondyloarthritis:</u>
	
	• Prescribed by Rheumatology or Dermatology
	• Diagnosis of moderate to severe plaque psoriasis, rheumatoid arthritis, psoriatic arthritis, or axial spondyloarthritis
	• Patient switched from Remicade, Avsola (infliximab-axxq), or Renflexis (infliximab-abda) to Inflectra (infliximab-dyyb) in the last 12 months
	• Patient had at least 2 infusions of preferred infliximab product (Inflectra) and experienced new or worsening symptoms confirmed by objective findings on physical exam and are persistent despite use of interventions to mitigate the occurrence
	• Patient was previously clinically stable on Remicade (infliximab), Avsola, or Renflexis for at least 3 months
	• Documented antibody testing following the conversion with undetectable antibodies (< 22 ng/mL) AND infliximab/infliximab-axxq/infliximab-dyyb trough between 3 to 7 mcg/mL (or greater).
	• Renflexis only: Documented treatment failure or intolerance to unbranded infliximab and Avsola.
	• Avsola only: Documented treatment failure or intolerance to unbranded infliximab.
	• Remicade (branded): Do not approve for coverage/use.
	Infliximab (unbranded) is identical in composition to Remicade (branded) is produced from the same cell line and at the same manufacturing site.
	
	<u>For Crohn's disease or ulcerative colitis:</u>
	
	• Prescribed by a gastroenterologist
	• Documented moderately to severely active Crohn's disease or ulcerative colitis
	• Age < 18 years OR
	• Patient switched from Remicade (infliximab), Avsola (infliximab-axxq), or Renflexis (infliximab-abda) to Inflectra (infliximab-dyyb) in the last 12 months and BOTH of the following:
	  ○ Patient had at least 2 infusions of preferred infliximab product (Inflectra) AND experienced loss of disease control that was previously asymptomatic or in clinical remission that is deemed to be related to switching from reference product to biosimilar and not due to disease progression, missed infusion(s), and/or change in dose, etc.
	  ○ Loss of disease control must be evidenced by worsening of at least one of the following:
	  ▪ Elevated fecal calprotectin
	  ▪ Elevated CRP
	  ▪ Elevated ESR
	  ▪ Documented infliximab/infliximab-dyyb trough and antibody testing following the conversion with trough between 3 to 7 µg/mL (or greater) AND undetectable antibodies (<22 ng/mL)

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	• Renflexis only: Documented treatment failure or intolerance to unbranded infliximab and Avsola.
	• Avsola only: Documented treatment failure or intolerance to unbranded infliximab.
	• Remicade (branded): Do not approve for coverage/use.
	  ○ Infliximab (unbranded) is identical in composition to Remicade (branded) is produced from the same cell line and at the same manufacturing site.
	• Do not approve in the following cases:
	  ○ Positive for latent tuberculosis and not taking TB prophylactic therapy
	  ○ History or antibody formation to Inflectra, Remicade or other infliximab product
	
	Initial approval**:** 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Continued approval**:** 12 months. Continue approval if the following criteria are met:
	For new members who were initiated on Infliximab (unbranded), Remicade (branded), Avsola or Renflexis outside of KPGA:
	
	• Patient must meet the full criteria above for approval. Remicade (branded): Do not approve for coverage/use. Note: If the physician's request for coverage of brand Remicade is based upon the physician's and/or member's unwillingness to change to the preferred alternative, the request will be denied unless the member meets the full criteria.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	For existing members who have previously met the full criteria above**:**
	• Documented adequate response and tolerance of medication during specialist follow up in the last 12 months.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**

Ingrezza (Valbenazine)	**Candidates for treatment with Ingrezza MUST meet ALL the following criteria:** Criteria for the diagnosis of chorea associated with Huntington's disease: • Documented diagnosis of chorea associated with Huntington's disease • Prescribed by a neurologist • Patient is 18 years or older • Documented inadequate response, intolerance or contraindication to tetrabenazine AND deutetrabenazine (Austedo). Criteria for tardive dyskinesia, must meet ALL the following criteria: • Documented diagnosis of tardive dyskinesia • Prescribed by a neurologist or psychiatrist

Drug	Prior Authorization Criteria

	• Patient is 18 years and older
	• Abnormal Involuntary Movement Scale (AIMS) score of at least 6
	• Documented intolerance or contraindication or failed a 12-week trial of tetrabenazine
	• Documented intolerance or contraindication or failed a trial of Austedo
	• Documented inadequate response, intolerance or contraindication to at least 2 of the agents or regimens listed below:
	  ○ Switching offending antipsychotic to quetiapine/quetiapine ER or clozapine
	  ○ Benzodiazepine
	  ○ Amantadine
	
	Reasons for Non-coverage:
	
	• Patients who are suicidal, or who have untreated or undertreated depression
	• Coadministration with or within 14 days of discontinuing monoamine oxidase inhibitors (MAOIs) [i.e., isocarboxazid, phenelzine, selegiline]
	• Patients taking other VMAT2 Inhibitors [tetrabenazine (Xenazine) or deutetrabenazine (Austedo)
	• Patients with congenital long QT syndrome or with arrhythmias associated with prolonged QT interval.
	• Coadministration with a strong CYP3A4 inducer (rifampin, carbamazepine, phenytoin, St. John's wort)
	• Severe renal impairment (creatinine clearance < 30 mL/min)
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition for tardive dyskinesia indication, patient has shown improvement by retaining or decreasing baseline AIMS score since starting the medication.
	• Discontinue therapy if no improvement over prior therapy after 3 months.

Inluriyo
(Imlunestrant)
	Candidates for treatment with Inluriyo (imlunestrant) should meet ALL the following criteria:
	• Prescribed by a hematologist/oncologist
	• Age ≥ 18 years
	• Diagnosis of advanced or metastatic estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, ESR1-mutated breast cancer
	• Documented disease progression after trial of **BOTH** of the following:
	  ○ At least one line of endocrine therapy (examples include fulvestrant, anastrozole, exemestane, and letrozole) **AND**
	  ○ At least one CDK4/6 inhibitor (examples include ribociclib, abemaciclib, and palbociclib)
	• For female patients, patient meets ONE of the following:
	  ○ Patient is post-menopausal

Drug	Prior Authorization Criteria
	Patient is pre/perimenopausal **AND** is prescribed a concurrent gonadotropin-releasing hormone (GnRH) agonist (e.g., leuprolide, goserelin (Zoladex), triptorelin (Trelstar), etc) **OR** has had surgical bilateral oophorectomy or ovarian irradiation Initial Approval: 12 months Continued Approval: 12 months. Continue approval if the following criteria are met: • Patient continues to meet the above criteria • No evidence of unacceptable toxicity or disease progression

Inlyta
(Axitinib)
	Candidates for Axitinib should meet ALL the following criteria:
	
	Diagnosis of Renal Cell Carcinoma:
	• Prescribed by a hematologist or oncologist.
	• Age ≥18 years
	• Diagnosis of relapsed OR metastatic (stage IV) renal cell carcinoma
	• Patient meets ONE of the following:
	  ○ Axitinib will be used in combination with pembrolizumab OR avelumab for first-line treatment **OR**
	  ○ Axitinib will be used as monotherapy AND patient has a documented treatment failure or intolerance to at least one prior systemic therapy
	  ▪ Examples of systemic therapy include: cabozantinib + nivolumab, levatinib + prembrolizumab, nivolumab + ipilimumab, pazopanib, cabozantinib, temisirolimus
	
	Diagnosis of Thyroid Cancer:
	• Prescribed by a hematologist or oncologist.
	• Age ≥18 years
	• Diagnosis of differentiated thyroid carcinoma
	• Disease is refractory to radioactive idodine therapy
	• Documented treatment failure or intolerance to at least one prior systemic therapy
	  ○ Examples of systemic therapy include: levatinib, dabrafenib, cabozantinib, entrectinib, larotectinib, etc
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. For continued approval for treatment with Axitinib, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria.
	• Patient is responding positively to therapy based on stabilization of disease or no disease progression

InPen Smart Insulin Pen	**Candidates for InPen must meet all the following criteria:**

Drug	Prior Authorization Criteria
	• Prescribed by an endocrinologist a) Endocrinology team educates patient on proper insulin delivery device use • Documented diagnosis of Type 1 DM • Age ≥ 7 years • Documentation patient has access to a device with the ability to install and use InPen app (e.g., smartphone, tablet, etc.) • Documented frequency of glucose self-testing of at least 3 times per day or regular use of calibrated CGM • Treatment program including at least three insulin injections per day requiring frequent self-adjustments of insulin dose for at least 6 months • Inadequate BG control despite multiple daily insulin injections as documented by **at least one** of the following: ○ A1C ≥ 7% ○ Recurrent hypoglycemic events (BG <70) in the past month ○ History of severe glycemic excursions ○ Dawn phenomenon with fasting sugars >200 mg/dL routinely • Medical rationale of need for smart pen with electronic dose documentation to achieve and maintain A1C control, rather than vial or standard pen • **Coverage is not authorized for patients with existing coverage for an alternate insulin pump device.** **Initial Approval:** 12 months **Continued Approval:** 12 months. Confirm patient continues to meet all criteria above without reasons for Non-coverage. In addition, endocrinologist to document improved glycemic control as evidenced by A1C improvement or decrease in glycemic variability. Note: • For new members who were initiated outside of KPGA: Confirm patient meets all the above criteria for continued approval. Reasons for Non-coverage: ▪ Unable or unwilling to test blood glucose levels as recommended by healthcare provider ▪ Unable or unwilling to return for routine diabetes follow-up
Inqovi (Decitabine and Cedazuridine)	**Candidates for treatment with Inqovi should meet ALL the following criteria:** Diagnosis of Myelodysplastic Syndrome (MDS) • Prescribed by a hematologist or oncologist • Age ≥ 18 years • Diagnosis of Myelodysplastic Syndromes (MDS) • Documented intermediate-1, intermediate-2 OR high-risk International Prognostic Scoring System Group (IPSS) • Documented treatment failure, intolerance, or contraindication to IV decitabine Diagnosis of acute myelogenous leukemia • Prescribed by a hematologist or oncologist • Patient meets ONE of the following:

Drug	Prior Authorization Criteria
	○ Age ≥ 75 years OR ○ Age <75 and documentation patient has comorbidities that preclude use of intensive induction chemotherapy • Medication will be used in combination with Venetoclax Initial Approval Period: 12 months Continued Approval: 12 months if the patient meets ALL the following: • Member continues to meet above criteria • Patient is responding positively to therapy as defined by stabilization of disease and no evidence of disease progression • Absence of unacceptable toxicity from the drug (i.e. febrile neutropenia)
Inrebic (Fedratinib)	**Candidates for Inrebic should meet ALL the following criteria:** Diagnosis of myelofibrosis: • Prescribed by a hematologist or oncologist. • Age ≥ 18 years • Patient has a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) • Patient has a documented history of treatment failure, intolerance, or contraindication to hydroxyurea **AND** ruxoltinib (Jakafi) Diagnosis of myeloproliferative neoplasms: • Prescribed by a hematologist or oncologist. • Age ≥ 18 years • Patient has a platelet count ≥50 x 10^9/L • Patient is not a candidate for transplant. • Patient has a documented history of treatment failure, intolerance, or contraindication to ruxoltinib (Jakafi) Diagnosis of myeloid/lymphoid neoplasms: • Prescribed by a hematologist or oncologist. • Age ≥ 18 years • Patient has a diagnosis of ONE of the following: ○ Myeloid/lymphoid neoplasm with eosinophilia and *JAK2* rearrangement in chronic phase or blast phase. ○ Blast phase lymphoid, myeloid, or mixed lineage neoplasm AND medication will be used in combination with ALL- or AML-type induction chemotherapy followed by allogenic stem cell transplant (if eligible). Initial Approval: 12 months with quantity limit of 120 capsules per 30 days Continued Approval: 12 months with quantity limit of 120 capsules per 30 days. For continued approval for treatment with Inrebic, patient should meet ALL the following criteria:

Drug	Prior Authorization Criteria
	• Patient continues to meet the above criteria. • Patient is responding positively to therapy based on stabilization of disease, decrease in spleen therapy, or improvement in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.) <u>For new members who were initiated on Inrebic outside of KPGA:</u> Patient should meet ALL the following criteria: • Prescribed by a hematologist or oncologist. • Age ≥ 18 years • Patient is responding positively to therapy based on stabilization of disease, decrease in spleen therapy, or improvement in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.) • Quantity limit of 120 capsules per 30 days.
Insulin Human: **Novolin 70/30** (Insulin Isophane/ Insulin Regular) **Novolin N** (Insulin Isophane) **Novolin R** (Insulin Regular)	**Candidates for treatment with Novolin R, Novolin N, or Novolin 70/30 products should meet ALL the following criteria:** • Clinically diagnosed with diabetes mellitus AND • For Novolin R, documented adequate trial of at least 3 months with Humulin R and Kirsty unless documented intolerance/contraindication • For Novolin N, documented adequate trial of at least 3 months with Humulin N or Humulin 70/30 and insulin glargine-yfgn unless documented intolerance/contraindication • For Novolin 70/30, documented adequate trial of at least 3 months Humulin 70/30 or Humulin N/R and insulin glargine-yfgn/Kirsty unless documented intolerance/contraindication <u>Initial Approval</u>: 12 months. <u>Continued Approval:</u> 24 months. Confirm patient meets all above coverage criteria. In addition, continue approval if **ALL** the following are met: • Patient is tolerating the requested Novolin formulation (i.e., no reports of severe adverse events) • Documented disease stabilization or improvement in disease on the requested Novolin formulation (i.e., hemoglobin A1C is stable or lower) • **Note: Approval is for vial formulations only. If requesting pen, MUST also meet one of the following for insulin administration device:** ○ Administers < 5 units of insulin ○ Impaired manual dexterity (e.g.,Parkinson's, RA, amputation, hemiparesis) ○ Age < 18 years ○ School or daycare requirements ○ Visual impairment
Interferon beta: **<u>Non-Preferred:</u>** **Avonex** **Betaseron**	**Candidates should meet ALL the following criteria:** • Diagnosis of relapsing multiple sclerosis AND • Prescribed by a neurologist AND • Medication is to be used as monotherapy disease-modifying treatment of MS AND

Drug	Prior Authorization Criteria
Plegridy **Rebif**	• Documented persistent or severe adverse effect to ALL preferred alternatives: glatiramer acetate (Glatopa), dimethyl fumarate and teriflunomide AND • **For Avonex or Plegridy:** Documented trial and failure of Betaseron • **For Rebif:** Documented trial and failure of Avonex AND Plegridy Reasons for Non-coverage: • History of treatment-resistant psychosis, depression or suicidal ideation/behavior • Severe hepatic impairment Initial approval period: 1 year • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** ○ **Initial Dose: Approve one-time subcutaneous dose given in office** ○ **Maintenance Dose: approve for member to fill via the outpatient pharmacy benefit only** Continued approval: 1 year. Continued approval for treatment should meet ALL the following criteria**:** For new members who were initiated on an Interferon beta medication outside of KPGA: patient must meet the full criteria above for approval without reasons for non-coverage. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** ○ **Avonex, Plegridy, Rebif: approve for member to fill via the outpatient pharmacy benefit only** For existing members who have previously meet the full criteria above: Documented beneficial effect from therapy during neurology follow up. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** ○ **Avonex, Betaseron, Plegridy, Rebif: approve for member to fill via the outpatient pharmacy benefit only**
Preferred: **Tolvaptan (generic for Jynarque)** **Non-Preferred:** Jynarque	**Candidates for tolvaptan should meet ALL the following criteria:** • Prescribed by Nephrology • Age 18 to 55 years • Documented diagnosis of rapidly progressing autosomal dominant polycystic kidney disease (ADKPD) confirmed by CT scan or MRI of the kidneys • Patient is high risk of disease progression defined by Mayo ADPKD Classification as "Typical (Class 1) ADPKD" and classified as either 1C, 1D, or 1E • Patient is ≤55 years of age with eGFR specified by age range ○ Age 18 to 29 years with eGFR ≥ 25 ml/min/1.73 m^2 ○ Age 30 to 39 years with eGFR 25-90 ml/min/1.73 m^2 ○ Age 40 to 55 years with eGFR 25-65 ml/min/1.73m^2

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ eGFR ≥ 25 • Baseline ALT, AST and bilirubin prior to initiation (See below) • For brand name Jynarque, patient has tried generic tolvaptan and had intolerance or allergic reaction that is likely due to inactive components of the generic medication and cannot be explained by other clinical or lifestyle factors. ○ If the request for coverage of brand Jynarque is based upon disease progression or side effects due to the active ingredient tolvaptan (e.g., polyuria, pollakiuria, or nocturia) the request will be denied unless the patient meets the full criteria ○ If the prescriber's request for coverage of BRAND Jynarque is based on upon prescriber or member's unwillingness to change to a preferred alternative, the request will be denied unless the member meets the full criteria. <u>Reasons for Non-coverage:</u> • History of signs or symptoms of significant liver impairment or injury or ALT, AST or bilirubin > 3 times ULN. Does not apply to uncomplicated polycystic liver disease • Taking strong CYP 3A inhibitors (i.e., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, and conivaptan) • Uncorrected abnormal blood sodium concentrations (e.g., hypernatremia) • Hypovolemia • Uncorrected urinary outflow obstruction • Anuria • Hypersensitivity (anaphylaxis or rash) to tolvaptan or any component of the product • eGFR <25 mL/min • Pregnancy or breastfeeding women <u>Initial Approval:</u> 6 months. If patient meets criteria, approve generic tolvaptan. <u>Continued Approval:</u> 6 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continue approval if the following are met: • Prescriber attestation of clinical response (e.g., slows eGFR decline) • eGFR remains > 25 mL/min (within past 1 month) • Age < 55 years • Provider is monitoring liver function monthly for the first 18 months, then every 3 months. • No signs or symptoms consistent with hepatic injury (see reasons for Non-coverage) * Tolvaptan is available only through a restricted distribution program supported by a Risk Evaluation and Mitigation Strategy (REMS) program due to risks of serious liver injury ***** Tolvaptan is dispensed by KP Specialty Pharmacy**.**
Iqirvo (Elafibranor)	**Candidates for treatment with Iqirvo (elafibranor) should meet ALL the following criteria:** • Prescribed by a Gastroenterologist/Hepatologist • Age ≥ 18 years • Diagnosed with primary biliary cholangitis (PBC) as confirmed by at least TWO of the following criteria:

Drug	Prior Authorization Criteria
	○ Elevated alkaline phosphatase (ALP) above the upper limit of normal (> 147 IU/L) ○ Presence of antimitochondrial antibodies (AMA) OR other PBC-specific autoantibodies, including sp100 or gp210, if AMA is negative ○ Histologic evidence (obtained by liver biopsy) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts. • Documented inadequate response (of a trial at least > 1 year), intolerance, or contradiction to ursodiol (ursodeoxycholic acid) • Iqirvo will be used in combination with ursodiol (ursodeoxycholic acid) unless patient is unable to tolerate ursodiol for a minimum of one year • Documented inadequate response (of a trial at least > 1 year and titrated to 10mg once daily), intolerance, or contradiction to Livedelzi (seladelpar) • Do not approve in the following cases: ○ Presence or history of decompensated cirrhosis (i.e., Child-Pugh score B or C) ○ History of a hepatic decompensation event (i.e., ascites, gastroesophageal varices, variceal bleeding, hepatic encephalopathy, and coagulopathy) ○ Active compensated cirrhosis with evidence of portal hypertension ○ For use in combination with another second-line PBC treatment (e.g., Livdelzi [seladelpar]) ○ Complete biliary obstruction Initial Approval Period: 6 months Continued Approval Period: 12 months. Confirm patient meets ALL the above criteria without reasons for non-coverage. In addition, the following must be met: • Patient has an alkaline phosphatase (ALP) level that is less than 1.67-times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Iqirvo
Imlygic (Talimogene laherparepvec)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM and AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** **Candidates for treatment with Imlygic should meet ALL the following criteria:** • Age ≥ 18 years • Prescribed by an oncologist or dermatologist • Diagnosed with unresectable cutaneious, subcutaneous, and nodal lesions in patients for the local treatment of melanoma recurrent after initial surgery Reasons for Non-coverage: • Pregnancy or Lactation • Immunocompromised patient, including those with a history of: ○ primary or acquired immunodeficient states ○ leukemia ○ lymphoma ○ AIDS or other clinical manifestations of infection with HIV

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• Concurrent treatment with an immunosuppressive therapy • Concurrent treatment with acyclovir or other antiherpetic viral agents Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: 12 months. Continue approval if patient continues to meet criteria above AND • No evidence of disease progression while on Imlygic • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM and AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Dosage and Administration: • Talimogene laherparepvec is available as Imlygic in 10^6 (1 million) plaque-forming units (PFU) per mL, and 10^8 (100 million) PFU per mL for injection, in single-use vials (1 mL). • The total injection volume for each treatment visit should not exceed 4 mL for all injected lesions combined. It may not be possible to inject all lesions at each treatment visit or over the full course of treatment. • Per labeling, previously injected and/or uninjected lesion(s) may be injected at subsequent treatment visits. • The initial recommended dose is up to 4 mL of Imlygic at a concentration of 10^6 (1 million) PFU per mL. • The recommended dose for subsequent administrations is up to 4 mL of Imlygic at a concentration of 10^8 (100 million) PFU per mL.

Isturisa
(Osilodrostat)
	Candidates for Isturisa should meet ALL the following criteria:
	• Prescribed by an endocrinologist
	• Age $\geq$ 18 years
	• Documented diagnosis of Cushing's disease
	• Documented inadequate response to pituitary surgery or patient is not a candidate for pituitary surgery.
	• Documented failure, intolerance or contraindication to ketoconazole, cabergoline, metyrapone, mitotane, and pasireotide.
	  ○ Note: ketoconazole required unless history of previous trial of ketoconazole resulting in increased liver enzymes 3x ULN
	• All the following baseline test completed:
	  ○ Serum potassium and magnesium with correction if abnormal before initiation of therapy
	  ○ Electrocardiogram (ECG)
	
	Reasons for Non-coverage:

Drug	Prior Authorization Criteria

	• QT interval prolongation
	
	Initial Approval: 6 months
	
	Continued Approval: 1 year if criteria above continues to be met in addition the patient meets the following:
	• Positive response to therapy as defined as the following:
	  ○ Patient has achieved and maintained at least 3 of the following:
	  ▪ A urinary free cortisol (UFC) ≤ the upper limit of normal (ULN)
	  ▪ Cortisol levels is within normal limits
	  ▪ No symptoms consistent with Cushing's disease
	  ▪ No evidence or symptoms of hypocortisolism
	  ▪ No evidence of disease progression
	• Patient has not developed any significant adverse effects from therapy (i.e adrenal insufficiency, QT interval prolongation, hypokalemia uncontrolled with supplementation and use of mineralocorticoid antagonist, severe hypocortisolism)
	
	ISTURISA is OUTSOURCED to Anovo Specialty Pharmacy at 1-844-288-5007 or www.anovorx.com.

Itovebi (Inavolisib)	**Candidates for treatment with Itovebi (inavolisib) should meet ALL the following criteria:** • Prescribed by an oncologist • Patient must be ≥18 years of age • Diagnosed with locally advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative AND a PIK3CA mutation • Itovebi will be used in combination with palbociclib (Ibrance) and fulvestrant (Faslodex) • Documentation the patient has experienced disease progression following at least one line of endocrine therapy (e.g., letrozole, anastrozole, tamoxifen, exemestane, toremifene) in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy • Patient must not have experienced disease progression on or following other PI3K inhibitors (e.g., alpelisib [Piqray], capivasertib [Truqap]) Reasons for Non-coverage: • Lactation • Pregnancy Initial Approval: 12 months Continued Approval: 12 months. Continue approval if the patient does not show evidence of progressive disease while on Itovebi therapy.
Jadenu **Exjade**	**Candidate for treatment with BRAND Jadenu or Exjade should meet ALL of the following criteria:** Treatment of chronic transfusion-related iron overload:

Drug	Prior Authorization Criteria

Preferred:
Deferasirox (generic Jadenu) tablets and granule packets (NOTE: available on the formulary)
 	
Deferasirox (generic Exjade) tablets for oral suspension (NOTE: available on the formulary)
 	
Non-preferred:
Jadenu (Deferasirox) tablets and granule packets
 	
Exjade (Deferasirox) tablets for oral suspension
	• Prescribed be a hematologist or oncologist.
	• Patient is ≥2 years of age.
	• Patient has a diagnosis of transfusional iron overload with thalassemia syndromes, sickle cell disease, or other anemias.
	• Patient has tried BOTH generic Jadenu AND Exjade and experienced a clinical rection that cannot be explained by other clinical or lifestyle factors and may be due to the **inactive** components of the generic products.
	  ○ If request for coverage of brand Jadenu or Exjade is based on side effects due to the active ingredients (e.g., diarrhea, stomach pain, upset stomach, throwing up, rash, signs of allergic reaction, etc.) the request will be denied.
	  ○ If the physician's request for coverage of brand Jadenu or Exjade is based upon the physician's and/or member's unwillingness to change to a preferred alternative, the request will be denied until the member meets the full criteria.
	
	<u>Treatment of chronic iron overload with non-transfusion-dependent thalassemia (NTDT) syndrome:</u>
	• Prescribed be a hematologist or oncologist.
	• Patient is ≥10 years of age.
	• Patient's liver iron concentration (LIC) is at least 5 mg Fe/gm of dry weight.
	• Patient's serum ferritin is >300 mcg/L
	• Patient has tried BOTH generic Jadenu AND Exjade and experienced a clinical rection that cannot be explained by other clinical or lifestyle factors and may be due to the **inactive** components of the generic products.
	  ○ If request for coverage of brand Jadenu or Exjade is based on side effects due to the active ingredients (e.g., diarrhea, stomach pain, upset stomach, throwing up, rash, signs of allergic reaction, etc.) the request will be denied.
	  ○ If the physician's request for coverage of brand Jadenu or Exjade is based upon the physician's and/or member's unwillingness to change to a preferred alternative, the request will be denied until the member meets the full criteria.
	
	<u>Treatment of iron overload in individuals diagnosed with myelodysplastic syndromes (MDS) who are at lower risk or potential transplant:</u>
	• Prescribed be a hematologist or oncologist.
	• Documentation is provided that induvial initially presents with serum ferritin levels >2,500 ng/mL
	• Patient has tried BOTH generic Jadenu AND Exjade and experienced a clinical rection that cannot be explained by other clinical or lifestyle factors and may be due to the **inactive** components of the generic products.
	  ○ If request for coverage of brand Jadenu or Exjade is based on side effects due to the active ingredients (e.g., diarrhea, stomach pain, upset stomach, throwing up, rash, signs of allergic reaction, etc.) the request will be denied.
	  ○ If the physician's request for coverage of brand Jadenu or Exjade is based upon the physician's and/or member's unwillingness to change to a preferred alternative, the request will be denied until the member meets the full criteria.
	
	<u>Reasons for non-coverage:</u>

Drug	Prior Authorization Criteria
	• Patient has high-risk MDS. Initial Approval: 12 months with quantity limit a 30-day supply. Continued Approval: 12 months with quantity limit of a 30-day supply. For continued approval for treatment with BRAND Jadenu or Exjade, patient should meet ALL the following criteria: • Patient continues to meet the above criteria. For new members who were initiated on BRAND Jadenu or Exjade outside of KPGA: Patient should meet ALL the following criteria: • Patient is responding positively to therapy based on stabilization of disease. • Patient has a documented trial of BOTH generic Jadenu AND Exjade and experienced a clinical rection that cannot be explained by other clinical or lifestyle factors and may be due to the **inactive** components of the generic products. o If request for coverage of brand Jadenu or Exjade is based on side effects due to the active ingredients (e.g., diarrhea, stomach pain, upset stomach, throwing up, rash, signs of allergic reaction, etc.) the request will be denied. o If the physician's request for coverage of brand Jadenu or Exjade is based upon the physician's and/or member's unwillingness to change to a preferred
Jascayd (Nerandomilast)	**Candidates for treatment with Jascayd should meet ALL the following criteria, plus the individual disease state criteria that follow:** • Prescribed by a pulmonologist • Age ≥ 18 years • Patient is a non-smoker (tobacco, cannabis, or vaping) or is actively attempting smoking cessation with a prescribed treatment plan in place • Then follow the disease state specific criteria below, based on diagnosis: Diagnosis of idiopathic pulmonary fibrosis (IPF) • Baseline forced vital capacity (FVC) < 50% of predicted value • Baseline carbon monoxide diffusing capacity (DLCO) < 30% of predicted • Inadequate response (trial of at least 6-months), intolerance, or contraindication to both pirfenidone AND nintedanib Diagnosis of progressive pulmonary fibrosis (PPF) • Diagnosis of PPF is supported by a documented multidisciplinary discussion (MDD) involving at two of the following: pulmonologist, rheumatologist, radiologist or pathologist • High-resolution computed tomography (HRCT) demonstrates fibrosing lung disease involving >10% of lung volume within the past 12 months • Documentation of disease progression despite therapy, as evidenced by at least TWO of the following within the past 12 months: - Worsening respiratory symptoms - Absolute decline in FVC ≥5% predicted value or absolute decline in DLCO ≥10% predicted value - Radiographic evidence of disease progression on HRCT

Drug	Prior Authorization Criteria
	• Inadequate response (trial of at least 6-months), intolerance, or contraindication to nintedanib Initial Approval: 12 months Continued Approval: 12 months. Continue approval if the following criteria are met: • For new members (who were initiated on Jascayd outside of KPGA): Confirm patients meets all of the above initial review criteria • For existing members who have previously met the full criteria above: Confirm patient has documented clinically significant benefit from the medication during a Specialist (e.g. Pulmonologist) follow-up in the last 12 months

Jaypirca
(Pirtobrutinib)
	Candidates for treatment with Jaypirca should meet ALL the following criteria:
	• Prescribed by an Oncologist
	• Patient is ≥18 years of age
	• Patient has a diagnosis of one of the following:
	  ○ Relapsed or refractory mantle cell lymphoma (MCL)
	  ○ Chronic lymphocytic leukemia (CLL)
	  ○ Small lymphocytic leukemia (SLL)
	• Patient has documentation of one of the following:
	  ○ For MCL: patient has received at least TWO prior therapies including a BTK inhibitor (e.g., acalburtinib, zanubrutinib, etc)
	  ○ For CLL or SLL: patient has received at least TWO prior therapies including a BTK inhibitor (e.g., acalburtinib, zanubrutinib, etc) AND a BCL-2 inhibitor (e.g, venetoclax)
	
	Reasons for Non-coverage:
	• Patient is pregnant
	• Patient is breastfeeding
	• Presence of major hemorrhage (defined as ≥grade 3 bleeding or any CNS bleeding)
	• Presence of uncontrolled arrythmia or symptomatic arrythmia
	
	Initial Approval Period: 12 months
	
	• Quantity limits:
	  ○ For 50 mg tablets, 30 tablets per 30 days.
	  ○ For 100 mg tablets, 60 tablets per 30 days.
	
	Continued Approval Period: 12 months. Patient must meet all criteria above without reasons for non-coverage in addition to the following:
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread
	• Quantity limits:
	  ○ For 50 mg tablets, 30 tablets per 30 days.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ For 100 mg tablets, 60 tablets per 30 days. Ordering Information: Pirtobrutinib is available through specialty pharmacies; information is available at https://www.jaypirca.com/hcp/savings-support#access-resources.
Jelmyto (Mitomycin)	**Candidates for treatment with Jelmyto should meet ALL the following criteria:** • Patient must be at least 18 years old • Prescribed by urologist (in consultation with urologic oncology) • Patient does not have perforation of the bladder or upper urinary tract • Therapy will be used for intra-pyelocaliceal instillation only • Must be used as a single agent • Patient has diagnosis of low-grade, upper tract urothelial cancer (LG-UTUC) • Patient has newly diagnosed or recurrent non-invasive disease • Patient has at least one measurable papillary tumor 5 to ≤15 mm, located above the ureteropelvic junction (in the absence of or following tumor debulking • Patient has not received intravesical BCG treatment within the previous 6 months of starting therapy • Patient does NOT have any of the following: ○ History of carcinoma in situ (CIS) in the urinary tract ○ Invasive urothelial carcinoma within 5 years ○ High grade papillary urothelial carcinoma within 2 years Initial approval period: 6 months. Continued approval: 6 months if the patient meets the following: • Patient continues to meet the criteria above • Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread • Patient has a complete response to initial therapy (consisting of 6 weekly cycles) defined as a negative ureteroscopic evaluation and negative cytology wash (required for extending treatment for an additional 11 monthly instillations) • Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe ureteric obstruction, severe thrombocytopenia and/or neutropenia • Patient has not received more than a total of 17 drug doses/instillations Dosing and Administration: • The dose to be instilled is 4 mg/mL via ureteral catheter or a nephrostomy tube, with total instillation volume based on volumetric measurements using pyelography, not to exceed 15 mL (60 mg of mitomycin). • Instill Jelmyto once weekly for six weeks. For patients with a complete response 3 months after therapy initiation, instillations may be administered once a month for a maximum of 11 additional instillations Ordering Information: • Jelmyto is only available through Cardinal Health
Joenja	**Candidates for Joenja should meet ALL of the following criteria:**

Drug	Prior Authorization Criteria
(Leniolisib)	• Prescribed by Allergy Specialist or Hematology-Oncology Specialist • Patient ≥ 12 years of age • Diagnosed with activated phosphoinositide 3-kinase delta syndrome (APDS) • Weight ≥ 45 kg • Confirmed PI3Kδ genetic mutation of either the PIK3CD (APDS1) or PIK3R1 (APDS2) gene • Documentation of at least one measurable nodal lesion on a computed tomography (CT) or magnetic resonance imaging (MRI) scan • Evidence of clinical findings and manifestations compatible with APDS/PASLI (e.g., history of repeated oto-sino-pulmonary infections and/ or organ dysfunctions) Reasons for Non-coverage: • Concurrent use of immunosuppressive therapy • Concurrent use of strong inhibitors of CYP3A4, moderate or strong inducers of CYP3A4, or metabolized by CYP1A2 • Moderate or severe hepatic impairment • Concurrent use of live vaccines • Known infection with HIV (detectable viral load) • Hepatitis B (HBsAG positive and detectable viral load) • Hepatitis C virus (anti-HCV positive and detectable viral load) • Pregnancy • Breastfeeding Initial Approval: 3 months Continued Approval: 12 months. Continue approval if patient demonstrates clinical benefit compared to baseline (e.g., reduced lymph node size) Ordering Information: Available via PANTHERx Specialty Pharmacy. Ordering form available at here.
Journavx (Suzetrigine)	**Candidates for treatment with Journavx (suzetrigine) should meet ALL of the following criteria:** • Prescribed by surgeon or podiatrist • Age ≥ 18 years • Diagnosed with post-surgical moderate to severe acute pain following abdominoplasty or bunionectomy ○ Documentation of moderate to severe acute pain following surgery with evidence that member has received Journavx doses in the perioperative setting (i.e., hospital, ambulatory surgical center) OR

Drug	Prior Authorization Criteria
	○ If patient has not received Journavx perioperatively, documentation specifying that each of the alternative pain medications below have not been effective or are not appropriate. ▪ Oral NSAID ▪ Diclofenac gel ▪ Acetaminophen ▪ Short acting opioid Reasons for Non-coverage: • Concomitant use with strong CYP3A inhibitors (e.g., itraconazole) • Concomitant use with moderate (e.g., efavirenz) or strong (e.g., rifampin) CYP3A inducers • Cardiac dysrhythmias requiring anti-arrhythmia treatment(s) • Severe hepatic impairment (Child-Pugh Class C) Approval: 6 weeks. Approve for a max quantity of 29 tablets
Julia (Efinaconazole 10%)	**Candidates for treatment with Julia should meet ALL the following criteria:** • Age ≥ 18 years • Documented diagnosis of toe onychomycosis with positive fungal culture that persists despite full treatment course with all first line agents (see below) • Treatment is requested due to medical condition and not for cosmetic purposes (e.g., patients with diabetes, history of cellulitis of the lower extremity who have ipsilateral toenail onychomycosis, or vascular disease) AND • If unable to complete full treatment course, documented intolerance or contraindication to the following antifungal agents: ○ Terbinafine 250mg DAILY x 12 weeks ○ Ciclopirox 8% Topical (lacquer) Solution DAILY x 12 weeks ○ Fluconazole 150 -300 mg once weekly ○ Itraconazole 100mg 2C QD x 12 weeks AND ○ Tavaborole 5% topical solution daily for 48 weeks Initial approval period: 24 weeks with quantity limited to 4 mL per 30 days Continuation: Up to 48 weeks total duration. Confirm patient meets all above criteria.
Juxtapid (Lomitapide)	**Candidates for treatment with Juxtapid should meet ALL the following criteria:** • Documented clinical and laboratory determined diagnosis of homozygous familial hypercholesterolemia (HoFH) • Age ≥ 18 years • Prescribed by a certified REMS provider demonstrated with supporting documentation (signed attestation) ○ ***NOTE:** For more information and to enroll, please go to the following site: http://www.juxtapidremsprogram.com/ • Tried and failed or intolerant to **at least THREE** of the following: ○ Simvastatin 40 mg daily

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ Pravastatin 80 mg daily ○ Atorvastatin 80 mg daily ○ Rosuvastatin 40 mg daily • Documented in the medical record that prior to the initiation of therapy, the patient has been and will continue to follow a low-fat diet supplying <20% of energy from fat • Documented Baseline laboratory measures of ALT, AST, alkaline phosphatase, and total bilirubin prior to starting Juxtapid • If patient is a female of childbearing age, must have a baseline negative pregnancy test (within 1 month) AND must be on at least one form of effective contraception Reasons for Non-coverage: • Moderate or severe hepatic impairment or active liver disease including unexplained persistent abnormal liver function tests Initial approval: 6 months Continued approval**:** 1 year. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continued approval for treatment with Juxtapid should meet ALL the following criteria: • Review of compliance to Juxtapid • Review of compliance to recommend liver enzyme laboratory testing • Documented cholesterol control as evidence by significant LDL lowering from pre-treatment levels Limitations of use: • The safety and effectiveness of Juxtapid have not been established in patients with hypercholesterolemia who do not have HoFH • The effect of Juxtapid on cardiovascular morbidity and mortality has not been determined Monitoring: • Before treatment, measure ALT, AST, alkaline phosphatase, and total bilirubin and then ALT and AST regularly as recommended; obtain a negative pregnancy test in females of reproductive potential • Measure ALT and AST before each dose increase, and test monthly (at a minimum) during the first year of maintenance therapy ○ After the first year, check ALT and AST every 3 months • During treatment, adjust the dose of Juxtapid if the ALT or AST are ≥ 3 x ULN Ordering Information: Juxtapid is only available from certified pharmacies that are enrolled in the Juxtapid REMS program. At this time, Juxtapid is not available through our KP Pharmacies or the KP Specialty Pharmacy. Prescriber's should complete the Juxtapid Prescriber Enrollment Form and fax to Juxtapid REMS Program at 855-898-2498 or scan form and email to REMS@aegerion.com. The Juxtapid Prescriber Enrollment form is available at: http://www.juxtapidremsprogram.com/_pdf/JUXTAPID_REMS_Program_Prescriber_Enrollment_Form_editable.pdf

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
Kalbitor (Ecallantide)	**Candidates for Kalbitor should meet ALL of the following criteria**: • A diagnosis of acute attacks of hereditary angioedema (HAE) • Prescriber must be an allergist. • Age ≥ 12 years • Lack of response to Berinert Reasons for Non-coverage: • Routine prophylaxis against angioedema attacks in adolescent and adult patients with HAE Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continue approval based on clinical documentation of functional improvement, a decrease in frequency of HAE attack, and an improvement in severity and duration of attacks. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
Kalydeco (Ivacaftor)	**Candidates for Kalydeco should meet ALL of the following criteria**: • Confirmed diagnosis of cystic fibrosis (CF) • Prescribed by a pulmonologist • Age ≥ 1 month • At least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: *G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N,* or *S549R* OR Patients with R117H mutation in the CFTR gene who have clinically significant disease. • Patient is not currently taking strong CYP3A4 Inducer (e.g., rifampin, St. John's wort, rifabutin, phenobarbital, carbamazepine, and phenytoin) Initial Approval: 12 months Continued Approval: 12 months. Confirm patient meets all above criteria. In addition, continue approval if: • Patient has documented evidence of response to therapy (e.g., improvement or stable ppFEV1, improvement in BMI, decrease in pulmonary exacerbations) AND • ALT/AST levels have been checked within the last 3 months (ALT/AST should be monitored at baseline, every three months for one year, then once yearly thereafter) • In the event of significant elevations of transaminases, e.g., patients with ALT or AST > 5 X upper limit of normal, therapy should be interrupted. Following the resolution of transaminase elevations consider the benefits and risks of resuming treatment.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Ordering information: Kalydeco is available through the KP Specialty Pharmacy. Prescribers must complete the KP Specialty Pharmacy Kalydeco Drug Order Form at Kalydeco Ordering Form Link and fax it to KP-Specialty Pharmacy (1-650-301-5790).

Kebilidi (Eladocagene exuparvovec)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	
	**Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel*
	
	Candidates for treatment with Kebilidi (eladocagene exuparvovec) should meet ALL of the following criteria:
	
	• Prescribed by a geneticist and/or pediatric neurologist
	• Genetically confirmed diagnosis of aromatic L-amino acid decarboxylase (AADC) deficiency due to biallelic mutations in the dopa decarboxylase (DDC) gene
	• Severe AADC deficiency phenotype confirmed by ONE of the following:
	  ○ Presence of clinical characteristics (e.g., oculogyric crises, hypotonia, developmental delay) of severe phenotype AND 2 known DDC gene variants; OR
	  ○ Presence of clinical characteristics (e.g., oculogyric crises, hypotonia, developmental delay) of severe phenotype AND biochemical markers found through blood or cerebrospinal fluid (CSF) for patients with 2 uncertain DDC gene variants or a combination of uncertain and pathogenic variants.
	  ▪ NOTE: CSF biochemical markers are not required if phenotype and blood biomarkers are suggestive of severe phenotype
	• Documentation that patient has delays in motor milestones
	• Documented failure, intolerance, contraindication to ALL of the following oral medications:
	  ○ Dopamine agonists (e.g., pramipexole, ropinirole, rotigotine)
	  ○ Monoamine oxidase (MAO) inhibitors (e.g., tranylcypromine, selegiline)
	  ○ Anticholinergics (trihexyphenidyl, benztropine)
	  ○ Vitamin B6
	• Documentation of risk-benefit discussion with patient or caregiver, including goals of care, expected outcomes of treatment, and shared decision making.
	
	Reasons for Non-coverage:
	
	• Patient does not have documented significant motor impairments
	• Patients who have not achieved skull maturity, assessed by neuroimaging.
	• Significant brain structure abnormality, any health, or neurological doubts that may increase the risk of surgery as assessed by consulted specialists
	
	Approval: One-time approval as this is a one-time treatment
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Dosing and Administration: • Administration setting: Inpatient setting • Eladocagene exuparvovec is a single-dose intraputaminal infusion only, delivered as four infusions (two sites per putamen-anterior and posterior) for a total of 27 minutes per site, administered in a single stereotactic surgery. • The recommended dosage is 1.8×1011 vector genomes (vg) (see Prescribing Information for details).

Kerendia
(Finerenone)
	Candidates for Kerendia should meet ALL of the following criteria:
	
	Diagnosis of heart failure with preserved ejection fraction (HFpEF)
	
	• Prescribed by Cardiologist
	• Age ≥ 40 years
	• Diagnosis of HFpEF with left ventricular ejection fraction > 40% within the past year **AND**
	  ○ Baseline eGFR > 25 ml/min
	  ○ NT-proBNP ≥ 300 pg/mL **OR** BNP ≥ 100 pg/mL
	• Documented structural heart abnormalities within the past 12 months (i.e., left ventricular hypertrophy or left atrial enlargement)
	• Currently prescribed a diuretic (e.g., furosemide, torsemide) for at least 3 months or documented failure, intolerance or contraindication
	• Currently prescribed SGLT2 inhibitor (e.g., empagliflozin, dapagliflozin) for at least 3 months or documented failure, intolerance, or contraindication
	• Baseline serum potassium ≤5 mEq/L
	
	Reasons for Non-coverage:
	• Coadministration with strong CYP3A4 inhibitors (e.g., rifampin, carbamazepine, phenytoin)
	• Patient is currently receiving therapy with anti-mineralocorticoid (e.g., spironolactone)
	
	Diagnosis of CKD associated with Type 2 Diabetes
	
	• Prescribed by Nephrologist or Endocrinologist
	• Documented diagnosis of type 2 diabetes mellitus in patients ≥18 years of age
	• Documented diagnosis of CKD Stages 2, 3, 4 **AND**
	  ○ eGFR > 25 ml/min
	  ○ UACR ≥ 300 mg/g
	• Currently prescribed ACE inhibitor or angiotensin receptor blocker (ARB) therapy for at least 3 months or documented failure, intolerance or contraindication.
	• Currently prescribed SGLT2 inhibitor (e.g., Jardiance, dapagliflozin) for at least 3 months or documented failure, intolerance or contraindication.
	• Documented baseline serum potassium ≤5 mEq/L at initiation
	
	Reasons for Non-coverage:
	• Coadministration with strong CYP3A4 inhibitors (e.g., rifampin, carbamazepine, phenytoin)
	• Patients with adrenal insufficiency
	• Documented proteinuria controlled by an SGLT2 inhibitor (e.g., urinary albumin <300 mg/g)

Drug	Prior Authorization Criteria

	• Patient is currently receiving therapy with anti-mineralocorticoid (e.g., spironolactone)
	• eGFR <25 mL/min
	
	Initial Approval: 6 months
	
	• Kerendia 20 mg tablets are approved for tablet splitting.
	• Please request conversion and approve Kendria 20 mg ½ tablet (10 mg) daily for 10 mg daily dose ONLY, unless patient is unable or unwilling to split tablets.
	• Quantity limit:
	  ○ For Kerendia 20 mg ½ tablet daily: QRM reviewer to approve 15 tablets per 30 days.
	  ○ For Kerendia 10 mg or 20 mg daily: QRM reviewer to approve 30 tablets per 30 days.
	
	Continued Approval: 12 months. Continued approval for treatment with Kerendia should meet ALL the following criteria:
	
	• The patient is confirmed stable on therapy
	• Documented beneficial response to therapy (i.e no documentation of initiation of dialysis, kidney transplant, or decrease in eGFR of 40% or greater)
	• Serum potassium and eGFR after initiation and/or within 3 months of continuation request
	• Kerendia 20 mg tablets are approved for tablet splitting.
	• Please request conversion and approve Kerendia 20 mg ½ tablet (10 mg) daily for 10 mg daily dose ONLY, unless patient is unable or unwilling to split tablets.
	• Quantity limit:
	  ○ For Kerendia 20 mg ½ tablet daily: QRM reviewer to approve 15 tablets per 30 days.
	  ○ For Kerendia 10 mg or 20 mg daily: QRM reviewer to approve 30 tablets per 30 days.

Kerydin
(Tavaborole)
	Candidates for treatment with Kerydin should meet ALL the following criteria:
	
	• Age ≥ 18 years
	• Documented diagnosis of toe onychomycosis with positive fungal culture that persists despite treatment with first line agents (see below)
	• Treatment is requested due to medical condition and not for cosmetic purposes (e.g., patients with diabetes, history of cellulitis of the lower extremity who have ipsilateral toenail onychomycosis, or vascular disease)
	• Documented intolerance or contraindication to 2 of the following antifungal agents:
	  ○ Terbinafine 250mg DAILY x 12 weeks
	  ○ Ciclopirox 8% Topical (lacquer) Solution DAILY x 12 weeks
	  ○ Fluconazole 150 -300 mg once weekly
	  ○ Itraconazole 100mg 2C QD x 12 weeks
	
	Initial approval period: 24 weeks with quantity limited to 4 mL per 30 days

Drug	Prior Authorization Criteria
	Continued Approval: Up to 48 weeks total duration. Confirm patient meets all above criteria
Kesimpta (Ofatumumab)	**Candidates for treatment with Kesimpta should meet ALL the following criteria:** Criteria for Relapsing Multiple Sclerosis indication: • Prescribed by a Neurologist • Age ≥ 18 years • Diagnosis of relapsing multiple sclerosis • Severe infusion reactions, persistent infusion reactions or loss of therapeutic response (recent clinical relapse or increased MRI activity) after initial adequate clinical response to intravenous rituximab infusion that may be due to suspected development of drug binding or neutralizing antibodies ○ ***NOTE:** The clinical significance of drug binding and neutralizing antibodies is debatable and has not been shown to impact the efficacy or severity of adverse events. In patients with no other reason for loss of therapeutic effect, a switch from rituximab to ocrelizumab may be considered. • Documented significant unresolvable barrier to receiving ocrelizumab OR ublituximab intravenously • Patient has been screened for hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (HBcAb) and is seronegative or liver specialist consult has been obtained for chronically infected patients (carriers of HBsAg) or patients with unclear status (HBsAg negative but HBcAb positive) • Patient has had a baseline (prior to treatment initiation) negative interferon-gamma release assay test for TB Infection within the past 24 months or is positive for latent TB and has completed treatment in the past or is currently on treatment • Not used in combination with another MS disease modifying agent • Absence of an active infection Reasons for Non-coverage: • Active HBV virus infection • History of life-threatening infusion reaction to rituximab or Kesimpta. • Concomitant use of antineoplastic or immunosuppressant therapies (e.g.: adalimumab, alefacept, anakinra, azathioprine, cladribine, cyclophosphamide, cyclosporine, daclizumab, efalizumab, etanercept, fludarabine phosphate, infliximab, leflunomide, mercaptopurine, methotrexate, mitoxantrone, mycophenolate mofetil, mycophenolic acid, pemetrexed and trastuzumab. ***NOTE:** Kaiser Permanente Inter-Regional Practice Recommendations for Multiple Sclerosis recommend rituximab as the preferred, highly effective agent in patients with positive JCV antibody status.

Drug	Prior Authorization Criteria
	Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for member to fill via the outpatient pharmacy benefit only** Continued Approval: 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for member to fill via the outpatient pharmacy benefit only** For new members who were initiated on Kesimpta outside of KPGA: patient must meet the full criteria above for approval without reasons for Non-coverage. For existing members who previously met the full criteria above: continue approval if patient has documented clinical benefit from medication and no reported severe adverse events to Kesimpta.

Preferred:
Dichlorphenamide (generic Keveyis)
 	
Non-preferred:
Keveyis (brand)
	Candidates for treatment with Keveyis should meet ALL the following criteria:
	• Documented primary hyperkalemic periodic paralysis or primary hypokalemic periodic paralysis, or related variants
	• Prescribed by a neurologist
	• Age ≥ 18 years
	• Documented inadequate response or intolerance, or contraindication to acetazolamide
	• Baseline measurement of serum potassium and bicarbonate
	• Must NOT have any of the following:
	  ○ Concomitant use with high dose aspirin
	  ○ Severe pulmonary disease, limiting compensation to metabolic acidosis caused by Keveyis
	  ○ Hepatic impairment
	• If all of the above criteria is met, approve preferred generic dichlorphenamide
	  ○ Brand Keveyis: must have a documented history of trial of generic dichlorphenamide and documentation of a significant reaction that is likely due to an inactive ingredient of the generic.
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. Confirm patient meets all above criteria. In addition, continue approval if patient has documented a clinically significant benefit from medication as defined by the Provider as well as documented measurement of serum potassium and bicarbonate while on therapy.
	
	Ordering/Availability:
	Generic dichlorphenamide may be filled at KP local or KP mail order pharmacies.

Drug	Prior Authorization Criteria
	Brand Keveyis is restricted to Panther Rx pharmacy.

Kevzara
(Sarilumab)
	Candidates for treatment should meet the following criteria:
	
	Criteria for the diagnosis of rheumatoid arthritis:
	
	• Age > 18 years old
	• Diagnosis of rheumatoid arthritis (RA)
	• Prescriber is a rheumatologist
	• Intolerance to tocilizumab (Actemra) (e.g., preferred Avtozma)
	• Patient has documented advanced disease or high disease activity as defined by ONE of the following:
	  ○ Patient has ever been on any biologic disease-modifying anti-rheumatic drug (DMARD) or janus kinase (JAK) inhibitor for the same condition. This includes a history of abatacept (Orencia), adalimumab (Amjevita, Humira), baricitinib (Olumiant), certolizumab pegol (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Inflectra, Remicade), rituximab (Riabni, Rituxan), sarilumab (Kevzara), tocilizumab (Actemra), tofacitinib, or upadacitinib (Rinvoq)
	  ○ Documentation of one or more features of poor prognosis such as functional limitation, extra-articular disease (skin nodules, vasculitis, ocular involvement, Sjogren's syndrome), or bone erosion on x-ray
	  ○ Inadequate response or intolerance after at least 6-week trial of oral methotxate AND at least 6-week trial of one of the following: subcutaneous methotrexate, hydroxychloroquine, leflunomide or sulfasalazine
	Reasons for Non-coverage:
	
	• Concurrent treatment with another biologic DMARD
	• Active tuberculosis (TB), latent TB infection or other active infection
	Initial approval: 12 months
	
	Continued approval: 12 months if the following criteria are met:
	
	For new members who were initiated on sarilumab prior to joining KPGA: approve medication if the patient has tried and failed the preferred IL-6 inhibitor tocilizumab (Actemra) (e.g. preferred Avtozma)
	
	For existing members who have previously met the full criteria above: approve medication if documented improvement in any of the following:
	
	• Patient self-reported pain level
	• Prescriber assessment of decrease in number of tender or swollen joints and physical function
	Criteria for the diagnosis of polymyalgia rheumatica (PMR):
	
	• Age ≥ 18 years
	• Diagnosis of active or relapsing polymyalgia rheumatica (PMR)

Drug	Prior Authorization Criteria
	• Prescribed by rheumatologist • Documented trial and failure after at least a 12-week trial or intolerance to off-label tocilizumab (e.g. preferred Avtozma) (see off-label evidence summary below)* • Documented inadequate response to corticosteroids or patient experienced a PMR flare while attempting to taper corticosteroid or patient needs a steroid sparing agent Reasons for Non-coverage: • Concurrent treatment with another biologic DMARD • Active tuberculosis (TB), latent TB infection without history of treatment or other active infection Initial approval: 12 months Continued approval: 12 months if the following criteria are met: For new members who were initiated on sarilumab prior to joining KPGA: approve medication if the patient has tried and failed the preferred IL-6 inhibitor tocilizumab (Actemra) For existing members who have previously met the full criteria above: approve medication if documented improvement in signs and symptoms of PMR. * Evidence for off-label use of tocilizumab for polymyalgia rheumatica: • Subcutaneous tocilizumab group had increased rate of glucocorticoid-free remission compared to placebo (63% vs 12%) and shorter time to relapse (Bonelli et al, 2022). • Intravenous tocilizumab group had a statistically significant reduction in disease activity and glucocorticoid dose (67.3% vs 31.4%) and more discontinuation of glucocorticoids compared to placebo (Devauchelle-Pensec et al, 2022). ○ Bonelli M, Radner H, Kerschbaumer A, et al. Tocilizumab in patients with new onset polymyalgia rheumatica (PMR-SPARE): a phase 2/3 randomised controlled trial. Ann Rheum Dis 2022; 81:838. ○ Devauchelle-Pensec V, Carvajal-Alegria G, Dernis E, et al. Effect of Tocilizumab on Disease Activity in Patients With Active Polymyalgia Rheumatica Receiving Glucocorticoid Therapy: A Randomized Clinical Trial. JAMA 2022; 328:1053.
Khindivi (Hydrocortisone) **Preferred: Hydrocortisone tablets** (available on the COM formulary, does not require PA review) **Non-preferred:**	**Candidates for treatment with Khindivi should meet ALL of the following criteria:** • Patient is ≥ 5 years of age • Prescribed by or in consultation with a Pediatric Endocrinologist • Patient has a diagnosis of adrenocortical insufficiency • Documented trial of hydrocortisone tablets unless unable to take tablets (e.g., G-tube) ○ Hydrocortisone tablets can be crushed and mixed with soft foods. • For patients < 6 years of age, must have documentation that treatment with Alkindi Sprinkle was not effective, not tolerated, or contraindicated Initial approval: 12 months

Drug	Prior Authorization Criteria
Alkindi Sprinkle (Hydrocortisone) **(see separate criteria)** **Khindivi** (Hydrocortisone oral solution)	Continued approval: 12 months. Member must continue to meet criteria listed above and ALL the following: • Member remains ineligible to transition to generic hydrocortisone tablets or crush tablets and mix in soft foods. • Member has exhibited improvement or stability of disease symptoms (e.g., improved cortisol levels over baseline, improvement in symptoms such as hypotension, hyponatremia).
Kimmtrak (Tebentafusp)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** **Candidates for Kimmtrak should meet ALL the following criteria:** • 18 years of age or older • HLA-A*02:01 genotype positive unresectable or metastatic uveal melanoma • Prescribed by an Oncologist Initial Approval: 12 months. • The first 3 infusions may be approved for administration at a KP-affiliated inpatient facility. • Subsequent doses should be approved for back-office administration in a KP-infusion center ONLY. • **NOTE:** If patient experiences a treatment delay >14 days, an additional cycle may be approved for administration at a KP-affiliated inpatient facility for therapy re-initiation. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** Continued Approval: 12 months. Confirm patient meets above criteria. In addition, patient should meet the following: : • No evidence of disease progression or unacceptable toxicity. • **Approve for back-office administration in a KP-infusion center ONLY.** ○ **NOTE:** If patient experiences a treatment delay >14 days, an additional cycle may be approved for administration at a KP-affiliated inpatient facility for therapy re-initiation. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** Dosing and Administration: • Day 1: 20 mcg IV • Day 8: 30 mcg IV • Day 15: 68 mcg IV • Day 22 and beyond: 68 mcg IV once weekly until disease progression • Administer the first 3 infusions in an appropriate health care setting with immediate access to medications and resuscitative equipment to manage cytokine release syndrome. If no ≥

Drug	Prior Authorization Criteria
	grade 2 hypotension (requiring medical intervention) during or after the third infusion, may administer subsequent doses in an ambulatory care setting.
Korlym (Mifepristone)	**Candidates for treatment with Korlym should meet ALL the following criteria:** • Documented diagnosis of Cushing's syndrome • Documented diagnosis of type 2 diabetes mellitus or glucose intolerant secondary to Cushing's syndrome • Prescribed by an endocrinologist • Patient has failed surgery or is not a candidate for surgery for Cushing's syndrome • Documented trial of maximum tolerated dose of ketoconazole (i.e., dosage range: 200 to 1,200 mg daily in 2-3 divided doses) unless patient is not a candidate (i.e., previous trial of ketoconazole resulting in increased of liver enzymes 3X ULN). o If patient is not a candidate for ketoconazole, must have a documented inadequate response to **ONE** of the following cortisol-blocking medications: metyrapone (Metopirone) or mitotane (Lysodren) unless documented failure, intolerance, or contraindication. • Failed to obtain adequate glycemic control on combination therapy with: o Maximum tolerated doses of metformin monotherapy (unless patient is not a candidate for metformin therapy) **and** o Maximum tolerated doses of a sulfonylurea (unless the patient is not a candidate for sulfonylurea therapy) **and** o Maximum tolerated titration of insulin **OR** meets the following criteria: i. Korlym™ may be initiated prior to insulin trial, if the Endocrinologist indicates hypoglycemia is uniquely undesirable, so unable to use insulin (e.g., in patients who have hazardous jobs) • If patient is a female of childbearing age (12-50 years of age), must have a baseline negative pregnancy test (within 1 month) <u>Reasons for Non-coverage:</u> • Pregnant women (Pregnancy Category X) • Concomitant use simvastatin or lovastatin and CYP3A substrates with narrow therapeutic range • Concurrent long-term corticosteroid use • Women with history of unexplained vaginal bleeding • Women with endometrial hyperplasia with atypia or endometrial carcinoma <u>Initial Approval</u>: 12 months <u>Continued Approval:</u> 24 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continue approval if patient has documented clinical benefit from medication and no reported adverse events to Korlym.

Drug	Prior Authorization Criteria
	Ordering information: Korlym is only dispensed by CuraScript specialty pharmacy. For more information, visit http://pharmacy.kp.org/KpCMS/California/DrugInformation/ViewMedSafetyDNMgmtCA.aspx?I32Object=1226&nodeValue=113
Komzifti (Ziftomenib)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** **Candidates for treatment with Komzifti (ziftomenib) should meet ALL the following criteria:** • Prescribed by a hematologist/oncologist • Age 18 years of age or older • Patient has a diagnosis of relapsed or refractory acute myeloid leukemia (AML) with a NPM1 mutation Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** Continued Approval: 12 months. Patient continues to meet all criteria above and does not show evidence of progressive disease while on Komzifti therapy. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.**
Koselugo (Selumetinib)	**Candidates for treatment with Koselugo should meet ALL of the following criteria:** • Prescribed by an oncologist or neurologist. • Age ≥ 1 year • Patient has body surface area ≥ 0.55 m^2 • Patient diagnosed with symptomatic Neurofibromatosis Type 1 (NF1). • Patient has plexiform neurofibromas (PN) that are inoperable. • Documented baseline ophthalmic assessment. • Documented baseline left ventricular ejection fraction (LVEF) and serum creatine phosphokinase (CPK) levels. Reasons for Non-coverage: • Documented retinal vein occlusion (RVO) or retinal pigment epithelial detachment • Patient has rhabdomyolysis. Initial Approval Period: 6 months Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, confirm patient meets all the following: • No documented disease progression • No documented unacceptable toxicity (i.e reduced LVEF, ocular toxicity, severe diarrhea, severe skin rashes, increased CPK)

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
Krazati (Adagrasib)	**Candidates for treatment with Krazati should meet ALL the following criteria:** • Prescribed by an oncologist/hematologist • Age ≥ 18 years • Patient is diagnosed with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer as determined by an FDA approved test • Documentation that patient has received at least 1 prior systemic therapy with a platinum-based regimen and an immune checkpoint inhibitor a. **Note:** Examples of systemic therapy include those containing one or more of the following products: Keytruda (pembrolizumab), Opdivo (nivolumab), Tecentriq (atezolizumab), Alimta (pemetrexed), Yervoy (ipilimumab), Abraxane (albumin-bound paclitaxel), bevacizumab, cisplatin, carboplatin, docetaxel, gemcitabine, paclitaxel, vinorelbine Initial Approval Period: 12 months Continued Approval Period: 12 months if patient meets ALL the initial criteria above and the following: • No documented disease progression Ordering Information: • Krazati is only available through Specialty Pharmacies - Biologics and Onco360 Oncology Pharmacy. Information on how to order Krazati is available at Mirati-and-Me-Distribution-Sell-Sheet.pdf (miratiandme.com).
Krystexxa (Pegloticase)	**Candidates for Krystexxa should meet ALL of the following criteria**: • Prescribed by a Rheumatologist or Nephrologist • Age ≥18 years • Diagnosis of chronic gout, defined by one of the following: ○ ≥2 gout flares per year OR ≥3 gout flares in the previous 18 months ○ ≥1 tophi ○ Gouty arthritis • Serum urate level ≥6 mg/dL • Documented failure, contraindication, or intolerance to all of the following after a 3-month trial of maximally tolerated dose: ○ Allopurinol ○ Febuxostat ○ Probenecid (alone or in combination with a xanthine oxidase inhibitor) Reasons for Non-coverage • Serious hypersensitivity to pegloticase or any of its ingredients • Glucose-6-phosphate dehydrogenase (G6PD) deficiency • Asymptomatic hyperuricemia • Concomitant use with oral urate-lowering agents

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	Initial Approval: 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Continued Approval: 12 months. Continue approval if the following criteria are met without reasons for non-coverage:
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	• Documented positive clinical response (i.e., reduction of gout flares, tophi, and/or symptoms)
	• Serum urate level being monitored prior to infusions
	
	Dosing and Administration:
	• 8 mg every two weeks as an IV infusion, co-administered with weekly oral methotrexate 15 mg and folic acid supplementation
	  ○ Methotrexate and folic acid supplementation should be started at least 4 weeks prior to Krystexxa initiation
	  ○ NOTE: if methotrexate is contraindicated or not clinically appropriate, Krystexxa may be used alone

Kuvan
(Sapropterin)
	Candidates for treatment with Sapropterin should meet ALL the following criteria:
	• Diagnosis of Phenylketonuria
	• Absence of the following medications:
	  ○ Medications known to inhibit folate metabolism (e.g., methotrexate)
	  ○ Nitric oxide-mediated vasorelaxation medications (e.g., sildenafil, vardenafil, tadalafil)
	  ○ Levodopa
	• Currently following a phenylalanine restricted diet
	• If request is for Brand Kuvan:
	  ○ Patient has tried generic sapropterin and experienced a clinical reaction that cannot be explained by other clinical or lifestyle factors and may be due to the **inactive** components of the generic sapropterin product.
	  i. Note: if the physician's request for coverage of brand Kuvan is based upon the physician's and/or member's unwillingness to change to generic sapropterin, the request will be denied unless the member meets the full criteria.
	
	Initial Coverage: 6 months
	
	Continued Coverage: 12 months. Confirm patient meets all above criteria. In addition, continue approval if patient's phenylalanine levels have decreased 30% from baseline level

Kygevvi	**Candidates for treatment with Kygevvi (doxecitine and doxribtimine) should meet ALL of the following criteria:**

Drug	Prior Authorization Criteria
(Doxecitine and doxribtimine)	• Prescribed by a neurologist or specialist experienced in managing genetic metabolic disorders • Age ≥ 12 years • Diagnosis of thymidine kinase 2 deficiency (TK2d) confirmed by genetic testing that detects variants in the TK2 gene • Clinical documentation of initial symptom onset at ≤12 years of age, consistent with infantile- or childhood-onset TK2d Initial Approval: 6 months Continued Approval: 12 months. Confirm patient has documented beneficial response by a specialist in the past year. Beneficial response is defined as stabilization or improvement of motor, respiratory or another clinical symptom. Ordering Information: • Kygevvi is only dispensed by PANGHERx Rare. Providers should complete the Kygevvi Start form at kygevvi-start-form.pdf

CAR-T Therapy
 	
Kymriah
(Tisagenlecleucel)
	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	
	Candidates for treatment with Kymriah should meet ALL the following criteria:
	
	• **MUST verify member's benefit information. If member's coverage is through Target, CLOSE the request.** Member must go through Aradigm for this therapy.
	
	For treatment of lymphoma:
	• Prescribed by an Oncologist
	• Age ≥ 18 years
	• Histologically confirmed lymphoma consistent with an FDA approved indication for the specific CAR-T therapy.
	• Chemotherapy-refractory disease, defined as one or more of the following:
	  ○ Refractory to two or more lines of therapy with less than partial response to last line of therapy OR
	  ○ Refractory post-autologous hematopoietic stem cell transplantation (HSCT)
	• Subjects must have received adequate prior therapy including at a minimum:
	  ○ anti-CD20 monoclonal antibody unless tumor is CD20-negative AND
	  ○ an anthracycline containing chemotherapy regimen
	  ○ For subjects with transformed FL must have received prior chemotherapy for follicular lymphoma and subsequently have chemo-refractory disease after transformation to DLBCL
	• Absolute neutrophil count ≥500/µL
	• Absolute lymphocyte count >100/µL

Drug	Prior Authorization Criteria

	• Platelet count ≥ 50,000/µL
	• Adequate organ function defined as (patients with borderline organ function may still be eligible based on center of excellence standards):
	  ○ Left Ventricular Ejection Fraction ≥ 45%
	  ○ Creatinine clearance ≥ 40 mL/min
	  ○ ALT ≤ 5 times the upper limit of normal (ULN) for age
	  ○ Total bilirubin < 2 mg/dL
	  ○ Baseline oxygen saturation >91% on room air
	
	Reasons for Non-coverage:
	• Presence of fungal, bacterial, viral, or other infection that is uncontrolled or requiring intravenous (IV) antimicrobials for management. Simple urinary tract infection (UTI) and uncomplicated bacterial pharyngitis are permitted if responding to active treatment.
	• Known infection with HIV (detectable viral load)
	• Hepatitis B (HBsAG positive and detectable viral load)
	• Hepatitis C virus (anti-HCV positive and detectable viral load)
	
	Initial Approval: ONE TIME DOSE ONLY. At this time, CAR-T therapy is intended as a one-time (single infusion) treatment. Repeat treatment of any CAR-T therapy is considered investigational and is not recommended outside of enrollment in a clinical trial.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	
	Continued Approval: Not applicable. CAR-T is intended as a one-time (single infusion) treatment.
	
	For the treatment of pediatric refractory/relapsed (r/r) B-cell acute lymphoblastic leukemia (ALL):
	• Prescribed by an Oncologist with expertise in malignant hematology
	• Age ≤ 25 years
	• Relapsed or refractory B-cell ALL
	  ○ Relapse defined as:
	  ▪ High risk minimal residual disease (MRD) value based on current Children's Oncology Group definition, or
	  ▪ Second or subsequent bone marrow (BM) or extramedullary (EM) relapse, or
	  ▪ Any BM or EM relapse after allogeneic hematopoietic stem cell transplantation (HSCT) and must be ≥6 months from HSCT at the time of tisagenlecleucel infusion
	  ○ Refractory is defined by not achieving an initial complete remission after 2 cycles of a standard chemotherapy regimen (primary refractory). Subjects who are refractory to subsequent chemotherapy regimens after an initial remission are considered chemo-refractory
	• Philadelphia chromosome positive (Ph+) ALL patients who:
	  ○ are intolerant to or have failed two lines of tyrosine kinase inhibitor (TKI) therapy, **OR**
	  ○ have contraindication to TKI therapy, **OR**
	  ○ declined or are ineligible for allogeneic stem cell transplant

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	• CD19 tumor expression in bone marrow, cerebrospinal fluid, or peripheral blood
	• Adequate organ function defined as (patients with borderline organ function may still be eligible based on center of excellence standards):
	  ○ Left Ventricular Ejection Fraction ≥45%
	  ○ Glomerular filtration rate ≥60 mL/min
	  ○ ALT ≤5 times the upper limit of normal (ULN) for age
	  ○ Total bilirubin <2 mg/dL
	  ○ Baseline oxygen saturation >91% on room air
	
	Reasons for Non-coverage:
	• Burkitt's lymphoma/leukemia
	• Active hepatitis B, C, or any uncontrolled infection
	• Active Grade 2 to 4 Graft versus Host Disease (GVHD)
	• Central Nervous System (CNS) 3 disease (white blood cell count ≥5/mL with blasts on cytocentrifuge and/or signs of CNS leukemia (e.g., cranial nerve palsy).
	
	Initial Approval: ONE TIME DOSE ONLY. Tisagenlecleucel is intended as a one-time (single infusion) treatment. However, there may be opportunities for re-infusion in select patients with relapses or early loss of B-cell aplasia.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	•
	Continued Approval: Not applicable. Tisagenlecleucel is intended as a one-time (single infusion) treatment.
	
	Dosing and Administration:
	• **KP members will be referred out to institutions that are certified to administer CAR-T therapies.**
	• **Kymriah is available only through restricted programs under a Risk Evaluation and Mitigation Strategy (REMS) Yescarta REMS/Kymriah REMS.**

Lamzede (Velmanase alfa-tycv)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval AND discuss optional sites of administration.** **Candidates for treatment with Lamzede should meet ALL the following criteria:** • Prescribed by, or in consultation with, a geneticist or metabolic specialist • Documented diagnosis of alpha-mannosidosis (AM) as defined by a deficiency in alpha-mannosidase enzyme activity or MAN2B1 gene mutation. • Patient has non-central nervous system manifestations of disease which may include, but are not limited to, myopathy, impaired fine motor control and coordination, facial and skeletal abnormalities, etc. Reasons for Non-coverage:

Drug	Prior Authorization Criteria
	• Pregnancy or lactation • Patients who cannot walk without support • Patients with a history of bone marrow transplant (BMT) Initial Approval Period: 12 months. Approve ONLY for healthcare provider administration. **Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval AND discuss optional sites of administration.** Continued Approval Period: 12 months if patient meets ALL the initial criteria above and the following: • Documentation of clinical response to therapy, attested by the provider (i.e., improvement or stabilization in motor function, forced vital capacity (FVC), reduction in frequency of infections, etc.) • Approve ONLY for healthcare provider administration. • **Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval AND discuss optional sites of administration.** Dosage and Administration: • 1 mg/kg (actual body weight) administered once every week • Intravenous administration by a healthcare provider

Lantidra
(Donislecel-jujn)
	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval and coordinate with Transplant Office.**
	
	Candidates for Lantidra (donislecel-jujn) should meet ALL the following criteria:
	
	• Prescribed by Endocrinology
	• Documented diagnosis of Type 1 diabetes for > 5 years duration
	• Age 18 to 75 years
	• Body Mass Index (BMI) < 27 kg/m2 (must have in office weight in past 30 days)
	• Recurrent, acute, and severe metabolic and potentially life-threatening complications requiring medical attention. **Two or more in the past 12 months resulting in emergency/ACC visits or hospitalization**
	  ○ Hyperglycemia
	  ○ Hypoglycemia
	  ○ Hypoglycemic unawareness with high risk of injury
	  ○ Ketoacidosis
	• Failure to reach A1C goal (A1C >8% but <12%) or recurrent hypoglycemia despite intensive insulin management (i.e., insulin pump, multiple daily insulin injections of basal, bolus insulin) **AND** use of continuous glucose monitoring (CGM)
	• Use in combination with concomitant immunosupressants
	  ○ Examples: daclizumab, basiliximab, sirolimus, everolimus, cyclosporin, tacrolimus, mycophenolate mofetil, etanercept

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Reasons for Non-coverage: • Cardiac disease including myocardial infarction, heart failure, stroke • C-peptide level >0.3 ng/mL (check for test in epic labs tab) • Insulin requirement >0.7 units/kg/day and/or A1C >12% • Pregnancy or breastfeeding • Psychiatric condition including schizophrenia, bipolar disorder, or major depression and unstable on medication • Recent (within the last 30 days) abnormal liver function defined as AST/ALT >3 times the upper limit of the normal • Recent (within the last 30 days) impaired renal function defined as creatinine clearance <80 mL/min, serum creatinine consistently >1.5 mg/dL, or macroalbuminuria >300 mg/24 h • History of transplant (e.g., pancreas, kidney) • Current or history of any malignancy (exception=skin cancer) Initial Approval: • Coverage provided for 1 infusion bag and may be renewed annually for up to 3 doses total in a lifetime. • There are no data regarding the effectiveness or safety for patients receiving more than three infusions. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval and coordinate with Transplant Office.** Continued Approval: Confirm patient meets all above coverage criteria without reasons for non-coverage AND • Patient is responding positively to therapy but still requires exogenous insulin within 1 year of last infusion. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval and coordinate with Transplant Office.** Dosing and Administration: • For infusion into the hepatic portal vein only • The recommended minimum dose is 5,000 equivalent islet number (EIN) per kg patient body weight for initial infusion (transplant) and 4,500 EIN/kg for subsequent infusions (same recipient) **NOTE: Lantidra is only available for administration through a single transplant center, University of Illinois Hospital.**

Drug	Prior Authorization Criteria
Lazcluze (Lazertinib)	**Candidates for treatment with Lazcluze (lazertinib) must meet ALL the following criteria:** • Prescribed by an oncologist • Age ≥ 18 years • Diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) • Documentation that patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations • Lazcluze (Lazertinib) will be used in combination with Rybrevant (amivantamab-vmjw) infusion • Documentation patient is not a candidate for treatment with Osimertinib (Tagrisso) due to contraindication or intolerance or patient has progressed on osimertinib Reasons for Non-Coverage: • Pregnancy • Lactation Initial Approval: 12 months • The following quantity limits will apply: o 80 mg tablets: 60 tablets per 30 days o 240 mg tablets: 30 tablets per 30 days Continued Approval: 12 months. Patient continues to meet above coverage criteria AND • Documented beneficial effect from therapy without disease progression or unacceptable toxicity (e.g., interstitial lung disease (ILD)/pneumonitis, ocular toxicity) • The following quantity limits will apply: o 80 mg tablets: 60 tablets per 40 days o 240 mg tablets: 30 tablets per 30 days
Lemtrada (Alemtuzumab)	**Candidates for treatment with Lemtrada should meet ALL of the following criteria:** • Diagnosis of relapsing multiple sclerosis (MS) • Prescribed by or in consultation with a multiple sclerosis specialist certified by the LEMTRADA REMS program (1-855-676-6326) • Patient enrolled in the LEMTRADA REMS program and Lemtrada to be administered at a certified healthcare facility with on-site access to equipment and personnel trained to manage infusion reactions • Lemtrada to be administered as monotherapy and not in combination with other disease-modifying therapies for MS • Evidence of continued inflammatory disease (new MRI lesions and/or relapses) on natalizumab (Tysabri) or a B-cell depleting agent such as rituximab (Rituxan) • CBC and thyroid function test within normal range, negative serum HIV antibody test, negative Hepatitis B surface antigen (or if Hepatitis B core antibody and Hepatitis B surface antibody positive should be Hepatitis B DNA negative), creatinine and urinalysis within

Drug	Prior Authorization Criteria

	normal limits, and negative TB test.
	• Females of childbearing age (12-50 years of age) have documentation of a baseline negative pregnancy test within the past month AND either a prescription for birth control (IUD or other contraceptive) or documentation of patient declining contraception and being counseled of the potential risk in pregnancy
	
	Reasons for Non-coverage:
	• Secondary progressive MS and no clinical or MRI evidence of relapses
	• Infection with Human Immunodeficiency Virus
	• History of thyroid cancer, melanoma and lymphoproliferative disorders
	• Concomitant use of antineoplastic or immunosuppressant therapies (e.g.: adalimumab, alefacept, anakinra, azathioprine, cladribine, cyclophosphamide, cyclosporine, daclizumab, efalizumab, etanercept, fludarabine phosphate, infliximab, intravenous immunoglobulin, leflunomide, mercaptopurine, methotrexate, mitoxantrone, mycophenolate mofetil, mycophenolic acid, pemetrexed, rituximab, trastuzumab)
	
	Approval period: 12 months.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	For new members who were initiated on Lemtrada outside of KPGA: patient must meet the full criteria above for approval without reasons for non-coverage.
	
	For existing members who previously met the full criteria above: continue approval if patient has documented clinical benefit from medication and no reported severe adverse events to Lemtrada.
	
	Dosing and Administration:
	• 12 mg IV infusion over 4 hours on 5 consecutive days then 12 mg IV infusion over 4 hours on 3 consecutive days 12 months later
	• Premedicate with corticosteroids prior to Lemtrada infusion for the first 3 days of each treatment course
	• Administer antiviral agents for herpetic prophylaxis starting on the first day of Lemtrada dosing and continue for a minimum of 2 months after completion of Lemtrada dosing or until CD4+ lymphocyte count is more than 200 cells/µL
	• Must be diluted prior to administration
	
	Monitoring:
	• Infusion reactions (may be delayed and may be life-threatening)
	• Recommended at baseline and monthly until 48 months after last treatment course:
	  ○ CBC w/ differential
	  ○ Serum creatinine
	  ○ Urinalysis with urine cell counts

Drug	Prior Authorization Criteria
	• Thyroid function tests at baseline and every 3 months until 48 months after last treatment course • Skin exam at baseline and yearly to monitor for melanoma • For females, human papillomavirus screening yearly • Autoimmune conditions including thyroid disorders and immune thrombocytopenia • Signs or symptoms of infection • Signs or symptoms of PML • ECG prior to each treatment course Ordering information: Prescriber, patient, pharmacy and infusion center must be enrolled in the LEMTRADA REMS program. For information on how to enroll in the program, please visit https://www.lemtradarems.com/ or call 1-855-676-6326. Lemtrada is distributed by the manufacturer **to certified pharmacies and infusion centers only.**

Lenacapavir Products
 	
Preferred:
Yeztugo
 	
Non-Preferred:
Sunlenca
	Candidates for treatment with lenacapavir should meet ALL the following criteria:
	
	Criteria for use for Pre-Exposure Prophylaxis (PrEP)
	• Prescribed by an Infectious Disease or HIV Specialist
	• Age ≥ 16 years
	• Weighs ≥ 35kg
	• Prescribed for pre-exposure prophylaxis (PrEP) of HIV
	• One of the following criteria must be met:
	  ○ Patient has a history of allergy or intolerance to all of the following:
	  ▪ Emtricitabine/tenofovir disoproxil fumarate (generic Truvada)
	  ▪ Emtricitabine/tenofovir alafenamide (Descovy)
	  ▪ Injectable cabotegravir (Apretude)- injection site pain is not a true intolerance of injectable cabotegravir (Apretude) as this is a known and expected side effect.
	  ○ Patient has a contraindication to generic Truvada AND Descovy AND injectable cabotegravir (Apretude) due to ALL the following:
	  ▪ For Descovy and generic Truvada: eGFR of < 30 on at least 2 back-to-back labs OR DEXA scan showing T-Score < -2.0.
	  ▪ Patient has a documented diagnosis of current substance use disorder, current psychosis, currently homeless, or currently another specific condition that would interfere with reliably taking oral medications or adhering to schedule of injectable cabotegravir (Apretude).
	
	Criteria for use for HIV:
	• Prescribed by an Infectious Disease Specialist
	• Age ≥ 18 years
	• Has a diagnosis of HIV-1 infection
	• Failing current antiretroviral (ARV) regimen for HIV documented by two consecutive HIV-1

Drug	Prior Authorization Criteria

	RNA (viral load) of greater than 400 copies/mL within the past 8 weeks
	• Adherence of ≥ 80% adherence to HIV therapy [MRAR ≥ 80%. If MRAR < 80%, reviewer can confirm adherence in the last 90 days based on medication sold dates found in Health Connect medication tab (e.g., 3 one month fills or one 90 day fill)]
	• Patient will maintain an optimized background therapy (OBT) with at least one highly active ARV medication (demonstrated by full viral sensitivity/susceptibility testing)
	• Has documented resistance, intolerable side effects or contraindications to at least two ARV medications in at least 3 different classes noted below:
	  ○ Protease Inhibitor (PI)
	  ○ Nucleoside reverse transcriptase inhibitor (NRTI)
	  ○ Non-nucleoside reverse transcriptase inhibitor (NNRTI)
	  ○ Integrase Inhibitors (INSTI)
	
	Reasons for Non-coverage:
	
	• Hypersensitivity to lenacapavir or any of its components
	• Concomitant use with strong CYP3A inducers (e.g., carbamazepine, phenytoin, rifampin, St. John's Wort)
	
	Initial Approval**:** 12 months (300mg tablet, #4 per 6 months)
	
	Continued Approval**:** 12 months (SubQ injections only)
	• Confirm patient meets all above coverage criteria without reasons for non-coverage.
	• Documentation of adherence to therapy (i.e., patient receiving maintenance dosing 26 weeks from date of last injection ± 2 weeks)
	• Patient continues an optimized background regimen with at least one highly active ARV medication
	
	For new members who were initiated on lenacapavir outside of KPGA, continue approval for 6 months if:
	• For PrEP and HIV treatment:
	  ○ Must meet all criteria previously stated for the respective indication.

Lenmeldy (Atidarsagene autotemcel)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** **Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).* **Candidates for treatment with Lenmeldy should meet ALL the following criteria:** • Prescribed by medical geneticist • Age ≤ 6 years

Drug	Prior Authorization Criteria

	• Patient is diagnosed with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD)
	• Confirmed diagnosis of MLD based on ALL the following:
	  ○ Arylsulfatase A (ARSA) activity below the normal range in peripheral blood mononuclear cells or fibroblasts
	  ○ Presence of two-disease causing mutations of either known or novel alleles
	  ○ Presence of sulfatides in a 24-hour urine collection to exclude MLD carriers and patients with ARSA pseudodeficiency
	• If patient is diagnosed with pre-symptomatic late-infantile MLD, 2 of the following criteria must be met:
	  ○ Age at onset of symptoms in the older sibling(s) ≤30 months
	  ○ Two null (0) mutant ARSA alleles
	  ○ Peripheral neuropathy at electroneurographic study
	• If patient is diagnosed with pre- or early-symptomatic early juvenile MLD, 2 of the following criteria must be met:
	  ○ Age at onset of symptoms (in the subject or in the older sibling) between 30 months and 6 years (had not celebrated their 7th birthday)
	  ○ One null (0) and one residual (R) mutant ARSA allele(s)
	  ○ Peripheral neuropathy at electroneurographic study
	
	<u>Reasons for Non-Coverage:</u>
	• Diagnosed with HIV, Hepatitis C
	• Acute or chronic stable Hepatitis B
	• Malignant neoplasia (except local skin cancer)
	• Myelodysplasia, cytogenetic alterations typical of myelodysplastic syndrome or acute myelogenous leukemia
	• If late infantile (LI) MLD variant, clinical manifestations of the disease defined as EITHER of the following:
	  ○ Delay in expected achievement of independent standing or independent walking, together with abnormal signs at neurological evaluation OR
	  ○ Documented neurological signs and symptoms of MLD associated with cognitive, motor, or behavioral functional impairment or regression (substantiated by neurological examination and/or neuropsychological tests appropriate for age).
	• If early juvenile (EJ) MLD variant, symptoms of MLD resulting in the loss of capacity of walking independently as defined by a Gross Motor Function Classification System (GMFC) level ≥2 or symptoms consistent with cognitive impairment as defined by an IQ <85 using age-appropriate neurocognitive instruments.
	
	<u>Approval</u>: One-time approval
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval**
	
	<u>Dosing and Administration:</u>

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>

For autologous use only
Dose administered is calculated based on the child's weight at time of LENMELDY infusion using the information provided on the Lot Information Sheet.
Minimum and Maximum Recommended dose

<table>
<tr><th>MLD Subtype</th><th>Minimum Recommended Dose (CD34+ cells/kg)</th><th>Maximum Recommended Dose (CD34+ cells/kg)</th></tr>
<tr><td>Pre-symptomatic late infantile</td><td>4.2 x 10^6</td><td>30 x 10^6</td></tr>
<tr><td>Pre-symptomatic early juvenile</td><td>9 x 10^6</td><td>30 x 10^6</td></tr>
<tr><td>Early symptomatic early juvenile</td><td>6.6 x 10^6</td><td>30 x 10^6</td></tr>
</table>

Lenmeldy can only be received at a designated Qualified Treatment Center (QTC). Information on QTCs are available at https://orchardassist.com/qualified-treatment-centers/

</td></tr>
<tr><td>Leqvio
(Inclisiran)</td><td>
Candidates for Leqvio should meet ALL of the following criteria:

Age ≥ 18 years
Prescribed by a cardiologist or endocrinologist
Documented diagnosis of heterozygous familial hypercholesterolemia, OR atherosclerotic cardiovascular vascular disease (ASCVD)*
NOT given in combination with a PCSK9 inhibitor (e.g., Repatha (evolocumab), Praulent (alirocumab), etc), Nexletol (bempedoic acid), Juxtapid (lomitapide), or LDL apheresis
The patient must have documented contraindication, intolerance, persistent adherence concerns [MRAR ≥ 80% for ≥ 6 months. If MRAR < 80%, reviewer can confirm adherence in the last 6 months based on medication sold dates found in Health Connect medication tab (e.g., 6 one month fills or two 90 day fills)], or self-administration issues (e.g., impaired manual dexterity, upper extremity amputation, visual impairment, or Parkinson's Disease) to PCSK9 inhibitors
Patient receiving maximally tolerated statin therapy (see additional criteria below)

Leqvio only indicated as an adjunct to diet and maximally tolerated statin therapy. Monotherapy with Leqvio may be considered for secondary prevention if the patient has tried/failed or is intolerant to statins + ezetimibe and is defined as being at very high risk** for recurrent ASCVD event.

*Clinical ASCVD includes: Acute coronary syndrome: Myocardial infraction, Stable or unstable angina, Coronary or other arterial revascularization procedures (e.g., PTCA, CABG), Transient ischemic attack (TIA), Peripheral arterial disease presumed to be of atherosclerotic origin, Findings from CT angiogram or catheterization consistent with clinical ASCVD

**Very High risk defined per 2018 AHA Blood Cholesterol Guidelines: Multiple ASCVD events OR one ASCVD event AND multiple very high-risk conditions. High risk conditions defined as: Age ≥ 65 years, heterozygous or homozygous familial hypercholesterolemia,
</td></tr>
</table>

Drug	Prior Authorization Criteria
	history of prior coronary bypass surgery or percutaneous coronary intervention outside of the major ASCVD event, diabetes mellitus, HTN, eGFR 15-59 mL/min/1.72m^2, current smoker, LDL of ≥100 mg/dL, or congestive heart failure. In addition, the following criteria should also be met: • Patient has had an adequate trial (of at least 3 months) of a high-intensity statin (atorvastatin 40 mg or 80 mg OR rosuvastatin 20 mg or 40 mg) OR • Statin therapy at the maximally tolerated dose PLUS ezetimibe 10 mg, and LDL remains ≥70 mg/dl (or ≥55 mg/dl in very high-risk patients** with multiple ASCVD events) despite optimal adherence [MRAR ≥ 80% for ≥ 6 months. If MRAR < 80%, reviewer can confirm adherence in the last 6 months based on medication sold dates found in Health Connect medication tab (e.g., 6 one month fills or two 90 day fills)] OR • Documented trial and intolerance of at least 3 different statins (atorvastatin, rosuvastatin, and 1 additional statin), including an attempted alternative dosing regimen (e.g., every other day, once or twice weekly) OR • Documented history of CPK >10x ULN or rhabdomyolysis attributed to a statin and not explained by drug interaction, fall, or prolonged immobility OR • An absolute contraindication to statin therapy (e.g., active, decompensated liver disease, nursing female, pregnancy, or plans to become pregnant, or hypersensitivity reaction) OR a. Other causes of muscle symptoms must be ruled out (e.g., hypothyroidism, Vitamin D deficiency, recent exercise), drug-drug interactions that can increase systemic statin exposure should be considered • Documented intolerance or contraindication to ezetimibe Initial Approval: 3 months. Patient must obtain LDL after 3 months of therapy. (This lab should be ordered when initiating therapy) Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, continue approval if the following criteria are met based on 3-month LDL: • Documented adherence [MRAR ≥ 80% for ≥ 3 months. If MRAR < 80%, reviewer can confirm adherence in the last 90 days based on medication sold dates found in Health Connect medication tab (e.g., 3 one month fills or one 90 day fill)]to maximum tolerated doses of statin and ezetimibe (unless the patient is not a candidate as outlined above) AND • Documented LDL lowering by ≥30% from starting Leqvio therapy AND • Adherence to follow-up assessments and injections (planned dose is not missed >3 months) • Per 2018 AHA guidelines, if patient has 2 consecutive LDL readings <25, use clinical judgment on whether therapy should be continued with Leqvio For new members who were initiated on Leqvio outside of KPGA: Approve Leqvio if patient has documented contraindication, intolerance, or self-administration issues to PCSK9 inhibitors and confirmed to be clinically stable on Leqvio by a Specialist in the last 6 months Dosing and Administration:

Drug	Prior Authorization Criteria
	• Subcutaneous injection: 284 mg once initially, again at 3 months, and every 6 months • Should be administered by a healthcare professional

Lerochol
(Lerodalcibep-liga)
	Candidates for treatment with Lerochol (lerodalcibep-liga) should meet ALL of the following criteria:
	
	• Prescribed by a cardiologist or endocrinologist
	• Patient is 18 years of age or older
	• Documented diagnosis of heterozygous familial hypercholesterolemia, OR atherosclerotic cardiovascular vascular disease (ASCVD)*
	• Documentation of the appropriate LDL for the treatment indication
	  ○ HeFH (familial): LDL >100 (age >/=10)
	  ○ Not high risk ASCVD: LDL >70 (age 40 to 75)
	  ○ Very high risk ASCVD**: LDL >55 (age 40 to 75)
	• Documented adequate trial of maximally tolerated statin (at least 3 months) or intolerance or contraindication, **must meet one of the following**:
	  ○ Currently prescribed high intensity statin (atorvastatin 40 or 80 mg OR rosuvastatin 20 or 40 mg). Check MRAR∞
	  ○ Currently prescribed maximally tolerated statin AND ezetimibe 10 mg. Check MRAR∞
	  ○ Previously prescribed atorvastatin, rosuvastatin, and 1 additional statin, including an attempted alternative dosing regimen (e.g. every-other day, once or twice weekly). Check med hx when available.
	  ○ Provider attestation and documentation that patient unable to take statin due to **one of the following:**
	  ▪ History of CPK >10xULN or rhabdomyolysis attributed to a statin and not explained by a drug interaction, fall or prolonged immobility
	  ▪ Acute liver failure or decompensated cirrhosis; nursing female, pregnancy, or plans to become pregnant; hypersensitivity reaction
	  ▪ Liver disease as unexplained aminotransferase values >3 times above upper normal range confirmed on repeat testing
	• Documented adequate trial, intolerance or contraindication to ezetimibe unless patient requires >25% LDL reduction
	• The patient must have documented contraindication, allergy, history of adverse events, or tried and failed an appropriate dose of evolocumab (Repatha) AND alirocumab (Praluent).
	• Patient receiving maximally tolerated statin therapy (see additional criteria below)
	  ○ Lerochol only indicated as an adjunct to diet and maximally tolerated statin therapy. Monotherapy with Lerochol may be considered for secondary prevention if the patient has tried/failed or is intolerant to statins + ezetimibe and is defined as being at **very high risk**** for recurrent ASCVD event.
	• NOT given in combination with a PCSK9 inhibitor (e.g., Repatha (evolocumab), Praulent (alirocumab), Leqvio (inclisiran)), Nexletol (bempedoic acid), Juxtapid (lomitapide), or LDL apheresis
	•

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	*Clinical ASCVD includes: Acute coronary syndrome: Myocardial infraction, Stable or unstable angina, Coronary or other arterial revascularization procedures (e.g., PTCA, CABG), Transient ischemic attack (TIA), Peripheral arterial disease presumed to be of atherosclerotic origin, Findings from CT angiogram or catheterization consistent with clinical ASCVD **Very High risk defined per 2018 AHA Blood Cholesterol Guidelines**:** Multiple ASCVD events OR one ASCVD event AND multiple very high-risk conditions. High risk conditions defined as: Age ≥ 65 years, heterozygous or homozygous familial hypercholesterolemia, history of prior coronary bypass surgery or percutaneous coronary intervention outside of the major ASCVD event, diabetes mellitus, HTN, eGFR 15-59 mL/min/1.72m^2, current smoker, LDL of ≥100 mg/dL, or congestive heart failure. ∞NOTE: [MRAR ≥ 80% for ≥ 3 months. If MRAR < 80%, reviewer can confirm adherence in the last 3 months based on medication sold dates found in Health Connect medication tab (e.g., 3 one-month fills or one 90-day fills)] Initial Approval: 3 months. Patient must obtain LDL after 3 months of therapy. (This lab should be ordered when initiating therapy) Continued Approval: 12 months. Continue approval if the following criteria are met based on 3-month LDL: • Documented LDL lowering by ≥30% from starting Lerochol therapy AND • Per 2018 AHA guidelines, if patient has 2 consecutive LDL readings <25, use clinical judgment on whether therapy should be continued with Lerochol For new members who were initiated on Lerochol outside of KPGA: Approve Lerochol if patient has documented contraindication, intolerance, or self-administration issues to Repatha and Praluent and is confirmed to be clinically stable on Lerochol by a Specialist in the last 6 months.

Leuprolide Products
 	
Fensolvi (Leuprolide Acetate)
 	
Lupron Depot-Ped 7.5 mg (1-month), 11.25 mg (3-month), 30 mg (3-month), 45 mg (6-month) (Leuprolide Acetate)
	Candidates for Leuprolide Products (Fensolvi and Lupron Depot-Ped) should meet ALL the following criteria:
	• Prescribed by Pediatric Endocrinologist. Pediatric Endocrinology referral approved by KPGA.
	• Diagnosis of central precocious puberty confirmed by ALL of the following:
	  ○ Measurement of blood concentrations of total sex steroids (estrogens/testosterone)
	  ○ Measurement of LH and FSH after stimulation with a GnRH analog
	  ○ Assessment of bone age vs. chronological age
	• Failed (failure defined as the inability to suppress physical signs of puberty), intolerant, or allergic to Lupron Depot AND Eligard.
	• Age ≥ 2 years and < 13 years
	• If request is for coverage of Lupron Depot-Ped:
	  ○ Do not approve for coverage/use if documented treatment failure or intolerance to Lupron Depot by AbbVie Inc. Lupron Depot is identical in composition of both active and inactive ingredients and release mechanisms as Lupron Depot-Ped. Both Lupron Depot and Lupron Depot-Ped have the same needle gauge and

Drug	Prior Authorization Criteria

	length.
	• If request is for coverage of Fensolvi:
	  ○ Do not approve for coverage/use if documented treatment failure or intolerance to Eligard by Tolmar Pharmaceuticals, Inc. Eligard has the same concentration of active ingredient and drug delivery system as Fensolvi. There are no pharmacological differences between Eligard and Fensolvi.
	
	Initial Approval Duration: 12 months
	
	Continued Approval: 12 months if patient meets the following requirements:
	• Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in growth velocity and bone age advancement, and improvement in final height prediction.
	• Absence of unacceptable toxicity from the drug. (i.e convulsions, development or worsening of psychiatric symptoms, etc.).
	• Will not be used in combination with growth hormone.
	• Patient is less than 13 years of age.
	
	Dosing and Administration:
	• Fensolvi
	  ○ Administer 45 mg subcutaneously once every six months.
	  ○ Must be administered by a healthcare professional
	• Lupron Depot-Ped:
	  ○ Fixed dosing: IM 7.5 mg every 4 weeks; titrate as needed
	  ○ Weight-directed dosing: as per packaging
	  ○ Must be administered by a healthcare professional
	
	Monitoring:
	• LH, FSH, estradiol, or testosterone (after 1 month then as needed to confirm adequate suppression of pituitary gonadotropins, sex steroids, and progression of secondary sexual characteristics); height, bone age (every 6-12 months); tanner staging

Lifyorli (Relacorilant)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** **Candidates for treatment with Lifyorli (relacorilant) should meet ALL of the following criteria:** • Prescribed by an oncologist • Patient is 18 years of age or older • Documented diagnosis of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma • Documented disease progression within 6 months of prior platinum-based therapy

Drug	Prior Authorization Criteria
	• Documented receipt of <u>at least one</u> prior systemic treatment regimens including at least one previous bevacizumab-containing regimen, unless patient has a documented contraindication or intolerance to bevacizumab • Lifyorli will be used in combination with nab-paclitaxel (paclitaxel protein-bound) consistent with FDA labeling <u>Reasons for non-coverage:</u> • Concurrent systemic glucocorticoid therapy for a lifesaving indication (e.g., immunosuppression after organ transplantation) <u>Initial Approval:</u> 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** <u>Continued Approval:</u> 12 months. Confirm patient meets all above criteria without reasons for non-coverage. In addition, patient should meet the following: • No evidence of disease progression or unacceptable toxicity. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**

Lipfendra
(enlicitide)
	Candidates for treatment with Lipfendra should meet ALL the following criteria PLUS the individual disease state criteria that follow:
	
	• Prescribed by cardiologist or endocrinologist
	• Documented adequate trial of maximally tolerated statin (at least 3 months) or intolerance or contraindication, must meet **one** of the following:
	  ○ Currently prescribed high intensity statin (atorvastatin 40 or 80 mg OR rosuvastatin 20 or 40 mg). Check MRAR∞
	  ○ Currently prescribed maximally tolerated statin. Check MRAR∞
	  ○ Previously prescribed atorvastatin, rosuvastatin, and 1 additional statin, including an attempted alternative dosing regimen (e.g. every-other day or twice weekly). Check med history when available.
	  ○ Provider attestation and documentation that patient is unable to take statin due to **one** of the following:
	  ▪ History of CPK > 10xULN or rhabdomyolysis attributed to a statin and not explained by a drug interaction, fall or prolonged immobility
	  ▪ Acute liver failure or decompensated cirrhosis; nursing female, pregnancy, or plans to become pregnant; hypersensitivity reaction
	  ▪ Liver disease as unexplained aminotransferase values >3 times above upper normal range confirmed on repeat testing
	• Currently prescribed ezetimibe 10 mg daily or documented adequate trial, intolerance or contraindication, unless statin intolerant. Check MRAR∞. NOTE: if patient has a statin

Drug	Prior Authorization Criteria
	intolerance or contraindication, patient does not require ezetimibe prior to use of PCSK9 inhibitor (e.g. Repatha, Praluent) as there is limited data supporting ezetimibe monotherapy. • Inadequate response (trial of at least 3 months), intolerance or contraindication to one PCSK9 (e.g., Repatha, Praluent) • NOT given in combination with another PCSK9 inhibitor (e.g. Repatha, Praluent, Leqvio), Lerochol (lerodalcibep-liga), Evkeeza (evinacumab-dgnb), Juxtapid (lomitapide), or LDL apheresis • Then follow the disease state specific criteria below, based on diagnosis: **Diagnosis of Atherosclerotic Cardiovascular Disease (ASCVD)** • Age 40-75 years • Diagnosis of ASCVD, demonstrated as **one** of the following: acute coronary syndrome, myocardial infarction, stable or unstable angina, coronary or other arterial revascularization procedure (such as PTCA, CABG), stroke, transient ischemic attack (TIA), or peripheral arterial disease • PCSK9 pretreatment LDL is elevated drawn within the past 3 months and on maximally tolerated statin and ezetimibe therapy or contraindication or intolerance ○ Not high-risk ASCVD: LDL ≥ 70 mg/dL ○ Very high-risk ASCVD*: LDL ≥ 55 mg/dL *Very High risk defined per 2026 AHA Guideline on Management of Dyslipidemia**:** Multiple ASCVD events OR one ASCVD event AND 2 or more high-risk features. High risk conditions defined as: age ≥ 65 years, coronary bypass, percutaneous coronary intervention outside of the major ASCVD event, current smoker, diabetes mellitus, heart failure, hypertension, LDL of ≥100 mg/dL despite maximally tolerated statin plus ezetimibe. **Diagnosis of Familial Hypercholesterolemia** • Age ≥ 18 years • Genetic confirmation of heterozygous familial hypercholesterolemia (HeFH) • PCSK9 pretreatment LDL ≥ 100 mg/dL drawn within the past 3 months and on maximally tolerated statin and ezetimibe therapy or contraindication or intolerance **Diagnosis of Severe Primary Hypercholesterolemia** • Age ≥ 18 years • Documented severe primary hypercholesterolemia, demonstrated by history of LDL ≥ 190 mg/dL • PCSK9 pretreatment LDL ≥ 100 mg/dL drawn within the past 3 months and on maximally tolerated statin and ezetimibe therapy or contraindication or intolerance ∞NOTE: MRAR ≥ 80% for ≥ 3 months. If MRAR < 80%, reviewer can confirm adherence in the last 3 months based on medication sold dates found in Health Connect medication tab (e.g., 3 one-month fills or one 90-day fills). Adherence can be reviewed via KPHC with the dot phrase **.mrar**

Drug	Prior Authorization Criteria
	Initial Approval: 12 months. Patient must obtain LDL after at least 3 months of therapy. (This lab should be ordered when initiating therapy). Continued Approval: Indefinite. Continue approval if the following criteria are met: For new members who were initiated on Lipfendra outside of KPGA: Confirm patient meets all medication trials in the initial coverage criteria and has a documented clinically significant benefit from the medication during specialist follow-up in the last 12 months. For existing members who have previously met the full criteria above: • Documented LDL lowering by ≥30% or at designated LDL goal since starting Lipfendra

Litfulo
(Ritlecitinib)
	For the treatment of Alopecia Areata:
	• Prescribed by a dermatologist
	• Age ≥ 12 years
	• Documented diagnosis of severe or very severe alopecia areata (AA) defined by:
	  ○ At least 50% hair loss as documented by provider AND
	  ○ No spontaneous improvement in hair loss over the past 6 months
	• Documented trial, contraindication, or inadequate response (after at least 4 months) to:
	  ○ All of the following:
	  ▪ Topical corticosteroid
	  ▪ Intralesional corticosteroid injections
	  ▪ Oral corticosteroid
	AND
	  ○ One of the following: Topical immunotherapy (ie. Squaric acid dibutyl ester (SADBE)), topical anthralin OR an oral immunomodulator (mtx, azathioprine, cyclosporine)
	AND
	  ○ Preferred oral JAK inhibitor [e.g., tofacitinib] (off-label)
	
	Reasons for Non-coverage:
	• Other forms of alopecia
	• Pregnant or breast-feeding
	• Active tuberculosis (TB), latent TB infection or other active infection
	
	Initial Approval Period: 6 months
	
	Continued Approval Period: 12 months if the following criteria are met:
	
	For new members who were initiated on Litfulo prior to joining KP: approve medication if the patient has tried and failed the preferred JAK inhibitor tofacitinib
	
	For existing member who have previously met the full criteria above: approve medication if physician documentation of improvement in scalp hair coverage from baseline (initiation of Litfulo)

Livdelzi (Seladelpar)	**Candidates for treatment with Livdelzi (seladelpar) should meet ALL the following criteria:**

Drug	Prior Authorization Criteria

	• Prescribed by a Gastroenterologist or Hepatologist
	• Age ≥ 18 years
	• Diagnosed with primary biliary cholangitis (PBC) as confirmed by at least TWO of the following criteria:
	  ○ An elevated alkaline phosphatase (ALP) level of > 147 U/L
	  ○ Presence of antimitochondrial antibodies (AMA) OR other PBC-specific autoantibodies, including sp100 or gp210, if AMA is negative
	  ○ Histologic evidence (obtained by liver biopsy) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts
	• Documented inadequate response (of a trial at least ≥ 1 year), intolerance, or contradiction to ursodiol (ursodeoxycholic acid) monotherapy
	• Livdelzi (seladelpar) will be used in combination with ursodiol (ursodeoxycholic acid) **OR** patient has documented intolerance or contraindication to tolerate ursodiol (ursodeoxycholic acid)
	• Do not approve in the following cases:
	  ○ Complete biliary obstruction
	  ○ Presence of or a history of decompensated cirrhosis (i.e., Child-Pugh score B or C)
	  ○ History of a hepatic decompensated event (e.g., ascites, gastroesophageal varices, variceal bleeding, hepatic encephalopathy and coagulopathy)
	  ○ Active compensated cirrhosis with evidence of portal hypertension
	  ○ For use in combination with any other second-line PBC treatments [e.g., Iqirvo (elafibranor)]
	
	Initial Approval Period: 6 months
	
	Continued Approval Period: 12 months if patient meets ALL the initial criteria above and the following:
	• Patient has an alkaline phosphatase (ALP) level that is less than 1.67-times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Livdelzi

Livmarli
(Maralixibat)
	Candidates for Livmarli should meet ALL of the following criteria:
	
	Criteria for cholestatic pruritis associated with Alagille Syndrome (ALGS):
	• Age ≥ 3 months and ≤ 18 years at initiation of therapy
	• Prescribed by Pediatric Hepatologist or Pediatric Gastroenterologist
	• Diagnosis of Alagille syndrome (ALGS) confirmed with genetic testing demonstrating one of the following:
	  ○ JAG1 gene mutation
	  ○ Notch2 gene mutation
	• Documented moderate to severe pruritis
	• Evidence of cholestasis demonstrated by at least one of the following:
	  ○ Total serum bile acid > 3 times upper limit of normal (ULN) for age
	  ○ Conjugated bilirubin > 1mg/dL

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ Fat-soluble vitamin deficiency otherwise unexplainable ○ Gamma-glutamyl transferase (GGT) > 3 times ULN for age ○ Intractable pruritus explainable only by liver disease • Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to Ursodiol (ursodeoxycholic acid) **and** TWO of the following therapies (indicated for symptomatic relief only of pruritis): ○ Cholestyramine (3-month trial) ○ Rifampin (3-month trial) ○ Naltrexone (3-month trial) Reasons for non-coverage: • Diagnosis of portal hypertension • Decompensated cirrhosis or decompensated hepatic events (e.g., variceal hemorrhage, ascites and hepatic encephalopathy) • Prior liver transplant • Chronic diarrhea requiring ongoing IV fluid or nutritional intervention • History of surgical interruption of enterohepatic circulation Criteria for cholestatic pruritis associated with progressive familial intrahepatic cholestasis (PFIC): • Age ≥ 5 years • Prescribed by Hepatologist or Gastroenterologist • Diagnosis of progressive familial intrahepatic cholestasis (PFIC) type 1 or type 2 confirmed by genetic testing ○ For PFIC type 2, member does not have ABCB11 gene variants resulting in nonfunctional or complete absence of the bile salt export pump protein (BSEP3); • Documented moderate to severe pruritis • Total serum bile acid concentration ≥ 100mcmol/L • Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to Ursodiol (ursodeoxycholic acid) **and** TWO of the following therapies (indicated for symptomatic relief only of pruritis): ○ Cholestyramine (3-month trial) ○ Rifampin (3-month trial) ○ Naltrexone (3-month trial) • Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to Bylvay (odevixibat) dosed at 40-120mcg/kg/d once daily Reasons for non-coverage: • Patients with PFIC type 2 subgroup with specific ABCB11 variant resulting in non-functional or complete absence of bile salt export pump (BSEP) protein Initial approval: 6 months Continued approval: 12 months if the patient meets ALL the following: • Member continues to meet above criteria • Documentation of the one of the following: ○ A decrease in pruritis from baseline. ○ A decrease in serum bile acid concentration

Drug	Prior Authorization Criteria
Livtencity (Maribavir)	**Candidates for Livtencity should meet ALL of the following criteria:** • Age ≥ 12 years and body weight ≥ 35 kg • Patient has received hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT) • Prescribed by Transplant Specialist, Infectious Disease Specialist or Oncologist • Diagnosis of post-transplant CMV infection/disease that is refractory to treatment with ganciclovir, valganciclovir, foscarnet, or cidofovir • Patient will be monitored for clinically significant drug interactions that could result in decreased therapeutic effect of maribavir Reasons for Non-coverage: • Concurrent treatment with other CMV antivirals (i.e., ganciclovir, valganciclovir, foscarnet, or cidofovir) • Coadministration with select strong CYP3A4 inducers (i.e., rifabutin, rifampin or St. John's wort) Initial Approval: 8 weeks (Note: 8 weeks is the total recommended treatment course) Continued Approval: Not Applicable
Loargys (Pegzilarginase-nbln)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** **Candidates for treatment with Loargys (pegzilarginase-nbln) should meet ALL the following criteria:** • Prescribed by a metabolic disease specialist or neurologist • Patient is ≥2 years of age • Documented diagnosis of arginase 1 deficiency (ARG1-D). Documentation may include either of the following biochemical evidence: a. Persistently elevated plasma arginine (pArg) levels b. Pathogenic variants in ARG1 c. Diminished erythrocyte ARG1 activity • Patient will use Loargys in conjunction with a protein-restricted diet Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: 12 months. • Continued approval for treatment with Loargys should demonstrate: o Beneficial response as documented by pArg levels 40–115 µmol/L

Drug	Prior Authorization Criteria
	○ Continued use of protein-restricted diet • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
Lodoco (Colchicine 0.5 mg) **Preferred Formulary Agent:** Colchicine 0.6 mg Colchicine 0.6 mg daily x 7 days = 4.2 mg/week Colchicine 0.5 mg daily x 7 days = 3.5 mg / week	Candidates for Lodoco should meet ALL the following criteria: • Prescribed by cardiology • Age ≥ 18 years • Documented diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD)* • Currently prescribed or adequate trial of at least 3 months on maximally tolerated dose of high intensity statin or alternative lipid lowering therapy (e.g., ezetimibe) if statin intolerant unless other intolerance or contraindication • BP <130/80 on maximally tolerated dose of ACE I/ARB (e.g., lisinopril, losartan) unless intolerance or contraindication • Currently prescribed aspirin or other antiplatelets (e.g., ticagrelor, clopidogrel) unless intolerance or contraindication. • Inadequate treatment response to an adequate trial of at least 3 months of colchicine 0.6 mg tablet unless intolerance or allergic reaction that is likely due to the **inactive** components of the generic medication and cannot be explained by other clinical or lifestyle factors. ○ If the request for coverage of Lodoco is based upon disease progression or side effects due to the active ingredient colchicine (e.g., GI issues including diarrhea and nausea/vomiting, myalgia, hair loss, etc) the request will be denied unless member meets the full criteria. ○ To reduce colchicine exposure symptoms, physician may consider reducing colchicine dose to 0.6mg 6 days per week (ie. Monday – Saturday), not taking colchicine one day per week (ie. on Sunday). ○ If the physician's request for coverage of Lodoco is based upon the physician's and/or member's unwillingness to change to a preferred alternative, the request will be denied unless the member meets the full criteria. • Recent labs (in the past 4 wks) ○ CrCl ≥ 50 ml/min ○ AST/ALT within normal range Initial Approval: 12 months Continued Approval: 12 months. Patient must meet all criteria above without reasons for non-coverage and prescriber attestation of patient demonstrating positive clinical response to therapy.
Loqtorzi (Toripalimab-tpzi)	**Candidates for treatment with Loqtorzi must meet ALL the following criteria:** • Age ≥ 18 years • Prescribed by Hematology/Oncology • Patient has a diagnosis of nasopharyngeal carcinoma (NPC)

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	• Used as first-line therapy for adult with metastatic or with recurrent locally advanced NPC disease in combination with cisplatin and gemcitabine OR
	• Used as a single agent for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum containing chemotherapy
	
	Initial Approval: 12 months. Approve for KP clinic/back-office administration OR KP home infusion program ONLY. **Do not approve for administration outside of KP facilities.**
	
	Continued Approval: 12 months. Approve for KP clinic/back-office administration OR KP home infusion program ONLY. **Do not approve for administration outside of KP facilities.**
	
	Continued approval for treatment with Loqtorzi should meet ALL of the criteria above in addition to the criteria below:
	• Patient does not show evidence of progressive disease while on Loqtorzi therapy
	• Absence of significant toxicity (e.g., ocular disorders, myocarditis, grade 4 immune-mediated reactions, etc)
	• Continued monitoring by Hematology/Oncology
	• Approve for KP clinic/back-office administration OR KP home infusion program ONLY. **Do not approve for administration outside of KP facilities.**
	
	Dosing and Administration:
	• Combination therapy with cisplatin and gemcitabine (first line NPC)
	  ○ 240 mg IV every three weeks
	  ○ Continue up to 24 months.
	• Single agent (recurrent NPC)
	  ○ 3 mg/kg IV every two weeks
	  ○ Continue until disease progression or unacceptable toxicity.

Lorbrena
(Lorlatinib)
	Candidates for Lorbrena should meet ALL the following criteria:
	
	• Prescribed by an oncologist.
	• Age ≥ 18 years
	• Patient has a diagnosis of advanced, recurrent, or metastatic non-small cell lung cancer.
	• Patient has ONE of the following:
	  ○ Disease is ALK-rearrangement positive AND patient has a documented failure, intolerance, or contraindication to alectinib (Alecensa)
	  ○ Disease is ROS-1 rearrangement positive AND patient has a documented failure, intolerance, or contraindication to entrectinib (Rozlytrek) OR repotrectinib (Augtyro)
	
	Initial Approval: 12 months
	• The following quantity limits apply:
	  ○ For 100 mg tablets, 30 tablets per 30 days
	  ○ For 25 mg tablets, 90 tablets per 30 days

Drug	Prior Authorization Criteria

	Continued Approval: 12 months. For continued approval for treatment with Lorbrena, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria.
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	• The following quantity limits apply:
	  ○ For 100 mg tablets, 30 tablets per 30 days
	  ○ For 25 mg tablets, 90 tablets per 30 days
	
	For new members who were initiated on Lorbrena outside of KPGA:
	• Prescribed by an oncologist.
	• Age ≥ 18 years
	• Patient has a diagnosis of advanced, recurrent, or metastatic non-small cell lung cancer that is ALK-rearrangement positive or ROS-1 rearrangement positive.
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	• The following quantity limits apply:
	  ○ For 100 mg tablets, 30 tablets per 30 days
	  ○ For 25 mg tablets, 90 tablets per 30 days

Lumakras
(Sotorasib)
	Candidates for Lumakras should meet ALL the following criteria:
	
	• Age ≥ 18 years
	• Prescribed by an Oncologist
	• Patient has a diagnosis of ONE of the following:
	  a. Locally advanced or metastatic non-small cell lung cancer (NSCLC)
	  b. Metastatic colorectal cancer (mCRC)
	• Patient has KRAS G12C-mutated disease
	• Patient has been previously treated with at least one systemic regimen:
	NOTE: examples of systemic therapy include those containing one or more of the following products: Keytruda (pembrolizumab), Opdivo (nivolumab), Tecentriq (atezolizumab), Alimta (pemetrexed), Yervoy (ipilimumab), Abraxane (albumin-bound paclitaxel), bevacizumab, cisplatin, carboplatin, docetaxel, fluoropyrimidine, gemcitabine, irinotecan, oxaliplatin, paclitaxel, vinorelbine
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage in addition to criteria below:
	
	• Member is responding positively to therapy and does not show evidence of progressive disease while on therapy

Lumryz (Sodium Oxybate)	**Candidates for treatment with Lumryz should meet ALL the following criteria:** • Prescribing restricted to sleep specialists AND

Drug	Prior Authorization Criteria

	• Patient is not currently drinking alcohol or have a current substance abuse comorbidity (12 months of full remission) or currently taking sedative hypnotic agents AND
	• Patient is negative for succinic semialdehyde dehydrogenase deficiency if clinical suspicion exists for inborn errors in metabolism AND
	• Documented trial and failure of sodium oxybate (generic Xyrem)
	• Documented diagnosis of cataplexy associated with narcolepsy OR excessive daytime sleepiness associated with narcolepsy
	  ○ If diagnosed with excessive daytime sleepiness associated with narcolepsy, patient must have documentation of all the following:
	  ▪ Patient has Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
	  ▪ Patient's self-reported sleep log demonstrates adequate sleep opportunity per Sleep Specialist (7 to 9 hours for most patients)
	  ○ Documented trial and failure of, or contraindication to at least three wake promoting agents or stimulants i.e., maximum tolerated dose of modafinil, traditional wake-promoting agent (e.g., amphetamine sulfate, methylphenidate, etc.) AND solriamfetol (Sunosi) If diagnosed with cataplexy associated with narcolepsy, patient must have documentation of the following:
	  ▪ Patient has tried and failed venlafaxine and at least one other agent for the treatment of cataplexy such as an SSRI (e.g., fluoxetine) or trial of pitolisant (Wakix) prior to KP. ***Note:** sodium oxybate (generic Xyrem) is preferred to Wakix at KP
	  ○ If diagnosed with idiopathic hypersomnia, must have documentation of the following:
	  ▪ Patient's self-reported sleep log demonstrates adequate sleep opportunity per Sleep Specialist (7 to 9 hours for most patients)
	  ▪ Trial and failure of, or contraindication to at least three wake promoting agents or stimulants (i.e maximum tolerated dose of modafinil, methylphenidate, dextroamphetamine, and amphetamines)
	
	<u>Initial Approval:</u> 12 months
	
	<u>Continued Approval:</u> 12 months if the following criteria are met:
	
	<u>For new members initiated on sodium oxybate outside of KPGA:</u>
	
	• Documented beneficial effect from therapy during sleep specialist follow up in the last 6 months AND
	• Documented trial and failure of sodium oxybate (generic Xyrem)
	• For narcolepsy with EDS and idiopathic hypersomnia, patient has a history of trial and failure of at least three wake- promoting agents or stimulants (e.g., amphetamine-dextroamphetamine, methylphenidate, modafinil or armodafinil) OR
	• For narcolepsy with cataplexy, patient has a history of trial and failure of venlafaxine

Drug	Prior Authorization Criteria
	For existing members who have previously met the full criteria above: approve if documented beneficial effect from therapy during sleep specialist follow up in the last 6 months. Ordering/Availability: Prescriber and patient enrollment required via the LUMRYZ REMS Program

Lunsumio (Mosunetuzumab-axgb)
 	
Lunsumio Velo (Mosunetuzumab-axgb)
	Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.
	
	Candidates for treatment with Lunsumio or Lunsumio Velo (Mosunetuzumab-axgb) should meet ALL the following criteria:
	• Prescribed by a hematologist or oncologist
	• Age ≥ 18 years
	• Diagnosis of
	  ○ Relapsed or refractory follicular lymphoma AND has previously received AT LEAST 2 lines of systemic therapy including:
	  ▪ An anti-CD20 monoclonal antibody (e.g., rituximab, obinutuzumab, etc)
	  ▪ An alkylating agent (e.g., bendamustine, cyclophosphamide)
	  OR
	  ○ Relapsed or refractory Mantle Cell Lymphoma AND patient has previously received a prior covalent BTKi (e.g.,: Ibrutinib, Acalabrutinib, Zanubrutinib etc.) AND medication is being used in combination with polatuzumab vedotin
	  OR
	  ○ Diagnosis of relapsed or refractory diffuse large B-Cell Lymphoma (DLBCL) AND disease has relapsed in <12 months and is not eligible for transplant OR disease has relapsed in >12 months and is not eligible for CAR-T. AND The patient has not received polatuzumab vedotin in the past AND medication is being used in combination with polatuzumab vedotin.
	
	Approval: 8 cycles. Treatment should not be continued if patient demonstrates complete response after 8 cycles of treatment.
	• Cycle 1 may be approved for administration at a KP-affiliated inpatient facility.
	• Subsequent cycles should be approved for back-office administration in a KP-infusion center ONLY.
	• **NOTE:** If patient experiences a treatment delay >14 days, an additional cycle may be approved for administration at a KP-affiliated inpatient facility for therapy re-initiation.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	
	Continued Approval: 9 cycles (for a total of *up to* 17 cycles). For continued approval for treatment, provider must document/attest to partial response to therapy or stable disease after 8 cycles.
	• **Approve for back-office administration in a KP-infusion center ONLY.**
	  ○ **NOTE:** If patient experiences a treatment delay >14 days, an additional cycle may be approved for administration at a KP-affiliated inpatient facility for therapy re-initiation.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**

***Does not apply to Medicare Benefit**

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>Dosing and Administration:
Mosunetuzumab IV Dosing Schedule[a,b] (21-Day Treatment Cycles)<table><tr><th>Cycle number</th><th>Day of treatment</th><th>Mosunetuzumab IV dose</th><th>Infusion duration</th></tr><tr><td rowspan="3">Cycle 1</td><td>Day 1</td><td>1 mg</td><td>At least 4 hours</td></tr><tr><td>Day 8</td><td>2 mg</td><td>At least 4 hours</td></tr><tr><td>Day 15</td><td>60 mg</td><td>At least 4 hours</td></tr><tr><td>Cycle 2</td><td>Day 1</td><td>60 mg</td><td rowspan="2">Infuse over 2 hours if cycle 1 infusions were well-tolerated</td></tr><tr><td>Cycle 3 and beyond[a]</td><td>Day1</td><td>30 mg</td></tr></table>[a] Administer for 8 cycles (in the absence of disease progression or unacceptable toxicity); no further treatment is required after 8 cycles if complete response is achieved. For patients achieving a partial response or with stable disease in response to treatment after 8 cycles, an additional 9 cycles (for a total of 17 cycles) should be administered (in the absence of disease progression or unacceptable toxicity).

Mosunetuzumab SUBQDosing Schedule[a,b] (21-Day Treatment Cycles)<table><tr><th>Cycle number</th><th>Day of treatment</th><th>Mosunetuzumab SUBQ dose</th></tr><tr><td rowspan="3">Cycle 1</td><td>Day 1</td><td>5 mg</td></tr><tr><td>Day 8</td><td>45 mg</td></tr><tr><td>Day 15</td><td>45 mg</td></tr><tr><td>Cycle 2 and beyond</td><td>Day 1</td><td>45 mg</td></tr></table>[a] Administer for 8 cycles (in the absence of disease progression or unacceptable toxicity); no further treatment is required after 8 cycles if complete response is achieved. For patients achieving a partial response or with stable disease in response to treatment after 8 cycles, an additional 9 cycles (for a total of 17 cycles) should be administered (in the absence of disease progression or unacceptable toxicity).</td></tr>
<tr><td>Lupkynis
(Voclosporin)</td><td>Candidates for treatment with Lupkynis should meet ALL the following criteria:

• Prescribed by a Nephrologist or Rheumatologist
• Age ≥ 18 years
• Kidney biopsy confirmed lupus nephritis of class III (focal lupus nephritis) or class IV (diffuse lupus nephritis) or class V (membranous lupus nephritis).
• Prescribed in combination with background immunosuppressive regimen mycophenolate mofetil (MMF) with or without corticosteroids.
• Patient has no history of kidney transplant.

Reasons for Non-coverage:
• Use in combination with cyclophosphamide
• Use in combination with belimumab (Benlysta)
• Documented baseline eGFR ≤45 mL/min/1.73 m^2
• Documented baseline BP >165/105 mmHg or with hypertensive emergency
• Use with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin)
• Severe hepatic impairment (Child-Pugh Class C)
• Pregnancy
• Diagnosed pure red cell aplasia (PRCA)

Initial Approval: 6 months

Continued Approval: 6 months. Patient continues to meet all criteria listed above in addition to the following:</td></tr>
</table>

Drug	Prior Authorization Criteria
	Approve if confirmed adequate tolerance to medication during Nephrologist or Rheumatologist follow up in the last 6 months and repeat eGFR measurement in the last 2 months. For new members who were initiated on Lupkynis outside of KPGA: Approve if confirmed history of lupus nephritis per biopsy or lab markers and adequate tolerance to medication during Nephrologist or Rheumatologist follow up in the last 3 months and eGFR measurement in the last 2 months. Ordering Information: • Lupkynis can be ordered via PANTHERx Rare Specialty Pharmacy or Biologics by McKesson
Luxturna (Voretigene neparvovec-rzyl [VN])	**Candidates for treatment with Luxturna should meet ALL the following criteria:** **Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).* • Prescribed by a retinal specialist • Genetic diagnosis of biallelic RPE65 gene mutations documented in the medical record. Retinal dystrophy panel may be ordered by the retinal specialist with confirmation of diagnosis by a geneticist. • Sufficient viable retinal cells defined as having any of the following: a. an area of retina within the posterior pole of >100 µm on optical coherence tomography (OCT) b. ≥3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole based on ophthalmoscopy c. remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent Reasons for Non-coverage: • Age < 12 months. There is potential for dilution or loss of VN effect after administration due to the active retinal cells proliferation in this age group. • No light perception (NLP) on exam • Intraocular surgery within past 3 months • Prior gene therapy administered to the intended eye Initial Approval: ONE TIME TREATMENT PER EYE. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: Not applicable. Repeat treatment is considered investigational and is not recommended outside of enrollment in a clinical trial. Administration: • Surgical suite for performing intraocular surgery under general anesthesia.

Drug	Prior Authorization Criteria
	• **VN is currently only available from select Ocular Gene Therapy Centers identified by the manufacturer. KP members who are deemed appropriate for VN administration will be referred out to these centers of excellence.**

Lynavoy
(Linerixibat)
	Candidates for treatment with Lynavoy should meet ALL the following criteria:
	• Prescribed by a hepatologist or gastroenterologist
	• Age ≥ 18 years
	• Diagnosed with primary biliary cholangitis (PBC) as confirmed by at least TWO of the following criteria:
	  ○ An elevated alkaline phosphatase (ALP) level of > 147 U/L
	  ○ Presence of antimitochondrial antibodies (AMA) OR other PBC-specific autoantibodies, including sp100 or gp210, if AMA is negative
	  ○ Histologic evidence (obtained by liver biopsy) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts
	• Documented moderate to severe pruritus
	• Documented inadequate response (trial of at least 12 months), intolerance, or contraindication to Ursodiol (ursodeoxycholic acid) **and** TWO of the following therapies indicated for symptomatic relief of pruritus:
	  ○ Cholestyramine (3-month trial)
	  ○ Naltrexone (3-month trial)
	  ○ Rifampin (3-month trial)
	• Does not have decompensated cirrhosis or prior/active hepatic decompensation events such as variceal hemorrhage, ascites, or hepatic encephalopathy
	
	Initial Approval: 6 months
	
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	
	Continued Approval: 12 months. Continue approval if the following criteria are met:
	
	• Documented clinically significant improvement in pruritus at hepatologist or gastroenterologist follow-up
	
	For new members who were initiated on Lynavoy outside of KPGA: Confirm patient meets all above coverage criteria and has a documented clinically significant benefit from the medication during hepatologist or gastroenterologist follow-up in the last 12 months.
	
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	
	For existing members who have previously met the full criteria above: Documented clinically significant benefit from the medication during hepatologist or gastroenterologist follow up in the last 12 months
	
	• **Approve for member to fill via the outpatient pharmacy benefit only**

Lynkuet (Elinzanetant)	**Candidates for treatment with Lynkuet (elinzanetant) should meet ALL of the following criteria:** • Prescribed by an Ob-Gyn or Gynecologic Oncology Specialist

Drug	Prior Authorization Criteria

	• Diagnosis of moderate to severe menopausal vasomotor symptoms (VMS)
	• Patient experiences ≥ 7 hot flashes per day
	• Documented inadequate response, intolerance, and/or contraindication to hormonal therapy (e.g., Prempro [conjugated estrogen/medroxyprogesterone], estrogen)
	• Documented inadequate response, intolerance, and/or contraindication after at least a 1-month trial to **2** of the following (from different classes):
	  ○ Paroxetine* HCL, citalopram, OR escitalopram. *Paroxetine should not be administered to women with prior breast cancer taking tamoxifen.
	  ○ Venlafaxine ER
	  ○ Gabapentin
	  ○ Oxybutynin
	• Documented inadequate response, intolerance, and/or contraindication to Veozah (fezolinetant)
	• Lynkuet will NOT be used concurrently with another hormonal (e.g., Prempro [conjugated estrogen/medroxyprogesterone], estrogen) or non-hormonal (e.g., Veozah [fezolinetant], Brisdelle [paroxetine mesylate]) agent for VMS
	
	Reasons for non-coverage:
	• Pregnancy
	• Moderate to severe hepatic impairment (Child-Pugh B and C)
	• End stage renal disease (e.g. eGFR <15 mL/min) with or without hemodialysis
	
	Initial Approval: 4 months
	
	Continued Approval: 12 months. For continued approval for treatment, patient should meet ALL the following criteria:
	• Patient has had a reduction in VMS frequency or severity due to Lynkuet treatment
	
	For new members who were initiated on Lynkuet outside of KPGA:
	• Confirm patient is clinically stable and still has a need for VMS treatment by a specialist in the past 6 months AND meets all the medication trials in the criteria.

Lynozyfic
(Linvoseltamab-gcpt)
	Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval
	
	Candidates for treatment with Lynozyfic (linvoseltamab-gcpt) should meet ALL the following criteria:
	• Prescribed by a hematologist/oncologist certified through the Lynozyfic REMS program
	• Age ≥ 18 years
	• Documented diagnosis of relapsed or refractory multiple myeloma (RRMM)
	• Documented trial of at least FOUR prior lines of therapy, including at least ONE drug from each of the following categories:
	  ○ A proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib, etc)
	  ○ An immunomodulatory agent (e.g., lenalidomide, pomalidomide, thalidomide, etc)

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ An anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc) • Patient has not received an allogeneic or autologous stem cell transplant within the previous 12 weeks • Patient has not received prior treatment with any BCMA-directed CAR-T cell therapy ○ Examples of BCMA-directed CAR-T cell therapy include elranatamab-bcmm (Elrexfio), decabtagene vicleucel (Abecma), and teclistamab-cqyv (Tecvayli) Initial Approval: 6 months • Cycles 1 to 2 may be approved for administration at a KP-affiliated inpatient facility. • Subsequent cycles should be approved for back-office administration in a KP-infusion center ONLY. • NOTE: If patient experiences a treatment delay >14 days, an additional cycle may be approved for administration at a KP-affiliated inpatient facility for therapy re-initiation. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** Continued Approval: 12 months. Continue approval if the following criteria are met: • Patient continues to meet the above criteria • No evidence of unacceptable toxicity or disease progression • Approve for back-office administration in KP-infusion center ONLY. NOTE: If patient experience a treatment delay >14 days, an additional cycle may be approved for administration at a KP-affiliated inpatient facility for therapy re-initation. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** Ordering Information: • Lynozyfic is only available through the Lynozyfic Risk Evaluation and Mitigation Strategy (REMS) program which requires the participation of prescribers, patients, and pharmacies
Lytgobi (Futibatinib)	**Candidates for treatment with Lytgobi should meet ALL the following criteria:** • Age ≥ 18 years • Diagnosed unresectable, locally advanced, or metastatic intrahepatic cholangiocarcinoma (CCA) with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test • Prescribed by an Oncologist • Patient has received and failed prior systemic therapy (e.g., pembrolizumab + cisplatin + gemcitabine, cisplatin + gemcitabine, durvalumab + cisplatin + gemcitabine, mFOLFOX7 (fluorouracil + leucovorin + oxaliplatin), gemcitabine, capecitabine, capecitabine + gemcitabine, etc)) Reasons for Non-coverage: • Pregnancy or breast-feeding • History and/or current evidence of clinically significant non-tumor related alteration of calcium-phosphorus homeostasis

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• History and/or current evidence of clinically significant ectopic mineralization/calcification • History and/or current evidence of clinically significant retinal disorder Initial Approval: 12 months Continued Approval: 12 months if the patient meets criteria above and ALL the following: • No documented disease progression • Patient has not developed unacceptable toxicity (i.e severe diarrhea despite use of antidiarrheal agents and/or severe hyperphosphatemia (defined as serum phosphate > 7 mg/dL within 2 weeks following 2 dose interruptions and reductions)
Mavenclad (Cladribine)	**Candidates for treatment with Mavenclad should meet ALL the following criteria:** • Age ≥ 18 years • Documented diagnosis of relapsing-remitting multiple sclerosis or active secondary progressive multiple sclerosis • Prescribed by a neurologist • Females of childbearing age (12 to 50 years of age) should have a baseline negative pregnancy test within the past month AND agreement to be on two forms of reliable birth control (confirm order for IUD or another contraceptive) a. Males should be advised of the potential for fetal harm and advised to use contraception • Documented negative PPD (tuberculin) test or negative quantiferon blood test • Mavenclad is prescribed for use as monotherapy for treatment of MS • Documented persistent or severe intolerance or relative contraindication to rituximab product (Riabni is the preferred product if rituximab has never been tried). Reasons for Non-coverage: Mavenclad should NOT be used in patients with ANY of the following: • Lymphopenia (< 1000 cells/mm^3) at baseline • Concomitant immunosuppressive therapy • Pregnancy or lactation • Chronic infection including HIV, hepatitis or tuberculosis • CrCl < 60 ml/min • Moderate to severe hepatic impairment (Child Pugh score > 6) • Prior or current malignancy • Clinically isolated syndrome (CIS) Initial Approval Period: 12 months Continued approval: 12 months in the year following initial treatment course (year 2). For new members who were initiated on Mavenclad outside of KPGA: Approve Mavenclad if patient has had a visit with MS Specialist and confirmed to be stable on the therapy and safety screenings have been ordered or completed.

Drug	Prior Authorization Criteria
	For existing members who have previously met the full criteria: continued approval with Mavenclad should meet ALL the following criteria: • Documented beneficial effect from therapy during neurology follow up • Lymphocytes ≥ 800 cells/mm^3 • No documentation of malignancy (malignant, benign or unspecified)

Mavyret
(Glecaprevir/Pibrentasvir)
	Candidates for treatment with Mavyret (glecaprevir/pibrentasvir) should meet ALL the following criteria:
	
	Hepatitis C (HCV):
	
	• Prescribed by Gastroenterologist or Infectious Disease specialist
	• Documented Hepatitis C virus (HCV) infection demonstrated by detectable quantitative HCV RNA level in previous 12 months
	• Documented **one** of the following:
	  ○ Treatment-naïve patients with a documented intolerance or contraindication to sofosbuvir/velpatasvir (Epclusa authorized generic), such as clinically significant drug interactions or hypersensitivity
	  ○ Direct-acting antiviral (DAA)-experienced patients with a documented intolerance or contraindication to Vosevi (sofosbuvir/velpatasvir/voxilaprevir) such as clinically significant drug interactions or hypersensitivity)
	• Do not approve if documented decompensated cirrhosis [Child-Turcotte-Pugh (CTP) class B or C]
	
	Solid Organ Transplant (e.g., heart, lung, liver, and kidney):
	
	• Prescribed by a Transplant Specialist for solid organ transplant
	
	Initial Approval:
	For DAA-naïve patients, approve for 8 weeks
	For DAA-experienced patients, approve for 16 weeks
	
	Continued approval for new members who were initiated on Mavyret outside of KPGA: confirm diagnosed with hepatitis C and Mavyret initiation date. Approve for a total of 16 weeks.

Mayzent (Siponimod)	**Candidates for treatment with Mayzent should meet ALL the following criteria:** • Documented diagnosis of relapsing-remitting multiple sclerosis (RRMS) or active secondary progressive multiple sclerosis (active SPMS) • Prescribed by a neurologist • Documented baseline CYP2C9 genotype test, CBC with differential, ophthalmologic exam, LFTs, serum bilirubin, and EKG • Females of childbearing age (12 to 50 years) should have a baseline negative pregnancy test within the past month AND either a prescription for birth control (IUD or other contraceptive) or documentation of the patient declining contraception and being counseled of the potential risk of pregnancy.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	• Mayzent is being prescribed as monotherapy for treatment of MS
	• Documented trial and intolerance to fingolimod (Gilenya) that is expected to be reduced with siponimod (Mayzent)
	• Documented trial and intolerance to ozanimod (Zeposia) OR ponesimod (Ponvory) that is expected to be reduced with siponimod (Mayzent)
	• Documented clinical barrier, therapeutic failure or intolerance to rituximab product (Riabni is the preferred product if rituximab has never been tried).
	
	Reasons for Non-coverage:
	
	Mayzent should NOT be used in patients with ANY of the following:
	
	• CYP2C9*3/*3 genotype
	• Recent (within the past 6 months)
	  ○ MI
	  ○ Unstable angina
	  ○ Stroke
	  ○ TIA
	  ○ Decompensated HF requiring hospitalization
	  ○ Class III/IV HF
	• Mobitz type II second-degree or third-degree atrioventricular block (history or current), unless the patient has a functional pacemaker
	• Sick-sinus syndrome (history or current), unless the patient has a functional pacemaker
	• QTc interval at baseline 500 milliseconds or greater
	• Heart rate less than 55 bpm
	• Active or opportunistic infection
	• Macular edema or significant risk factors for macular edema (uveitis or uncontrolled diabetes), unless documentation that benefit of Mayzent outweighs risk
	• Pregnancy or lactation
	• Patients with uncontrolled hypertension
	• Concomitant Class Ia or Class III anti-arrhythmic drugs (beta-blockers, diltiazem, verapamil, quinidine, disopyramide, procainamide, amiodarone, dofetilide, ibutilide, dronedarone, sotalol)
	• Concomitant strong CYP2C9 inhibitors (e.g., fluconazole)
	
	Initial Approval Period: 12 months
	
	Continued Approval: 1 year.
	
	For new members who were initiated on Mayzent outside of KPGA: Approve Mayzent if
	
	• Patient has had a visit with neurologist preferably the MS Specialist
	• Patient has tried and failed the preferred alternatives rituximab AND fingolimod (Gilenya)
	• Patient is confirmed to be stable on the therapy and safety screenings have been ordered or completed.

Drug	Prior Authorization Criteria
	For existing members who previously met the full criteria: continued approval for treatment with Mayzent should meet ALL the following criteria: • Documented beneficial effect from therapy during neurology follow up • Documentation of at least one examination of the fundus of the eye or optical coherence tomography imaging test after therapy initiation (recommended 3-4 months after therapy initiation) • No documentation of malignancy (malignant, benign or unspecified)

Mektovi
(Binimetinib)
	Candidates for treatment with Braftovi PLUS Mektovi should meet ALL the following criteria:
	
	Diagnosis of Melanoma
	• Prescribed by a hematologist or oncologist.
	• Age ≥ 18 years
	• Patient has a diagnosis of advanced, metastatic, or unresectable melanoma.
	• Patient has ONE of the following:
	  ○ Cancer is positive for BRAF V600E or BRAF V600K mutations AND patient meets all the following:
	  • Patient has a documented treatment failure, intolerance, or contraindication to vemurafenib (Zelboraf) PLUS cobimetinib (Cotellic)
	  • Medication will be used in combination with encorafenib (Braftovi)
	  OR
	  ○ Cancer is positive for NRAS mutation AND Mektovi will be used as a single agent.
	
	Diagnosis of non-small cell lung cancer
	• Prescribed by a hematologist or oncologist.
	• Age ≥ 18 years
	• Patient has advanced or metastatic disease.
	• Cancer is positive for BRAFV600E mutation.
	• Patient has a documented treatment failure, contraindication or intolerance to dabrafenib (Tafinlar) PLUS trametinib (Mekinist), KP's preferred treatment, OR vemurafenib (Zelboraf) PLUS cobimetinib (Cotellic), KP's preferred alternative treatment.
	• Medication will be used in combination with encorafenib (Braftovi)
	
	Reasons for non-coverage:
	• Patient with wild-type BRAF melanoma, wild-type BRAF colorectal cancer, or wild-type BRAF NSCL
	
	Initial Approval: 12 months
	• The following quantity limits will apply: 180 tablets per 30 days.
	
	Continued Approval: 12 months. For continued approval for treatment with Tafinlar, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria.
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.

Drug	Prior Authorization Criteria

	• Quantity limit – 180 capsules / 30 days
	
	For new members who were initiated on Tafinlar outside of KPGA: Patient should meet ALL the following criteria:
	• Prescribed by a hematologist or oncologist.
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	• Patient meets ONE of the following:
	  ○ For BRAF mutation positive melanoma or NSCLC, medication will be prescribed in combination with encorafenib (Braftovi).
	  ○ For NRAS mutation melanoma, medication will be used as a single agent.

Metformin ER Products: **Preferred Formulary:** generic metformin and metformin SR – no PA required **QRM Metformin Products: PA Required** **Preferred QRM:** Fortamet (e.g., metformin ER [OSM] 24 HR or metformin HCL ER [MOD] 24 HR) **Non-Preferred QRM:** Glumetza (e.g., metformin ER [OSM] 24 HR or metformin HCL ER [MOD] 24 HR)	**Candidates for treatment with metformin HCL 500 mg, 1000 mg ER (generic and brand Glumetza, Fortamet) should meet ALL of the following criteria:** • Age ≥ 18 years • Type 2 diabetes diagnosis • Documented contraindication, intolerance to metformin and metformin SR. Metformin SR 500 mg should be titrated slowly, start metformin SR 500mg daily x7 days, then increase to bid. Should have documented adequate therapeutic trial to metformin SR (at least 3 months) • For Glumetza coverage: Must ALSO have documented contraindication, intolerance to Fortamet (preferred ER formulation) Initial Approval: 12 months Continued Approval: 24 months**.** Confirm patient meets all above criteria. In addition, continue approval based on: • Documented A1C lowering of 1% from initial A1C
Miplyffa (Arimoclomol)	**Candidates for treatment with Miplyffa should meet ALL the following criteria:** • Prescribed by or in consultation with a neurologist or geneticist • Diagnosed with Niemann-Pick disease type C (NPC) • Documented genetic testing showing pathogenic variants in either the NPC1 gene OR NPC2 gene • Age ≥ 2 years • Used in combination with miglustat (Zavesca) • Patient is NOT taking Aqneursa (levacetylleucine) Reasons for Non-coverage: • Females who are pregnant or plan to become pregnant Initial Approval: 6 months with quantity limit of 3 tablets per day.

Drug	Prior Authorization Criteria
	Ordering Information: • Miplyffa is sent directly to patients through Zevra Therapeutics, Inc. specialty pharmacy. • Enrollment form is downloaded from MIPLYFFA.com. • Completed form is sent to AmplifyAssist to initiate prescription.
Mirvaso Gel (Brimonidine)	**Candidates for treatment with Mirvaso should meet ALL the following criteria:** • For topical treatment of rosacea with erythema • Age ≥ 18 years • Prescribed by a dermatologist • Intolerant/contraindication or did not have a documented adequate response to all of the following alternatives after at least an 8-week course of therapy: a. Topical metronidazole 0.75%-1% b. Sulfacetamide-sulfur 10/5% cleanser c. Topical azelaic acid 15% d. One of the following oral antibiotics a. Doxycycline or azithromycin Initial Approval: 12 weeks with quantity limited to 30 grams per 30 days Continued Approval: 1 year with quantity limited to 30 grams per 30 days only if documented evidence of improvement in erythema
Modeyso (Dordaviprone)	**Candidates for treatment with Modeyso (dordaviprone) should meet ALL of the following criteria:** • Prescribed by a neuro-oncologist, pediatric oncologist, or specialist in CNS tumors • Diagnosed with diffuse midline glioma with confirmed H3 K27M mutation • Age ≥ 1 year • Documentation that patient's disease has progressed following at least ONE prior therapy (e.g., temozolomide, bevacizumab, lomustine, carmustine, radiation therapy, etc) Reasons for Non-coverage: • Pregnancy or breastfeeding Initial Approval: 6 months Continued Approval: 12 months. For continued approval for treatment, patient should meet ALL the following criteria: • Documented beneficial effect from therapy without disease progression or unacceptable toxicity.
Monjuvi (Tafasitamab-cxix)	**Candidates for treatment with Monjuvi should meet ALL the following criteria:** • Prescribed by Hematologist/Oncologist. • Age ≥ 18 years • Patient has a diagnosis of relapsed/refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma.

Drug	Prior Authorization Criteria

	• Patient is NOT eligible for autologous stem cell transplant or high dose chemotherapy.
	• Patient has not received prior therapy with immunomodulatory imide class agents (e.g., lenalidomide).
	• Patient has not received prior therapy with CD19-directed therapy **OR** patient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease.
	  a. Examples of CD-19 therapy include: Aucatzyl (obecabtagene), Blincyto (blinatumomab), Breyanzi (lisocabtagene), Kymriah (tisagenlecleucel), Tecartus (brexucabtagene), Yescarta (axicabtagene), Zynlonta (loncastuximab)
	• Prior therapy with 1 or more lines of chemotherapy for relapsed/refractory DLBCL.
	• Patient does not have a history of malignancies other than DLBCL unless disease-free for ≥5 years.
	• Therapy will be initiated in combination with lenalidomide for up to 12 cycles only.
	  a. Note: Monjuvi can continue as a single agent maintenance therapy until disease progression or unacceptable toxicity
	
	<u>Reasons for Non-Coverage:</u>
	• CNS lymphoma involvement
	• Seropositive for hepatitis B, hepatitis C, or HIV
	• Diagnosis of double-hit lymphoma (DHL) with rearrangements in MYC AND BCL2 or BCL6 genes
	• Diagnosis of triple-hit lymphoma (THL) with rearrangements in the MYC, BCL2, AND BCL6 genes
	
	<u>Initial Approval</u>: 6 months
	• **Approve for administration ONLY in KPGA infusion center, absent director level approval.**
	
	<u>Continued Approval:</u> 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continue approval if the following is met:
	• Disease response with treatment defined as stabilization of disease or decrease in size of tumor or tumor spread
	• Combination therapy with lenalidomide does not exceed a maximum of 12 cycles (tafasitamab single-agent maintenance therapy may be continued until disease progression or unacceptable toxicity)
	• Absence of unacceptable toxicity from the drug (i.e severe infusion type reactions, severe thrombocytopenia, severe neutropenia, severe infection, etc.)
	• **Approve for administration ONLY in KPGA infusion center, absent director level approval.**
	
	<u>Dosage and Administration:</u>
	• The recommended dosage of Monjuvi is 12 mg/kg as an intravenous infusion according to the following dosing schedule:
	• Cycle 1: Days 1, 4, 8, 15 and 22 of a 28-day cycle.
	• Cycles 2 and 3: Days 1, 8, 15 and 22 of each 28-day cycle.

Drug	Prior Authorization Criteria
	• Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle. • Administer Monjuvi in combination with lenalidomide for a maximum of 12 cycles and then continue Monjuvi as monotherapy until disease progression or unacceptable toxicity.
Mulpleta (Lusutrombopag)	**Candidates for treatment with Mulpleta should meet ALL the following criteria:** • Prescribed by Gastroenterology • Age ≥ 18 years • Diagnosis of thrombocytopenia (platelet count < 50 x 109/L) AND • Chronic liver disease who are undergoing a scheduled, high bleeding risk invasive procedure (See KPGA Perioperative Anticoagulation Management Guidelines for examples of high bleeding risk procedures) Reasons for Non-coverage: • Treatment of thrombocytopenia outside of a scheduled high-risk invasive procedure in a patient with chronic liver disease. Initial Approval: 7 days Continued Approval: Continued approval is NOT warranted with this medication as the patient should only get a 7 day supply prior to a scheduled procedure
Myalept (Metreleptin)	**Candidates for treatment with Myalept should meet ALL the following criteria:** • Diagnosis of congenital or acquired generalize lipodystrophy associated with leptin deficiency (less than 12.0 mg/mL in females and less than 8.0 mg/mL in males) • Prescribed by or in consultation with an endocrinologist or geneticist • Prescriber must be certified by the Myalept REMS program (Myalept REMS Website) • Patient will be using Myalept as an adjunct to replacement therapy • Patient has at least one complication of lipodystrophy: a. Diagnosis of uncontrolled diabetes mellitus or insulin resistance with persistent hyperglycemia (A1c ≥6.5%) despite treatment with dietary interventions AND optimized insulin therapy at maximum tolerated doses b. Diagnosis of uncontrolled hypertriglyceridemia (TG >200 mg/dL) despite treatment with dietary interventions AND optimized therapy with at least two triglyceride-lowering agents from different classes (e.g., fibrates, statins) at maximally tolerated doses Reasons for Non-coverage: • Patients with general obesity not associated with congenital leptin deficiency • Treatment of complications of partial lipodystrophy • Treatment of liver disease, including nonalcoholic steatohepatitis (NASH) • Patients with HIV-related lipodystrophy • Patients with metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of congenital or acquired generalized lipodystrophy

Drug	Prior Authorization Criteria
	Initial Approval: 12 months Continued Approval: 12 months. Continued approval for treatment with Myalept should meet ALL of the criteria above in addition to the criteria below: • Member has documentation of positive clinical response and/or stabilization of laboratory parameters provided in initial authorization (e.g., fasting triglyceride concentrations, and/or A1c) Dosage and Administration: • Weight ≤40 kg: starting dose 0.06 mg/kg/day, increase or decrease by 0.02 mg/kg to a maximum daily dose of 0.13 mg/kg • Males >40 kg body weight: starting dose 2.5 mg/day, increase or decrease by 1.25 to 2.5 mg/day to maximum dose of 10 mg/day • Females >40 kg body weight: starting dose 5 mg/day, increase or decrease by 1.25 to 2.5 mg/day to a maximum dose of 10 mg/day • Myalept is only available through restricted programs under a Risk Evaluation and Mitigation Strategy (REMS)
Mycapssa (Octreotide) Preferred: **Sandostatin LAR (octreotide) injection – NO PA Required** **Somatuline Depot (PA required)** **Lanreotide injection 120 mg/0.5 mL – NO PA Required**	**Candidates for treatment with Mycapssa should meet ALL of the following criteria:** • Prescribed by an Endocrinologist • Age ≥ 18 years • A confirmed diagnosis of acromegaly in an individual who had an inadequate response to surgery or radiation or had documentation these are not appropriate. • Individual has responded to and tolerated stable long-term treatment with injectable somastatin receptor ligands (SRLs): Sandostatin LAR (octreotide) injection AND Somatuline Depot (lanreotide) injection. • Documented baseline assessment of the following: a. Elevated insulin-like growth factor 1 (IGF-1) level for the patient's age and gender, elevated growth hormone (GH) level within 2-hours after 75 g of oral glucose, and blood glucose level. • Documented reason patient unable to receive injectable somastatin receptor ligands (SRLs). Examples include the following: a. Patient temporarily resides outside of the KP network and unable to return for injections **OR** b. Documented injection site reaction or other adverse drug reaction to injectable somastatin receptor ligands (SRLs). Reasons for Non-coverage: • Hypersensitivity to octreotide or any of the components of octreotide acetate. Initial Approval period: 12 months. Continued approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage and meets the following:

Drug	Prior Authorization Criteria
	• Patient continues to be seen by an Endocrinologist • No documented evidence of disease progression • GH levels are < 1 µg/L within 2-hours after 75 g of oral glucose • IGF-1 levels are less than or equal to the upper limit of normal for the patient's age and gender. • Patient has not developed any adverse drug effects (i.e., cholelithiasis, cholecystitis, cholangitis, pancreatitis)

Myfembree (Relugolix, Estradiol, and Norethindrone Acetate)	**Candidates for Myfembree should meet ALL of the following criteria:**
	
	• Female and age ≥ 18 years and premenopausal
	• Documented diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) OR moderate to severe pain with endometriosis
	• Prescribed by obstetrician or gynecologist (OB/GYN)
	• Documented minimum three-month trial, intolerance OR contraindication to the following
	  ○ One combined oral contraceptive **AND**
	  ○ One progestin therapy (MPA, IUD, progestin only pill) **AND**
	  ○ Tranexamic acid (i.e., Lysteda)*
	
	*Note: Trial of Tranexamic acid NOT required for endometriosis
	
	Reasons for Non-coverage:
	• Previously completed 24 months of treatment with Oriahnn or Myfembree or Orilissa
	• Pregnant, planning pregnancy in next 24 months, or breastfeeding
	• Current or history of thrombotic or thromboembolic disorders
	• Patient at high risk or thrombotic events (i.e., age 35 years and older with current nicotine use, uncontrolled hypertension)
	• Known osteoporosis
	• Undiagnosed abnormal uterine bleeding
	• Current or history of breast cancer or other hormonally sensitive malignancies (i.e., mutations with BRCA malignancies)
	• Known hepatic impairment or disease
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months if the member meets all criteria above and the following requirements listed below:
	• Clinically significant improvement in pain or fibroid-induced heavy menstrual bleeding, defined as at least 50% reduction in menstrual blood loss from baseline
	• Total treatment duration does not exceed 24 months

Myqorzo (Aficamten)	**Candidates for treatment with Myqorzo (aficamten) should meet ALL the following criteria:** **Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).* • Age ≥ 18 years • Prescribed by a Cardiologist

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	• Diagnosed with obstructive hypertrophic cardiomyopathy (oHCM) consistent with current AHA/ACC guidelines and satisfies both of the following:
	  ○ Echocardiogram within the past 6 months with left ventricular ejection fraction (LVEF) ≥55%
	  ○ NYHA class II or III
	• Documented peak Valsalva left ventricular outflow tract (LVOT) gradient ≥50 mmHg
	• Symptomatic oHCM despite highest tolerated dose of a non-vasodilating beta-blocker (e.g., bisoprolol) (or non-dihydropyridine calcium channel blocker if beta-blocker is not tolerated, e.g., verapamil)
	• If clinically indicated, consider other AHA/ACC Guideline Class 1 therapies before aficamten:
	  ○ Disopyramide
	  ○ Septal reduction therapy for NYHA class III patients
	• Absence of pregnancy and using effective contraception, if of childbearing potential
	
	Reasons for Non-coverage:
	• Known infiltrative or storage disorder causing cardiac hypertrophy that mimics oHCM (e.g., Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy)
	• History of syncope or sustained ventricular tachyarrhythmia with exercise within 6 months prior to initiation of Myqorzo
	• History of resuscitated sudden cardiac arrest (at any time) or known history of appropriate implantable cardioverter defibrillator discharge for life-threatening ventricular arrythmia within 6 months prior to initiation of Myqorzo
	• Poorly controlled atrial fibrillation. Treatment of atrial fibrillation should be optimized prior to considering Myqorzo
	• Concomitant use of rifampin
	• QTc Interval > 500 milliseconds
	
	Initial Approval: 6 months
	
	Continued Approval: 6 months
	• Echocardiogram within the past 6 months with LVEF ≥ 40%
	• Documented adequate response to therapy by a Cardiologist within the past 6 months
	• Patient should continue to meet all above coverage criteria without reasons for non-coverage or discontinuation (criteria for discontinuation listed below).
	
	For new members who were initiated on Myqorzo outside of KPGA:
	• Patients should continue to meet all above coverage criteria without reasons for non-coverage or discontinuation (criteria for discontinuation listed below).
	
	Criteria for Discontinuation:
	• LVEF <40% while taking Myqorzo
	• Patient is on concomitant use with rifampin
	• Documented non-adherence to medication, recommended diet and lifestyle measures, or follow-up labs and assessments.
	
	Ordering Information:
	• Myqorzo is only available through the MYQORZO REMS Program

Drug	Prior Authorization Criteria
	Each clinician must submit the Healthcare Provider Enrollment Form AND the Patient Enrollment Form at https://www.myqorzorems.com
Mytesi (Crofelemer)	**Candidates for Mytesi should meet ALL of the following criteria:** • Prescribed by an Infectious Disease specialist or Gastroenterologist • Age ≥ 18 years • Documented diagnosis of non-infectious diarrhea associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) and currently receiving antiretroviral therapy • Documented failure of, contraindication or intolerance to at least two preferred therapies for non-infectious diarrhea for at least one month (e.g., loperamide, diphenoxylate/atropine, bismuth subsalicylate, bulk-forming fiber supplements) • Infectious etiologies of diarrhea have been ruled out via stool testing or blood cultures Initial Approval: 12 months Continued Approval: 12 months if the member has experienced any of the following: • Patient meets all of the above criteria for coverage • Documented clinically significant benefit from medication
Neffy (Epinephrine)	**Candidates for treatment with Neffy nasal spray should meet ALL the following criteria:** • Patient weighs at least 15kg (33 lbs) Currently at risk for or has a history of serious allergic emergencies. • **Clinician documentation that the patient or patient's caregiver is unable to utilize an alternative epinephrine auto-injector device (e.g., Auvi-Q [preferred], Epipen).** Reasons for Non-coverage: • Injection fatigue or fear of needles Initial Approval: 12 months Continued Approval: 12 months
Nemluvio (Nemolizumab)	**Candidates for treatment with Nemluvio should meet ALL the following criteria PLUS the individual disease state criteria that follow:** • NOT used in combination with another biologic medication [e.g., omalizumab (Xolair), rituximab (Rituxan), dupilumab (Dupixent), lebrikizumab-lbkz (Ebglyss), tralokinumab-ldrm (Adbry), etanercept (Enbrel), Infliximab (Inflectra), etc] or Janus Kinase Inhibitor [e.g. upadacitinib (Rinvoq), baricitinib (Olumiant), etc] for the same condition. Diagnosis of prurigo nodularis: • Prescribed by a dermatologist, immunologist, or allergist • Patient is 18 years of age or older

Drug	Prior Authorization Criteria

	• Documented presence of multiple localized or general pruriginous lesions
	• Documented history of inadequate response, contraindication, or intolerance to ALL of the following (of at least a 2 month trial):
	  ○ High or super-high potency topical corticosteroid (e.g., betamethasone dipropionate, augmented 0.05% cream, clobetasol propionate 0.05% ointment, lotion, gel)
	  ○ Topical vitamin D analog (e.g., calcipotriene 0.005% solution, calcitriol 3mcg/g ointment)
	  ○ Topical calcineurin inhibitor (e.g. tacrolimus 0.1% ointment)
	• Phototherapy (PUVA, UVB with coal tar or dithranol, UVB standard or narrow-band, or home UVB) of at least a 3-month trial, excluding patients with:
	  ○ Involvement of sensitive areas (e.g. hand, feet, face, body folds or genitals)
	  ○ Concomitant use of medications that cause photosensitivity
	  ○ History of photosensitivity disorder (e.g. Lupus, Dermatomyositis, Porphyria, Xeroderma pigmentosum)
	  ○ History of melanoma or abnormal moles or multiple non- melanoma skin cancers
	• Documented inadequate response, contraindication, or intolerance to Dupixent.
	
	Diagnosis of atopic dermatitis:
	• Prescribed by a dermatologist
	• Age ≥ 12 years
	• Documented moderate-to-severe atopic dermatitis (such as BSA ≥ 10%, involvement of high-impact areas [e.g., face, hands, feet, genitals, skin folds], or documented major impact on quality of life)
	• Documented inadequate response (minimum of 16 weeks trial), intolerance, or contraindication to at least ONE of the following:
	  ○ Tralokinumab (Adbry)
	  ○ Dupilumab (Dupixent)
	
	Initial Approval: 6 Months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.**
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	
	Continued Approval: 12 months. Continue approval if the following criteria are met:
	
	For new members who were initiated on Nemluvio outside of KPGA:
	
	• Confirm patient has a documented adequate response and tolerance to the medication during specialist follow-up in the past 6 months.
	• For patients with clear or nearly clear skin after at least 16 weeks of Nemluvio:
	  ○ Prescribed dose is 30mg every 8 weeks unless there is a special circumstance documented (e.g., resistant disease, flare with previous attempted dose extension).

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** • **Approve for member to fill via the outpatient pharmacy benefit only** <u>For existing members who have previously met the full criteria above:</u> • Documented adequate response and tolerance of medication during specialist follow up in the last 12 months. • For patients with clear or nearly clear skin after at least 16 weeks of Nemluvio: ○ Prescribed dose is 30mg every 8 weeks unless there is a special circumstance documented (e.g., resistant disease, flare with previous attempted dose extension). • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** • **Approve for member to fill via the outpatient pharmacy benefit only**

Nerlynx
(Neratinib)
	Candidates for Nerlynx should meet ALL the following criteria:
	
	<u>Diagnosis of recurrent or metastatic disease:</u>
	• Prescribed by an oncologist.
	• Age ≥ 18 years
	• Patient has HER-2 positive advanced or metastatic breast cancer.
	• Patient has a documented treatment failure, contraindication, or intolerance to lapatinib PLUS capecitabine PLUS at least <u>two</u> additional anti-HER2 based regimens **in** the metastatic setting.
	  ○ Examples of anti-HER2 based regimens include:
	  ▪ pertuzumab + trastuzumab + docetaxel
	  ▪ pertuzumab + trastuzumab + paclitaxel
	  ▪ Enhertu (fam-trastuzumab deruxtecan-nxki IV)
	  ▪ Kadcyla (ado-trastuzumab emtansine IV)
	  ▪ Tukysa (tucatinib tablets) + trastuzumab + capecitabine
	  ▪ trastuzumab + capecitabine
	  ▪ lapatinib + capecitabine
	  ▪ trastuzumab + lapatinib
	• The medication will be prescribed in combination with capecitabine (Xeloda).
	
	<u>Diagnosis of early or nonmetastatic breast cancer:</u>
	KP does not recommend the routine use of extended adjuvant therapy with neratinib in HER2-postive early-stage breast cancer due to no overall survival benefit, significant toxicity, and high cost.
	• Prescribed by an oncologist.
	• Age ≥ 18 years
	• Patient has a diagnosis of high risk (stage II-IIIC) HER2-positive breast cancer.

Drug	Prior Authorization Criteria

	• The medication will NOT be used in combination with HER2 antagonists (e.g., trastuzumab, pertuzumab)
	• Patient meets ONE of the following:
	  ○ The medication is requested for extended adjuvant therapy after the patient has completed 12 months of adjuvant therapy with a trastuzumab product.
	  ○ Patient has a documented intolerance to trastuzumab and was unable to tolerate 12 months of therapy according to the prescriber.
	• The medication will be started within 1 year of completing adjuvant trastuzumab alone.
	
	<u>Initial Approval:</u> 12 months with a quantity limit of 180 tablets per 30 days
	
	<u>Continued Approval:</u> 12 months with a quantity limit of 180 tablets per 30 days
	For continued approval for treatment with Nerlynx, patient should meet ALL the following criteria:
	• For patients with HER2-positive, advanced, or metastatic breast cancer:
	  ○ Patient continues to meet the above criteria AND
	  ○ Patient is responding positively to therapy based on stability of disease and/or decrease in size of tumor or tumor spread.
	• For patients with HER2-postivie, early or non-metastatic breast cancer, do not approve. Treatment in this setting should only be continued for a maximum of 12 months.
	
	<u>For new members who were initiated on Nerlynx outside of KPGA:</u>
	• Prescribed by an oncologist.
	• Age ≥ 18 years
	• Patient is diagnosed with ONE of the following:
	  ○ HER2-positive, advanced, or metastatic breast cancer AND the patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread AND the medication will be prescribed in combination with capecitabine.
	  ○ HER2-positive, early, or non-metastatic breast cancer AND the patient has previously completed 12 months of trastuzumab therapy OR the patient was unable to complete 12 months of trastuzumab due to documented toxicity AND the medication was started within 1 year of completing adjuvant trastuzumab alone.
	  ▪ NOTE: treatment duration should NOT exceed 12 months in patient with early or non-metastatic breast cancer.
	• Quantity limit of 180 tablets per 30 days.

Neupogen (Filgrastim)
 	
Filkri (filgrastim-laha) pre-filled syringes is KP's preferred short-acting filgrastim product and available on the formulary. **No PA required.**
	Filkri (filgrastim-laha) is KP's preferred short-acting filgrastim product and available on the formulary. Requests for other non-formulary filgrastim biosimilar products (e.g., Granix, Nivestym, Zarxio, Releuko, etc) should be sent to the Pharmacy Consult Service for review.
	
	Candidates for Neupogen (filgrastim) should meet ALL the following criteria:
	• Prescribed by Hematology or Oncology
	• Patient has a documented failure or intolerance to **ALL** the following:
	  ○ Filkri (filgrastim-laha) – KP's preferred formulary filgrastim product
	  ○ Granix (tbo-filgrastim)
	  ○ Nivestym (filgrastim-aafi)

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ Zarxio (filgrastim-sndz) i. Note, for patients requiring doses <180 mcg, a trial of Zarxio is NOT required. ○ Releuko (filgrastim-ayow) Initial Approval: 12 months. • **Approve for member to fill via the outpatient pharmacy benefit ONLY.** Continued Approval: 12 months if patient meets the following: • Patient meets all above coverage criteria • Patient has documented improvement and requires continued treatment. • **Approve for member to fill via the outpatient pharmacy benefit ONLY.**
Nexletol (Bempedoic Acid) **Nexlizet** (Bempedoic Acid and Ezetimibe)	**Candidates for Nexletol/ Nexlizet should meet all the following criteria:** • Age ≥ 18 years • The requested medication is prescribed by or given in consultation with a cardiologist or endocrinologist. • The LDL remains >70 (or LDL remains ≥55 in very high-risk patients** with multiple ASCVD events) despite current use ≥3 months of maximally tolerated dose of statin and ezetimibe unless documented contraindication/intolerance. • Patient has one of the following: ○ Patient has documented established cardiovascular disease (e.g., acute coronary syndromes, history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, carotid stenosis ≥50%, or symptomatic peripheral arterial disease presumed to be of atherosclerotic origin) **OR** ○ Patient has heterozygous familial hypercholesterolemia [HeFH] OR ○ High risk for a CVD event (i.e., high-risk primary prevention) ▪ Reynolds Risk score >30% or a SCORE Risk score >7.5% over 10 years OR ▪ Coronary artery calcium score >400 Agatston units (AU) at any time in the past, OR ▪ Patients with type 1 or type 2 diabetes, aged >65 years (women) or >60 years (men) • Patient has had an adequate trial (of at least 3 months) of a high-intensity statin (atorvastatin 40 mg or 80 mg OR rosuvastatin 20 mg or 40 mg) OR statin therapy at the maximally tolerated dose PLUS ezetimibe 10 mg, AND LDL remains ≥ 70 (or ≥55 in very high-risk patients with multiple ASCVD events) despite optimal adherence [MRAR ≥ 80% for ≥ 3 months. If MRAR < 80%, reviewer can confirm adherence in the last 3 months based on medication sold dates found in Health Connect medication tab (e.g., 3 one month fills or one 90 day fill)] **OR** • Documented trial and intolerance of at least 3 different statins (atorvastatin, rosuvastatin, and 1 additional statin), including an attempted alternative dosing regimen (e.g., every-other day, once or twice weekly) OR documented history of CPK> 10 x ULN or rhabdomyolysis attributed to a statin and not explained by a drug interaction, fall, or

Drug	Prior Authorization Criteria
	prolonged immobility OR an absolute contraindication to statin therapy (active, decompensated liver disease; nursing female, pregnancy, or plans to become pregnant; hypersensitivity reaction) ○ Other causes of muscle symptoms must be ruled out (e.g., hypothyroidism, Vitamin D deficiency, recent exercise), drug-drug interactions that can increase systemic statin exposure should be considered • Patient must continue current lipid lowering therapies in combination Nexletol/Nexlizet with unless documented intolerance/ contraindication. • **Nexletol ONLY:** Documented intolerance, contraindication and/or previous trial of ezetimibe. • **Nexlizet ONLY:** The patient had a previous trial of ezetimibe (If patients with clinical ASCVD require > 25% additional lowering of LDL-C and does not have a documented trial of ezetimibe - proceed without trial of ezetimibe.) **Very High risk defined per 2018 AHA Blood Cholesterol Guidelines: Multiple ASCVD events OR one ASCVD event AND multiple very high-risk conditions. High risk conditions defined as: Age ≥ 65 years, heterozygous or homozygous familial hypercholesterolemia, history of prior coronary bypass surgery or percutaneous coronary intervention outside of the major ASCVD event, diabetes mellitus, HTN, eGFR 15-59 mL/min/1.72m^2, current smoker, LDL of ≥100 mg/dL, or congestive heart failure. Reasons for Non-coverage: • Patient is pregnant or lactating. • Concomitant use with simvastatin dose greater than 20 mg. • Concomitant use with pravastatin dose greater than 40 mg. Initial Approval: 12 months Continued Approval: 12 months. Confirm patient does not have any reasons for non-coverage and has documented low density lipoprotein-cholesterol (LDL-C) lowering of at least 15%. For new members who were initiated on Nexletol or Nexlizet outside of KPGA: Approve Nexletol or Nexlizet indefinitely if patient is confirmed to be clinically stable on it by a Specialist in the past 12 months. *Adherence can be reviewed via KPHC with the dot phrase **.mrar**
Niktimvo (Axatilimab-csfr)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** **Candidates for treatment with Niktimvo should meet ALL the following criteria:** • Diagnosis of chronic Graft-Versus-Host Disease (cGVHD) • Patients weighing ≥40 kg (88.2 lbs) • Prescribed by or in consultation with an oncologist, hematologist, or transplant specialist • Failure of at least two prior lines of systemic therapy • Patient has steroid-refractory disease defined as ONE of the following:

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>

Lack of response or disease progression after administration of prednisone (or equivalent dose of another corticosteroid) at ≥ 1 mg/kg/day for at least one week
Disease persistence without improvement despite continued treatment with prednisone (or equivalent dose of another corticosteroid) at ≥0.5 mg/kg/day or ≥1 mg/kg every other day for at least 4 weeks

Documented failure or intolerance of Jakafi (ruxolitinib) at up to maximally indicated doses

<u>Reasons for non-coverage</u>:

Pregnancy or lactation

<u>Initial Approval</u>: 6 months. Approve ONLY for back-office administration at KP infusion center.

Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)

<u>Continued Approval:</u> 12 months. Approve ONLY for back-office administration at KP infusion center.

Demonstrated clinical benefit from treatment (e.g., improvement in cGVHD symptoms, reduced steroid use)
No disease progression
No unacceptable toxicity

Grade 3 or 4 infusion-related reaction
ALT or AST ≥ 3 times ULN with total bilirubin ≥ 2 times ULN and ALP < 2 times ULN OR Grade 4 elevation of AST or ALT
Symptomatic ≥ Grade 3 elevation of CPK, amylase or lipase

Continued need for therapy, as determined by the prescriber
Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)

<u>Dosage and Administration:</u>

0.3 mg/kg (up to a maximum of 35 mg) IV infusion every 2 weeks

Premedicate with an antihistamine and an antipyretic for patients who have previously experienced an infusion-related reaction to NIKTIMVO

<u>Appendix A: Steroid Equivalencies: Comparison of systemic glucocorticoid preparations</u>

<u>Appendix B:</u>
<table>
<tr><th>Systemic Corticosteroids</th><th>Dosing Regimen</th><th>Dose Limit/ Maximum Dose</th></tr>
<tr><td>Methylprednisolone, prednisone</td><td>Varies</td><td>Varies</td></tr>
<tr><th>Systemic Immunosuppressants</th><th>Dosing Regimen</th><th>Dose Limit/ Maximum Dose</th></tr>
<tr><td>Jakafi (ruxolitinib)</td><td>10 mg PO BID</td><td>20 mg/day*</td></tr>
<tr><td>Imbruvica (ibrutinib)</td><td>420 mg PO QD</td><td>420 mg/day</td></tr>
<tr><td>Rezurock (belumosudil)</td><td>200 mg PO QD</td><td>200 mg/day</td></tr>
<tr><td>Campath® (alemtuzumab) †</td><td>10 mg SC QD for 3 days
or</td><td>See regimen</td></tr>
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</td></tr>
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<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>
<table>
<tr><td></td><td>3 mg IV TIW, then 10 mg IV weekly</td><td></td></tr>
<tr><td>tacrolimus (Prograf®)†</td><td>0.15 mg/kg PO BID</td><td>Based on serum concentrations</td></tr>
<tr><td>cyclosporine (Gengraf®, Neoral®, Sandimmune®)†</td><td>6 mg/kg PO BID</td><td>Based on serum concentrations</td></tr>
<tr><td>Enbrel® (etanercept)†</td><td>0.4 mg/kg SC TIW</td><td>50 mg/week</td></tr>
<tr><td>imatinib (Gleevec®)†</td><td>100 mg PO QD</td><td>400 mg/day</td></tr>
<tr><td>sirolimus (Rapamune®)†</td><td>0.25 to 0.5 mg PO QD</td><td>40 mg/day*</td></tr>
<tr><td>mycophenolate mofetil (Cellcept®)†</td><td>240 mg PO QID or
1 g PO BID</td><td>2 g/day*</td></tr>
<tr><td>Nipent (pentostatin)†</td><td>4 mg/m^2 IV every 2 weeks</td><td>4 mg/m^2 /2 weeks*</td></tr>
<tr><td>rituximab (Riabni®, Rituxan®, Ruxience®, Truxima®)†</td><td>375 mg/m^2 IV weekly</td><td>1,000 mg/week*</td></tr>
</table>
*Maximum dose of the drug, not indication specific
†Off-label
</td></tr>
<tr><td>Nitrofurantoin oral suspension</td><td>
Candidates for treatment with nitrofurantoin oral suspension should meet ALL the following criteria:

For UTI treatment in infants, children, and adolescents must trial ALL the following unless there is a documented failure, intolerance, contraindication or the medication is not available:

Nitrofurantoin macrocrystal (Macrodantin) capsules* for infants ≥ 6 month of age, children and adolescents
<ol type="a">
Note: Nitrofurantoin macrocrystal (Macrodantin) capsules are contraindicated in infants less than 1 month of age.
ALL oral antibiotics to which urine culture is sensitive and are not contraindicated. Only require oral antibiotics available in liquid form for infants < 6 months of age.
Please note: Contact the QRM Doctor of the Day for requests for UTI treatment for expedited review

For UTI Prophylaxis in infants, children, and adolescents, must be prescribed by Pediatric Urologist AND must trial ALL of the following unless there is a documented failure, intolerance or contraindication:

Nitrofurantoin macrocrystal (Macrodantin) capsules* for infants ≥ 6 months of age and taking solid foods, children, and adolescents
Sulfamethoxazole and trimethoprim (SMZ-TMP) for infants ≥ 2 months of age, children, and adolescents
<ol type="a">
Note: SMZ-TMP is contraindicated in pediatric patients less than 2 months of age

*May be opened and contents mixed with formula, expressed breast milk, food or juice OR mixed with water and administered in enteral feeding tubes
</td></tr>
</table>

Drug	Prior Authorization Criteria
	Reasons for Non-Coverage • Prescribed to treat pyelonephritis Initial Approval: 1 month Continued Approval: 12 months. For continued approval for treatment with Nitrofurantoin 25 mg/5 ml oral suspension, patient should meet ALL the following criteria: For new members who were initiated on nitrofurantoin oral suspension outside of KPGA: • Confirm patient meets all the above coverage criteria without reasons for non-coverage. Patient is responding positively to UTI prophylaxis therapy. For existing members who previously met the full criteria above: Continued approval will be based on clinical documentation of the following: • Patient is responding positively to UTI prophylaxis therapy. • Age remains < 6 months

Northera
(Droxidopa)
	Candidates for treatment with Northera should meet ALL the following criteria:
	
	• Prescribed by or in consultation with a Neurologist or Cardiologist
	• Age ≥ 18 years
	• Documented diagnosis of neurogenic orthostatic hypotension (NOH) defined as consistent decrease in systolic blood pressure of at least 20 mmHg or decrease in diastolic blood pressure of at least 10 mmHg within 3 minutes of standing AND
	• Documentation of ONE of the following conditions:
	  ○ Parkinson's disease
	  ○ Multiple system atrophy
	  ○ Pure autonomic failure
	  ○ Dopamine beta-hydroxylase deficiency
	  ○ Non-diabetic autonomic neuropathy
	• Diagnostic evaluation has excluded other causes associated with orthostatic hypotension (e.g., congestive heart failure, fluid restriction, hypovolemia, malignancy)
	• Patient has initiated and maximized at least TWO non-pharmacologic measures including but not limited to:
	  ○ Discontinuation of drugs which can cause orthostatic hypotension [e.g., diuretics, antihypertensive medications (primarily sympathetic blockers and vasodilators), anti-anginal drugs (nitrates), alpha-adrenergic antagonists, alpha-2 agonists (clonidine), phosphodiesterase-5 inhibitors, and antidepressants]-
	  ○ Raising the head of the bed 10 to 20 degrees
	  ○ Compression garments (e.g., thigh-high compression stockings)
	  ○ Physical maneuvers to improve venous return (e.g., regular modest intensity exercise)

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ Increased salt and water intake, if appropriate ○ Avoiding precipitating factors (e.g., overexertion in hot weather, arising too quickly from supine to sitting or standing) • History of failure, contraindication or intolerance to ALL of the following medications: ○ Florinef (fludrocortisone) ○ ProAmatine (midodrine) ○ Generic Droxidopa Note: If the physician's request for coverage of brand Northera is based upon the physician's and/or member's unwillingness to change to a preferred alternative, the request will be denied. Reasons for Non-coverage: • Supine hypertension Initial Approval: 12 months Continued Approval: 24 months. Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, continue approval if documentation of positive clinical response.
Noxafil (Posaconazole)	**Candidates for treatment with Noxafil should meet ALL the following criteria:** • Prescribed by Hematology, Oncology, Bone Marrow Transplant, or Infectious Diseases specialist • Treatment or prophylaxis in patients with ONE of the following conditions: ○ Acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS) ○ Graft versus host disease (GVHD) currently treated with steroids ○ Hematopoietic stem cell transplant (HSCT) ○ Invasive fungal infection with documented failure, intolerance, or contraindication to the following agents to fluconazole, itraconazole, and voriconazole, as appropriate. • Formulation specific criteria: ○ For delayed release tablets: a. Age ≥ 2 years and weight > 40 kg b. If request is for brand Noxafil tablets, patient has tried and had a potential intolerance or allergic reaction to the inactive components of generic Noxafil tablets that cannot be explained by other clinical factors ○ For immediate release oral suspension: a. Age ≥ 13 years b. If request is for brand Noxafil IR suspension, patient has tried and had a potential intolerance or allergic reaction to the inactive components of generic Noxafil IR suspension that cannot be explained by other clinical factors ○ For delayed release suspension: a. Age ≥ 2 and < 18 years and weight < 40 kg b. Unable to swallow tablets

Drug	Prior Authorization Criteria
	Coverage Notes: • Generic posaconazole tablets are preferred over suspension when appropriate. • The three oral formulations of posaconazole (delayed-release tablets, immediate release oral suspension, and delayed release oral suspension) are not interchangeable and cannot be directly substituted without a change in dosage. • All orders for posaconazole must specify the dosage form, strength, and frequency • Documented failure, intolerance, or contraindication to posaconazole tablets is required prior to approval of Noxafil suspension coverage. Initial Approval**:** 3 months Continued Approval: 12 months. Confirm patient meets all above criteria. In addition, continue approval if the following: • AML or MDS diagnosis OR • Hematopoietic stem cell transplant (HSCT) • Continued used of high dose steroids or other anti-GVHD therapies OR • For prophylaxis or treatment of invasive fungal infection: ○ Documented failure, intolerance, or contraindication to fluconazole and voriconazole

Nubeqa
(Darolutamide)
	Candidates for treatment with Nubeqa must meet ALL the following criteria:
	• Patient is a male
	• Prescribed by an oncologist or urologist
	• Age ≥ 18 years
	• Diagnosis of Prostate Cancer that is;
	  ○ Non-metastatic , Castration resistant with PSA doubling time less than or equal to 10 months **OR**
	  ○ Metastatic, hormone sensitive:
	  i. In patient with **high volume disease**, and ECOG PS of 0-1, with documented intolerance or contraindication, or treatment failure to the following: (KP's preferred therapy)Docetaxel + Abiraterone combination (KP's preferred 1st line)or with Abiraterone + prednisone **OR**
	  ii. In patient with high volume disease, and ECOG PS > 1, with documented intolerance or contraindication to Abiraterone + Prednisone (KP's preferred 1st line) **OR**
	  iii. In patient with **low volume disease**, with documented intolerance or contraindication to Abiraterone + Prednisone (KP's preferred 1st line) **OR enzalutamide (Xtandi)**
	• Prescribed in combination with;
	  ○ Gonadotropin-releasing hormone (GnRH) agonist or antagonist **OR**
	  ○ Patient has had bilateral orchiectomy
	
	Notes:

***Does not apply to Medicare Benefit**

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>

High volume disease defined as: presence of visceral metastasis or ≥4 bone lesions with ≥1 beyond the vertebral bodies and pelvis
Low volume disease defined as: no visceral metastases and <4 bone lesions with ≥1 lesion in the spine or pelvis
Relative contraindication to abiraterone defined as: type 2 diabetes with A1c > 7, patient is on insulin, severe liver disease (Child-Pugh Class C), cardiovascular risk clearly documented by pro (e.g., heart failure with LVEF < 50%; recent MI, or ventricular arrhythmia)

<table>
<tr><th colspan="2">ECOG PERFORMANCE STATUS*</th></tr>
<tr><th>Grade</th><th>ECOG</th></tr>
<tr><td>0</td><td>Fully active, able to carry on all pre-disease performance without restriction</td></tr>
<tr><td>1</td><td>Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work</td></tr>
<tr><td>2</td><td>Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours</td></tr>
<tr><td>3</td><td>Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours</td></tr>
<tr><td>4</td><td>Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair</td></tr>
</table>
<u>Approval period:</u> 12 months

<u>Continued Approval</u>: 12 months

Member continues to meet the above criteria
Continues to be seen by an oncologist
Member is responding positively to therapy as defined by stabilization of disease or decrease in size of tumor or tumor spread
Absence of unacceptable toxicity from the drug.

</td></tr>
<tr><td>Nucala
(Mepolizumab)</td><td>
Candidates for treatment with Nucala should meet ALL of the following criteria:

<u>Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA):</u>

Prescribed by an Allergist or Pulmonologist
Age ≥ 18 years
Documented diagnosis of severe eosinophilic granulomatosis with polyangiitis (EGPA)
Documented inadequate response, intolerance, or contraindication to standard therapy with systemic corticosteroids (e.g., prednisone, methylprednisolone) with or without immunosuppressive therapy (e.g., cyclophosphamide, rituximab)
Documented inadequate response (trial ≥ 4 months), intolerance, or contraindication to benralizumab (Fasenra)
Patient is NOT currently receiving Nucala in combination with any other biologic for the same indication (e.g., Dupixent, Xolair, Fasenra, Cinqair, Tezspire).

<u>Diagnosis of severe eosinophilic asthma:</u>

Prescribed by an Allergist or Pulmonologist
Age ≥ 6 years
Eosinophilic phenotype indicated by one of the following within the previous 12 months:

Non-OCS dependent: blood eosinophil count of ≥ 300 cells/mm^3
OCS dependent: blood eosinophil count of ≥ 150 cells/mm^3
Current or recent (prior 6 months) biologic use: current blood eosinophil count not required. Confirm patient has a diagnosis of an eosinophilic asthma phenotype.

Documented uncontrolled asthma defined as ONE of the following:

</td></tr>
</table>

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ Two or more asthma exacerbations in the past 12 months requiring systemic corticosteroids for ≥ 3 days OR at least one serious exacerbation requiring hospitalization or ER visit in the past 12 months ○ Asthma Control Test (ACT) consistently < 20 over the past 12 months ○ Dependence on oral corticosteroid (OCS) for asthma control • Receiving high-dose or maximally tolerated inhaled corticosteroid plus long-acting beta-agonist (ICS/LABA)[‡] for ≥ 3 consecutive months with or without OCS [‡]For age ≥ 12 years: fluticasone/salmeterol 500/50 mcg 1 puff twice daily or budesonide/formoterol 160/4.5 mcg 2 puffs BID For ages 6 to < 12 years: fluticasone /salmeterol 100/50 mcg 1 puff twice daily or budesonide/formoterol 80/4.5 mcg 2 puffs BID • Documented inadequate response (trial ≥ 4 months), intolerance, or contraindication to standard therapy with benralizumab (Fasenra) and then dupilumab (Dupixent) • Nucala (mepolizumab) is used as add-on therapy to a high-dose, or maximally tolerated, ICS and at least one additional asthma controller medication, such as a LAMA, LABA, or LRTA <u>Criteria for Chronic Obstructive Pulmonary Disease (COPD):</u> • Prescribed by an Allergist or Pulmonologist • Age ≥ 18 years • Diagnosis of moderate to severe COPD with an eosinophilic phenotype with blood eosinophil count of > 300 cell/mcl in the past 12 months. Blood eosinophil count not required if current or recent (prior 6 months) biologic therapy. Only confirm diagnosis of COPD with an eosinophilic phenotype • Documented exacerbation history in the past 12 months as demonstrated by one of the following: ○ ≥ 2 moderate exacerbations requiring systemic glucocorticoids ○ ≥ 1 severe exacerbation requiring hospitalization, ER visit or IV glucocorticoids • Documented inadequate response (trial of ≥ 3 months), intolerance, or contraindication to ONE of the following: ○ High-dose triple (ICS/LABA/LAMA) combination therapy* *Fluticasone/salmeterol 500/50 mcg 1 puff BID plus Spiriva Respimat 2.5mcg 2 puffs daily OR Stiolto Respimat 2 puffs daily plus Alvesco 160 mcg 1 puff BID OR Breyna 160/4.5 mcg 2 puffs BID plus Spiriva Respimat 2 puffs daily OR Trelegy 1 puff daily OR Breztri 2 puffs BID ○ High-dose dual (LAMA/LABA) combination therapy** **Stiolto Respimat 2 puffs daily OR Anoro Ellipta 1 puff daily • Patient will continue to use dual or triple maintenance therapy for COPD • NOT currently receiving another monoclonal antibody for the treatment of asthma—e.g., omalizumab (Xolair), reslizumab (Cinqair), benralizumab (Fasenra), Tezepelumab-ekko (Tezspire) <u>Initial Approval Duration:</u> 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Approve for member to fill via the outpatient pharmacy benefit only.** <u>Continued Approval:</u> 12 months. For continued approval for treatment with Nucala, patient should meet ALL the following criteria: • **<u>For new members who were initiated on Nucala outside of KPGA:</u>** confirm patient has eosinophilic asthma or COPD phenotype and is documented as clinically stable by a

Drug	Prior Authorization Criteria
	specialist in the past 6 months AND meets all the medication trials in criteria for their respective indication. • **For existing members who previously met the full criteria above:** Confirm patient has clinically significant benefit documented during specialist follow-up within the last 12 months AND • **For Asthma:** Nucala is being used in combination with a high-dose (or maximally tolerated) ICS and at least one additional asthma controller medication such as a LAMA, LABA, or LRTA • **For COPD:** Nucala is being used in combination with a dual (LAMA/LABA) or triple (ICS/LABA/LAMA) maintenance therapy for COPD • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Approve for member to fill via the outpatient pharmacy benefit only.** Criteria for Chronic rhinosinusitis with Nasal Polyps (CRSwNP): • Prescribed by Otolaryngologist or Allergist • Age ≥ 18 years • Otolaryngologist or Allergist documentation of bilateral nasal polyposis after full endoscopic sinus surgery • History of failure, intolerance, or contraindication to all of the following after full endoscopic sinus surgery: o Two or more short courses of systemic corticosteroids in the last 12 months o Intranasal steroid spray or rinse (i.e., fluticasone, triamcinolone, mometasone spray and/or budesonide rinse) for 3 months o Montelukast for 3 months o Dupixent for 6 months • Not currently receiving any of the following: o Dupixent, Xolair, Fasenra, Tezspire, Cinqair, or Adbry • Patient will continue a nasal corticosteroid with Nucala unless contraindicated or intolerance to nasal corticosteroids. Initial Approval Duration: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Approve for member to fill via the outpatient pharmacy benefit only. There is not an elevated risk for anaphylaxis with patient self-administration that warrants observed injection** Continued Approval: 12 months. For continued approval for treatment with Nucala, patient should meet ALL the following criteria: • **For new members who were initiated on Nucala outside of KPGA:** confirm patient meets all the above criteria without reasons for non-coverage. • **For existing members who previously met the full criteria above:** patient must have completed an appointment with an Otolaryngologist or Allergist with documented clinically significant benefit within the last 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Approve for member to fill via the outpatient pharmacy benefit only.**

Drug	Prior Authorization Criteria

	Criteria for Hypereosinophilic Syndrome:
	• Prescribed by an allergist, immunologist, hematologist, cardiologist, pulmonologist, or rheumatologist
	• Patient is ≥12 years old
	• Diagnosed with hypereosinophilic syndrome (HES) for greater than or equal to 6 months without an identifiable non-hematologic secondary cause.
	  ○ Examples of secondary causes of HES include drug hypersensitivity, parasitic helminth infection, human immunodeficiency virus infection, non-hematologic malignancy
	• Documentation that HES **IS** FIP1L1-PDGFRα-**negative**
	• History of two or more HES flares within the past 12 months
	• Documented baseline blood eosinophil level ≥1000 cells/µL prior to initiating therapy with any monoclonal antibody therapy
	  ○ Examples of monoclonal antibody therapies that may lower blood eosinophil levels include Nucala, Adbry (tralokinumab-ldrm subcutaneous injection), Cinqair (reslizumab intravenous infusion), Dupixent (dupilumab subcutaneous injection), Fasenra (benralizumab subcutaneous injection), Tezspire (tezepelumab-ekko subcutaneous injection), and Xolair (omalizumab subcutaneous injection)
	• Patient has tried at least one other treatment for HES for a minimum of 4 weeks
	  ○ Example of treatments for HES include systemic corticosteroids, hydroxyurea, cyclosporine, methotrexate, tacrolimus, azathioprine, imatinib, or pegylated-interferon
	• Nucala (mepolizumab) will not be used as monotherapy
	
	Reasons for Non-coverage:
	• Concurrent therapy with any of the following:
	  ○ anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)]
	  ○ anti-IgE therapy [e.g., Xolair (omalizumab)]
	  ○ anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
	  ○ thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]
	• HES **IS** FIP1L1-PDGFRA kinase-**positive**
	• Nucala (mepolizumab) will be used as monotherapy
	
	Initial Approval: 8 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	• **Approve for member to fill via the outpatient pharmacy benefit only.**
	
	Continued Approval: 12 months. For continued approval for treatment with Nucala, patient should meet ALL the following criteria:
	• Reduction in frequency of HES flares
	• Maintenance or reduction in background HES therapy requirements
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	• **Approve for member to fill via the outpatient pharmacy benefit only.**
	
	Dosing and Administration:
	• 300 mg administered subcutaneously once every 4 weeks

Drug	Prior Authorization Criteria
Nuedexta (Dextromethorphan/ Quinidine)	**Candidates for treatment with Nuedexta should meet ALL the following criteria:** • Prescribed by a neurologist • Age ≥ 18 years • Documented diagnosis of pseudobulbar affect (PBA) associated with at least ONE of the following underlying neurologic conditions associated with PBA: amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS), Alzheimer's disease, dementia, stroke, traumatic brain injury, Parkinson's disease, or Lou Gehrig's disease • Documented Baseline Center for Neurologic Study-Lability Scale (CNS-LS) score >13 • Documented inadequate response, intolerance, or contraindication to treatment with both: a. Selective serotonin reuptake inhibitor (SSRI) (e.g., citalopram, escitalopram, sertraline) b. Tricyclic antidepressant (TCA) (e.g., amitriptyline, nortriptyline, imipramine) <u>Reasons for Non-coverage</u> • Concurrent use with quinidine, quinine, or mefloquine • Presence of heart failure, prolonged QT interval, congenital long QT syndrome, or a history of torsades de pointes • Complete atrioventricular (AV) node block without implanted pacemakers or high risk of complete AV block • Current use of a monoamine oxidase inhibitor (MAOI) or use of a MAOI within the preceding 14 days • Concomitant use of drugs that are both metabolized by CYP2D6 and cause QT interval prolongation (e.g., thioridazine and pimozide). • Concurrent use with another dextromethorphan containing product <u>Initial Approval:</u> 12 months <u>Continued Approval</u>: 24 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, patient should meet ALL the following criteria: • Documented improvement of symptoms (e.g., number of laughing and crying episodes has decreased from baseline) • Patient has not developed any contraindications for use as listed above as reasons for Non-coverage or any significant adverse effects (e.g., immune -mediated drug thrombocytopenia, hepatitis, serotonin syndrome, etc.)
Nulibry (Fosdenopterin)	**Candidates for treatment with Nulibry should meet ALL the following criteria:** • Prescribed by or in consultation with a neonatologist, neurologist, or specialist with expertise in the management of inborn errors of metabolism (e.g., pediatric geneticist) • Patient has one of the following (a or b): ○ Patient has a documented diagnosis of molybdenum cofactor deficiency type A (MoCD Type A) confirmed by genetic testing OR

Drug	Prior Authorization Criteria
	○ Patient is a neonate (up to 28 days after birth) and has a presumptive diagnosis of MoCD Type A based on **one (1)** of the following: ▪ Prenatal genetic diagnosis ▪ Onset of clinical signs and symptoms consistent with MoCD Type A deficiency (e.g., seizures, feeding difficulties, high-pitched cries, exaggerated startle reaction, increased/decreased muscle tone) within the first 28 days after birth ▪ Onset of laboratory signs and symptoms consistent with MoCD Type A deficiency (e.g., elevated urinary sulfite and/or S-sulphocysteine, elevated xanthine in urine or blood, or low or absent uric acid in the urine or blood) within the first 28 days after birth Reasons for Non-coverage: • MoCD Type A is not confirmed with genetic test results • Diagnosis of MoCD Type B or C Initial Approval: 4 months Continued Approval: 12 months. Continued approval for treatment with Nulibry should meet ALL of the criteria above in addition to the criteria below: • If the diagnosis of MoCD Type A was presumptive at the time of initial authorization, it has since been confirmed by genetic testing • Documentation that the patient has experienced a therapeutic response as evidenced by **one (1)** of the following: ○ Improved change in the molybdenum cofactor deficiency biomarkers ○ Improved growth parameters ○ Improved feeding patterns
Nuplazid (Pimavanserin)	**Candidates for treatment with Nuplazid should meet ALL the following criteria:** • Prescribed by a neurologist or psychiatrist • Age ≥ 18 years • Documented diagnosis of Parkinson's disease (PD) psychosis in patients with ALL the following: ○ The presence of hallucinations or delusions (which may include illusions or false sense of presence) ○ The psychotic symptoms occur after the diagnosis of PD was made or are as a result of PD ○ The psychosis is NOT secondary to Alzheimer's, schizophrenia, schizoaffective disorder, or delusional disorder ○ The symptom(s) are recurrent or continuous for at least one month • Must have a documented trial of a dose reduction or discontinuation of medications that may cause or contribute to hallucinations (e.g., anticholinergic medications, monoamine oxidase inhibitors, or dopamine agonists). OR documentation of the clinical rationale for why dose reduction or discontinuation was not performed • Documented trial, intolerance or contraindication to clozapine OR quetiapine • Patients must have a QTc on record within the last 30 days

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	Reasons for Non-coverage:
	
	• QTc exceeding 500 msec
	• Any history or diagnosis of cardiac arrhythmias
	  ○ Concomitant use of:
	  ▪ Class 1A antiarrhythmics (disopyramide, quinidine, procainamide)
	  ▪ Class 3 antiarrhythmics (sotalol, amiodarone, dronedarone, ibutilide, etc.)
	  ▪ Moxifloxacin, gatifloxacin
	  ▪ Ziprasidone, chlorpromazine, OR thioridazine.
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, continue approval if:
	
	• Documentation of clinical benefit during follow up
	• Adherence to follow-up assessments and the medication

Nurtec ODT (Rimegepant)	**Candidates for treatment with Nurtec ODT should meet the following criteria:** **Criteria if prescribed as acute migraine attack abortive therapy (as needed dosing):** • Age ≥ 18 years • Prescribed by a Neurologist, or providers in the Department of Neurology who specialize in headache management • Documented inadequate response or intolerance to Ubrelvy (ubrogepant) • A documented contraindication to treatment with triptans, such as coronary artery disease, history of stroke, peripheral vascular disease, ischemic bowel disease, basilar or hemiplegic migraine, unstable angina, and uncontrolled hypertension **OR d**ocumented inadequate response and/or intolerance to three different triptans or triptan dosage forms e.g., sumatriptan tablet, naratriptan tablet, rizatriptan ODT, sumatriptan intranasal. **Criteria if prescribed as migraine preventative therapy (every other day dosing):** • Age ≥ 18 years • Prescribed by a Neurologist, or providers in the Department of Neurology who specialize in headache management • Documented diagnosis of episodic migraine • Documented adequate trial of 2 preventative agents with strong evidence for migraine (e.g., tricyclic antidepressant, beta-blocker, topiramate, valproate, serotonin-norepinephrine reuptake inhibitor, ACE-inhibitor or angiotensin-receptor blocker) • Documented trial and failure of two CGRP injectable medication (e.g., Ajovy [fremanezumab-vfrm] is preferred, Emgality (galacanezumab-gnlm), Aimovig (erenumab-aooe) • Documented trial and failure of Qulipta (atogepant) • Documented compliance with a headache diary for at least 1 month prior to initiation • Patient is not currently receiving injectable monoclonal antibody against CGRP or its receptor i.e., Emgality (galcanezumab), Aimovig (erenumab), Ajovy (fremanezumab), or Vyepti (eptinezumab)

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Initial Approval: 6 months. Quantity limit of 16 tablets per 30 days Continued Approval: 12 months. Quantity limit of 16 tablets per 30 days will apply. Continue approval if the following criteria are met: • **For new members who were initiated on Nurtec ODT for acute migraine abortive treatment outside of KPGA**, approve Nurtec ODT if patient has previously tried and failed 2 or more abortive migraine therapies including Ubrelvy (ubrogepant). Otherwise, patient must meet the above coverage criteria without reasons for Non-coverage. • For new members who were initiated on Nurtec ODT for migraine preventative treatment outside of KPGA, approve Nurtec ODT if patient has previously tried and failed three or more preventive migraine therapies including at least one CGRP injectable medication (Ajovy is the KP preferred CGRP injectable). • Documented beneficial effect and tolerance of the medication. • Not prescribed concurrent CGRP monoclonal antibody therapy for migraine prevention i.e., Emgality (galcanezumab), Aimovig (erenumab), Ajovy (fremanezuma) or Vyepti (eptinezumab) if Nurtec ODT is prescribed for migraine prevention.
Ocrevus (Ocrelizumab) **Ocrevus Zunovo** (SC Formulation Back Office ONLY)	**Candidates for treatment with Ocrevus should meet ALL the following criteria:** Criteria for Relapsing Multiple Sclerosis indication: • Diagnosis of relapsing multiple sclerosis • Prescribed by a Neurologist • For Ocrevus: age ≥ 10 years AND weight ≥ 25 kg (55 lbs) • For Ocrevus Zunovo: age ≥ 18 years • Severe infusion reactions, persistent infusion reactions or loss of therapeutic response (recent clinical relapse or increased MRI activity) after initial adequate clinical response to intravenous rituximab infusion AND intravenous ublituximab (Briumvi) that may be due to suspected development of drug binding or neutralizing antibodies o ***NOTE:** The clinical significance of drug binding and neutralizing antibodies is debatable and has not been shown to impact the efficacy or severity of adverse events. In patients with no other reason for loss of therapeutic effect, a switch from rituximab to ocrelizumab may be considered • Patient has been screened for hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (HBcAb) and is seronegative or liver specialist consult has been obtained for chronically infected patients (carriers of HBsAg) or patients with unclear status (HBsAg negative but HBcAb positive) • Patient has had a baseline (prior to treatment initiation) negative interferon-gamma release assay test for TB Infection within the past 24 months or is positive for latent TB and has completed treatment in the past or is currently on treatment • Not used in combination with another MS disease modifying agent • Absence of an active infection Criteria for Primary Progressive Multiple Sclerosis indication:

Drug	Prior Authorization Criteria
	• Diagnosis of primary progressive multiple sclerosis • Prescribed by a Neurologist • Must be 18 years of age or older • Adequate clinical response to intravenous (IV) rituximab infusion ○ NOTE: If loss of clinical response to IV rituximab, Ocrelizumab should NOT be used for primary progressive multiple sclerosis • Presence of severe or persistent infusion reactions on IV rituximab infusion • Patient has been screened for hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (HBcAb) and is seronegative or liver specialist consult has been obtained for chronically infected patients (carriers of HBsAg) or patients with unclear status (HBsAg negative but HBcAb positive) • Patient has had a baseline (prior to treatment initiation) negative interferon-gamma release assay test for TB Infection within the past 12 months or is positive for latent TB and has completed treatment in the past or is currently on treatment • Not used in combination with another MS disease modifying agent • Absence of an active infection Reasons for Non-coverage: • Active HBV virus infection • History of life-threatening infusion reaction to rituximab or Ocrevus. • Concomitant use of antineoplastic or immunosuppressant therapies (e.g.: adalimumab, alefacept, anakinra, azathioprine, cladribine, cyclophosphamide, cyclosporine, daclizumab, efalizumab, etanercept, fludarabine phosphate, infliximab, leflunomide, mercaptopurine, methotrexate, mitoxantrone, mycophenolate mofetil, mycophenolic acid, pemetrexed and trastuzumab. ***NOTE:** Kaiser Permanente Inter-Regional Practice Recommendations for Multiple Sclerosis recommend rituximab as the preferred, highly effective agent in patients with positive JCV antibody status. Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** For new members who were initiated on Ocrevus outside of KPGA: patient must meet the full criteria above for approval without reasons for Non-coverage.

Drug	Prior Authorization Criteria
	For existing members who previously met the full criteria above: continue approval if patient has documented clinical benefit from medication and no reported severe adverse events to Ocrevus.

Odomzo
(Sonidegib)
	Candidates for treatment with Odomzo must meet ALL the following criteria:
	
	• Prescribed by a dermatologist or oncologist.
	• Age ≥18 years
	• Patient has a diagnosis of ONE of the following:
	  ○ Locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy OR patient is not a candidate for surgery or radiation therapy.
	  ○ Nodal basal cell carcinoma
	
	Initial Approval: 12 months with quantity limit of 30 capsules per 30 days
	
	Continued Approval: 12 months with quantity limit of 30 capsules per 30 days. For continued approval for treatment with Odomzo, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria.
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	
	For new members who were initiated on Odomzo outside of KPGA: Patient should mee ALL the following criteria:
	• Prescribed by a dermatologist or oncologist.
	• Age ≥ 18 years
	• Patient has a diagnosis of locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, patient is not a candidate for surgery or radiation therapy OR has nodal basal cell carcinoma.
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	• Quantity limit of 30 capsules per 30 days

Ogsiveo (Nirogacestat)	**Candidates for treatment with Ogsiveo must meet ALL the following criteria:** • Patient is ≥18 years of age • Prescribed by Hematology/Oncology • Documented diagnosis of progressing desmoid tumors ○ Progressing desmoid tumors are defined as ≥ 20% progression (according to the Response Evaluation Criteria in Solid Tumors [RECIST], version 1.1) within 12 months • The desmoid tumors are not amenable to surgery. • Physician documents medication will not be used with moderate or strong CYP3A inducer or inhibitor. Reasons for Non-coverage: • Pregnancy or lactation Initial Approval: 12 months

Drug	Prior Authorization Criteria
	Continued Approval: 12 months. Continued approval for treatment with Ogsiveo should meet ALL of the criteria above in addition to the criteria below: • Patient does not show evidence of progressive disease while on Ogsiveo therapy • Continued monitoring by Hematology/Oncology
Ojemda (Tovorafenib)	**Candidates for treatment with Ojemda should meet ALL the following criteria:** • Prescribed by an Oncologist • Age ≥ 6 months • Patient is diagnosed with relapsed or refractory pediatric low-grade glioma (pLGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation Reasons for Non-coverage: • Pregnant or breastfeeding Initial Approval: 6 months Continued Approval: 12 months. Confirm patient meets all the above coverage criteria and has documented clinical benefit from treatment. Ordering Information: • Ojemda is available through 2 specialty pharmacies: Biologics By McKesson and Onco360 Oncology Pharmacy

Ohtuvayre
(Ensifentrine)
	Candidates for Ohtuvayre (ensifentrine) should meet ALL the following criteria:
	• Age ≥ 18 years
	• Prescribed by a pulmonologist
	• Diagnosis of moderate to severe chronic obstructive pulmonary disease (COPD) with both:
	  ○ Blood eosinophil level of 100 cells/microliter or greater
	  ○ FEV_1/FVC ratio <0.7 post-bronchodilation
	• An exacerbation history, in the past 12 months with one of the following:
	  ○ One of more severe exacerbations (i.e., requiring hospitalization or ER visit)
	  ○ Two or more moderate exacerbations (i.e., requiring short acting bronchodilators and systemic corticosteroids, with or without antibiotics)
	• Patient is currently adherent to ONE of the following:
	  ○ High-dose triple combination therapy (LAMA/LABA/ICS): fluticasone 500 mcg/salmeterol 50 mcg (Wixela Inhub) 1 puff twice daily plus Spiriva Respimat (tiotropium 2.5mcg) 2 puffs daily OR Stiolto Respimat (tiotropium 2.5/olodaterol 2.5mcg) 2 puffs daily plus Alvesco (ciclesonide 160mcg) 1 puffs twice daily
	  ○ High-dose dual combination therapy (LAMA/ICS): Stiolto Respimat (tiotropium 2.5/olodaterol 2.5mcg) 2 puffs daily
	• Documented trial, intolerance or contraindication to both of the following:
	  ○ Azithromycin 250-500mg three times per week (trial of at least 18 months) AND
	  ○ Roflumilast 500mg daily (trial of at least 1 year)
	• Patient will continue to use dual or triple maintenance therapy for COPD
	• Patient is not being treated for relief of acute bronchospasm

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Reasons for Non-coverage: • Primary diagnosis of asthma • Concomitant use of roflumilast Initial Approval: 12 months Continued Approval: 12 months. Continued approval if patient meets all above coverage criteria without reasons for non-coverage and the following: • Member has experienced a decrease in COPD exacerbation frequency • Member has experienced an increase in FEV_1/FVC ratio • Continued use of dual or triple therapy in conjunction with ensifentrine
Ojjaara (Momelotnib dihydrochloride)	**Candidates for treatment with Ojjaara must meet ALL the following criteria:** • Prescribed by a hematologist or oncologist • Age ≥ 18 years • Patient diagnosed with intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF (post-polycythemia vera [PV] and post-essential thrombocythemia (ET)) • Patient has transfusion dependent anemia associated with MF AND Hgb <10 g/dL • Documented splenomegaly (size greater than 14 cm) Reasons for non-coverage: • Pregnancy or breastfeeding • Patients taking other JAK inhibitors (e.g ruxolitinib, pacritinib, fedratinib) Initial Approval: 12 months Continued Approval: 12 months. Patient must meet all criteria above without reasons for non-coverage in addition to: • Documented clinical benefit from medication • No reported adverse events to Ojjaara • Reduction in spleen size by ≥ 35% from baseline
Olumiant (Baricitinib)	**Candidates for treatment with Olumiant should meet ALL the following criteria PLUS the individual disease state criteria below:** • Patient has had a negative interferon-gamma release assay test for TB Infection within the past 24 months or is positive for latent TB and has completed treatment in the past or is currently on treatment. • Medication is NOT being used in combination with another biologic medication [omalizumab (Xolair), rituximab (Rituxan), adalimumab (Amjevita, Humira), etc], Janus kinase inhibitor [abrocitinib (Cibinqo), baricitinib (Olumiant), tofacitinib], or other potent immunosuppressants [azathioprine, cyclosporine]. • Then follow the disease state specific criteria below, based on diagnosis:

Drug	Prior Authorization Criteria

	Diagnosis of rheumatoid arthritis:
	
	• Age ≥ 18 years
	• Prescribed by rheumatology
	• Documented contraindication, intolerance, or inadequate response to at least a 3 month trial of each of the following:
	  ○ 1 conventional synthetic disease modifying antirheumatic drug:
	  ▪ Methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine
	  ○ 1 TNF inhibitor:
	  ▪ Infliximab (Infliximab-dyyb/Inflectra [preferred], Remicade)
	  ▪ Adalimumab (Amjevita [preferred], Humira)
	  ▪ Others: Golimumab (Simponi), Certolizumab (Cimzia)
	  ○ 1 IL-6 inhibitor:
	  ▪ Tocilizumab (Avtozma [preferred], Actemra), Kevzara (sarilumab)
	  ○ Tofacitinib
	
	Initial approval: 12 months
	
	Continued approval: 12 months if the following criteria are met:
	
	For new members who were initiated on baricitinib prior to joining KPGA: Patient must meet all above coverage criteria and have documented adequate response and tolerance of the medication during specialist follow-up in the last 6 months.
	
	For existing members who have previously met the full criteria above: documented adequate response and tolerance of medication follow-up during the last 12 months
	
	Diagnosis of Alopecia Areata:
	
	• Age ≥ 18 years
	• Prescribed by dermatology
	• Documented diagnosis of severe or very severe alopecia areata (AA) defined by:
	  ○ At least 50% hair loss as documented by provider AND
	  ○ No spontaneous improvement in hair loss over the past 6 months
	  ○ **NOTE:** Other forms of alopecia are excluded from coverage
	• Documented trial, contraindication, or inadequate response after at least 4 months to all of the following:
	  ○ Topical corticosteroid
	  ○ Intralesional corticosteroid injections
	  ○ Oral corticosteroid
	  ○ At least 1 topical immunotherapy (e.g., squaric acid dibutyl ester [SADBE], topical anthralin) or oral immunomodulator (methotrexate, azathioprine, cyclosporine)
	  ○ Tofacitinib (off-label)
	  ○ Litfulo (ritlecitinib)
	
	Initial Approval: 6 months

Drug	Prior Authorization Criteria
	Continued Approval: 12 months if the following criteria are met: For new members who were initiated on baricitinib prior to joining KPGA: Approve the medication if the patient has a documented adequate response and tolerance of Olumiant during a specialist follow-up in the last 6 months AND has tried and failed **BOTH** of the following: • Xeljanz (tofacitinib) • Litfulo For existing members who have previously met the full coverage criteria: Patient must meet all above coverage criteria above and have physician documentation of improvement in scalp hair coverage from baseline (initiation of Olumiant)

Omnipod 5 System and Pods	**Candidates for Omnipod 5 Insulin Pump System must meet ALL the following criteria:**
	
	• Prescribed by an endocrinologist
	  ○ Endocrinology team educates patient on proper device use
	• Documented diagnosis of Type 1 DM and age >/= 2 years OR
	  ○ Type 2 DM and age >/=18
	• Documented frequency of glucose self-testing of at least three times per day or regular use of calibrated CGM
	• Treatment program including at least three insulin injections per day requiring frequent self- adjustments of insulin dose for at least 6 months
	• Total rapid acting insulin requirement < 200 units per 72 hours
	  ○ Rapid acting insulin examples: insulin aspart or Kirsty, insulin lispro or Humalog, insulin glulisine or Apidra
	• Medical need for a tubeless delivery device, instead of a traditional insulin pump such as patient is at increased risk of dislodging traditional insulin pump tubing through, work in a hazardous environment or routinely participates in strenuous exercise for more than 1 hour per day
	• Inadequate BG control despite multiple daily insulin injections as documented by **at least one** of the following:
	  ○ A1C ≥ 7%
	  ○ Recurrent hypoglycemic events (BG <70) in the past month
	  ○ History of severe glycemic excursions
	  ○ Dawn phenomenon with fasting sugars >200 mg/dL routinely
	• **Coverage is not authorized for patients with existing coverage for an alternate insulin pump device.**
	
	Initial Approval: Indefinite. Approve for quantity of 10 pods per 30 days
	
	Continued Approval: Indefinite 10 pods approved per 30 days.
	
	Notes:
	• For new members stable on Omnipod insulin pump, continue if evaluated by endocrinology (visit or PCP consult to endo), deemed stable on existing insulin pump and utilizing <200 units of rapid acting insulin every 72 hrs.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• To request any other (i.e., non-Omnipod) insulin pump, submit via DME referral process.

Omnipod DASH Intro Kit and Pods	**Candidates for Omnipod DASH Intro Kit and Pods must meet ALL the following criteria:**
	
	• Prescribed by an endocrinologist
	  ○ Endocrinology team educates patient on proper device use
	• Member has one of the following conditions:
	  ○ Documented diagnosis of Type 1 DM
	  ○ Documented diagnosis of Type 2 DM AND insulinopenia (defined as a fasting c-peptide level of ≤ 0.88 ng/mL with a concurrent glucose of 70-225 mg/dL)
	• Documented frequency of glucose self-testing of at least three times per day or regular use of calibrated CGM
	• Treatment program including at least three insulin injections per day requiring frequent self-adjustments of insulin dose for at least 6 months
	• Total rapid acting insulin requirement < 200 units per 72 hours
	  ○ Rapid acting insulin examples: Kirsty or insulin aspart, insulin lispro or Humalog, insulin glulisine or Apidra
	• Medical need for a tubeless delivery device, instead of a traditional insulin pump such as patient is at increased risk of dislodging traditional insulin pump tubing through, work in a hazardous environment or routinely participates in strenuous exercise for more than 1 hour per day
	• Inadequate BG control despite multiple daily insulin injections as documented by **at least one** of the following:
	  ○ A1C ≥ 7%
	  ○ Recurrent hypoglycemic events (BG <70) in the past month
	  ○ History of severe glycemic excursions
	  ○ Dawn phenomenon with fasting sugars >200 mg/dL routinely
	• **Coverage is not authorized for patients with existing coverage for an alternate insulin pump device.**
	
	Initial Approval: Pods: 12 months. Approve for quantity of 10 pods per 30 days (***Note:** Kit: One time approval, no refills allowed); Pods and intro kits require separate approvals/ referral numbers.
	
	Continued Approval: 12 months for pods only. Confirm patient continues to meet all criteria above without reasons for Non-coverage. In addition, endocrinologist to document improved glycemic control as evidenced by A1C improvement or decrease in glycemic variability.
	
	Notes:
	• For new members who were initiated outside of KPGA: Confirm patient meets all the above criteria for continued approval.
	• To request any other (i.e., non-Omnipod) insulin pump, submit via DME referral process.

Omvoh (Mirikizumab)	**Candidates for treatment with Omvoh (mirikizumab) must meet ALL the following criteria:**

Drug	Prior Authorization Criteria

	• Patient has had a negative interferon-gamma release assay test for TB infection within the past 24 months or is positive for latent TB and has completed treatment in the past or is currently on treatment
	• Not prescribed in combination with another biologic agent for the same indication or advanced small molecule (e.g., tofacitinib, upadacitinib) for the same indication
	• Then follow the disease state specific criteria below, based on diagnosis:
	
	<u>Criteria for ulcerative colitis:</u>
	• Age ≥ 18 years
	• Prescribed by a gastroenterologist
	• Documented moderately to severely active ulcerative colitis (UC)
	• Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL the following:
	  ○ Infliximab product (e.g., Inflectra [preferred])
	  ○ Ustekinumab product (e.g., Yesintek [preferred])
	  ○ Tofacitinib (preferred JAK-inhibitor) OR Rinvoq (upadacitinib). If patient is pregnant, tofacitinib or Rinvoq trial is NOT required
	  ○ Tremfya (guselkumab)
	
	<u>Criteria for Crohn's Disease (CD):</u>
	• Age ≥ 18 years
	• Prescribed by a gastroenterologist
	• Documented moderately to severely active Crohn's Disease (CD)
	• Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL the following:
	  ○ Infliximab product (e.g., Inflectra [preferred])*
	  ○ Adalimumab product (e.g., Amjevita [preferred])*
	  ○ Ustekinumab product (e.g., Yesintek [preferred])
	  ○ Entyvio (vedolizumab) – a trial is not required for CD, if documentation of small bowel, perianal or fistulizing / penetrating disease
	  ○ Rinvoq (upadacitinib). If patient is pregnant, Rinvoq trial is NOT required
	  ○ Tremfya (guselkumab)
	  ○ *Patient must try/fail all of the agents listed above unless provider documents rationale why additional anti-TNF agent is inappropriate (i.e., primary or secondary non-response despite therapeutic drug level +/- presence of anti-drug antibodies or adverse effect requiring a different mechanism of action, member temporarily located outside of our KP network and cannot receive infusions)
	
	<u>Initial Approval:</u> 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	• **Induction: Approve intravenous dose given in office at week 0, week 4 and week 8 ONLY**
	• **Maintenance: Approve for member to fill via the outpatient pharmacy benefit only**

Drug	Prior Authorization Criteria
	Continued Approval: 12 months. • For new members and existing members Documented clinical benefit (asymptomatic or in remission) from therapy, by a gastroenterology specialist within the past 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Induction: Approve intravenous dose given in office at Week 0, Week 4, and Week 8 ONLY** • **Maintenance: Approve for member to fill via the outpatient pharmacy benefit only** Dosing and Administration: • For Crohn's disease (CD): ○ Induction dose: One dose of 900mg administered by intravenous infusion over at least 90 minutes at Week 0, Week 4, and Week 8 by a healthcare professional ○ Maintenance dose: Inject 300mg subcutaneously starting at Week 12 and every 4 weeks thereafter. • For ulcerative colitis (UC): ○ Induction dose: One dose of 300mg administered by intravenous infusion over at least 30 minutes at Week 0, Week 4, and Week 8 by a healthcare professional ○ Maintenance dose: Inject 200mg subcutaneously starting at Week 12 and every 4 weeks thereafter.
Preferred: Clindamycin Phosphate and Benzoyl Peroxide Gel, 1.2%/3.75% (generic Onexton) Non-Preferred: Onexton (Clindamycin Phosphate and Benzoyl Peroxide Gel, 1.2%/3.75%)	**Candidates for Onexton should meet all of the following criteria. If criteria is met, approve for generic Clindamycin Phosphate and Benzoyl Peroxide Gel, 1.2%/3.75%** • Prescribed by a dermatologist • For topical treatment of acne vulgaris in patients 12 years of age and older • Intolerant/contraindication or did not have an adequate response to all of the following alternatives (in order of preference): ○ OTC Benzoyl Peroxide 2.5% AAA DAILY ○ Topical retinoid (e.g., OTC Differin 0.1% Gel AAA DAILY or Retin-A 0.025-0.1% Cream, Gel AAA QHS ○ Clindamycin Phosphate/Benzoyl Peroxide 1.2 (1% base) /5% Gel (generic for Duac) AAA BID ○ Erythromycin/benzoyl peroxide 3/5% (generic for Benzamycin) topical gel AAA BID ○ Tazarotene 0.1% Cream AAA QHS NF ○ Dapsone 5% Gel AAA BID NF
Onureg (Azacitidine)	**Candidates for treatment with Onureg should meet ALL the following criteria:** • Patient must be ≥ 18 years old of age • Documented diagnosis of Acute Myeloid Leukemia (AML) • Prescribed by a Hematologist/Oncologist • Patient achieved complete remission or complete remission with incomplete blood count recovery following induction chemotherapy and is not able to complete intensive consolidation/curative therapy • Documentation supports inability to use SC/IV azacitidine (e.g., contraindication to excipients)

Drug	Prior Authorization Criteria
	Reasons for Non-coverage: • Documented hypersensitivity to azacitidine • Intended use of Onureg as a substitute for intravenous or subcutaneous azacitidine Initial approval period**:** 12 months. Continued approval**:** 12 months if the patient meets ALL the following: • Patient continues to meet above criteria • Patient continues to be monitored and treated by a hematologist/oncologist • Patient does not have any evidence of progressive disease while on Onureg
Opdualag (Nivolumab and Relatlimab)	**Candidates for Opdualag should meet ALL the following criteria:** • Prescribed by an Oncologist • Age ≥ 12 years • Weight ≥ 40 kg • Individual has unresectable or metastatic melanoma Reasons for Non-coverage: • Uveal melanoma • Patient with active autoimmune disease • Patient with active untreated leptomeningeal or brain metastasis Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage in addition to criteria below: • Stabilization of disease or absence of disease progression • Absence of unacceptable toxicity from the drug (i.e infusion-related and hypersensitivity reactions, myelosuppression, infections, etc.) • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Dosing and Administration: • Nivolumab 480 mg and relatlimab 160 mg administered intravenously once every 4 weeks
Opsynvi (Macitentan and tadalafil)	**Candidates for treatment with Opsynvi (macitentan and tadalafil) must meet ALL the following criteria:** • Prescribed by a pulmonologist, pulmonary arterial hypertension (PAH) specialist or rheumatologist

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
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Age ≥ 18 years
Diagnosis of pulmonary arterial hypertension based on right heart catheterization
Patient is WHO Functional Class II-III (i.e., Class II patients exhibit slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope; Class III patients exhibit marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope.
Documented failure of, contraindication or intolerance to ALL of the following:

Ambrisentan (generic Letairis) [KPGA's preferred Endothelin Receptor Antagonist] + a PDE5 inhibitor (i.e., sildenafil 20mg TID, tadalafil 40mg (two 20mg tablets) daily
Bosentan (generic Tracleer) + a PDE5 inhibitor (i.e., sildenafil 20mg TID, tadalafil 40mg (two 20mg tablets) daily
Macitentan (generic Opsumit) + a PDE5 inhibitor (i.e., sildenafil 20mg TID, tadalafil 40mg (two 20mg tablets) daily

Documentation that patient is unable to take individual components (macitentan and tadalafil) separately
If patient is a female of childbearing age (18-50 years), must have a baseline negative pregnancy test (within 1 month) AND must be on at least one form on effective contraception
NOT currently receiving another endothelial receptor antagonist (ERA) agent such as ambrisentan or bosentan
Do not approve in any of the following cases:

Patient is pregnant or lactating/breastfeeding
For doses higher than 10mg (1 tablet) per day
For any indication other than pulmonary arterial hypertension

<u>Initial Approval:</u> 12 months

<u>Continued Approval</u>: 12 months. Confirm patient meets all above coverage criteria without reasons for non-coverage.

<u>Ordering Information:</u>

<u>OPSYNVI®</u> (macitentan and tadalafil) is only available through a network of certified pharmacies. KPNSP has access to Opsynvi and dispenses to KP members in ALL regions.

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<tr><td>Opzelura
(Ruxolitinib)</td><td>
Candidates for Opzelura treatment should meet ALL the following criteria:

<u>Criteria for use for the diagnosis of atopic dermatitis:</u>

Documented mild-to-moderate atopic dermatitis (BSA 5%-20%)
Prescribed by a dermatologist
Age ≥ 12 years
Documented inadequate response, intolerance or contraindication to all of the following:

Medium to very high potency topical corticosteroid for a minimum of 2 weeks:

<table>
<tr><th>Medium Potency</th><th>High and Very High Potency</th></tr>
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Drug	Prior Authorization Criteria

Triamcinolone acet 0.1%, 0.025% O, C	Betameth diprop aug 0.05% C
Betamethasone val 0.1% C	Fluocinonide 0.05% O, C, G
Mometasone 0.1% O, C	Fluocinonoide-emollient 0.05% C
Triamcinolone acet 0.5% C	Desoximetasone 0.25% C
Betamethasone diprop 0.05% C	Betamethasone diprop aug 0.05% O, G
Betamethasone val 0.1% L	Clobetasol 0.05% O, C

O = oint, C = cream, G = gel, L = lotion

- Topical calcineurin inhibitors [Pimecrolimus (Elidel) or tacrolimus (Protopic)] for a minimum of 2 weeks
- Phototherapy (unless documented that pediatric patient is developmentally unable to stand in light unit by him/herself)
- Systemic corticosteroids (i.e prednisone, methylprednisolone)

Reasons for Non-coverage:

- History of thrombosis (e.g., DVT, PE) or increased risk for developing thrombosis
- Active tuberculosis (TB), latent TB infection or other active infection
- Pregnant or breastfeeding

Initial Approval: 4 months (with quantity limited to 60 grams (1 tube) per 30 days)

Continued Approval: 12 months if patient has documented a clinically significant benefit from medication as defined by the Provider.

Criteria for use for the diagnosis of nonsegmental vitiligo:

- Age ≥ 12 years
- Prescribed by a dermatologist
- Documented diagnosis of nonsegmental vitiligo with the following:
  - Depigmented areas affecting ≥ 0.5% facial body surface area (F-BSA) OR ≥ 3% non-facial BSA
    AND
  - Treatment of total body vitiligo area (facial and non-facial, including hands, feet, upper and lower extremities, and trunk body areas) does not exceed 10% BSA
- Documented trial and failure, contraindication, or intolerance to all of the following:
  - Topical calcineurin inhibitors (e.g., tacrolimus) for at least 3 months
  - Medium to high potency topical corticosteroid for at least 2 months
  - Phototherapy for at least 6 months

Reasons for Non-coverage:

Drug	Prior Authorization Criteria
	• Other forms of vitiligo (e.g., segmental) or other differential diagnosis of vitiligo or other skin depigmentation disorders (e.g., piebaldism, pityriasis alba, leprosy, postinflammatory hypopigmentation, progressive macule hypomelanosis, nevus anemicus, chemical leukoderma, and tinea versicolor) Other Clinical Considerations: • History of thrombosis (e.g., DVT, PE) or increased risk for developing thrombosis • Active tuberculosis (TB), latent TB infection or other active infection • Pregnant or breastfeeding • Concurrent therapy with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine Initial approval: 6 months Continued approval: 12 months if patient has documented a clinically significant benefit from medication as defined by the provider and does not have reasons for Non-coverage
Nitisinone Products **Preferred: Nitisinone (generic Orfadin) capsule** **Non-Preferred Orfadin (Nitisinone) capsule or suspension** **Nityr** (Nitisinone) tablets	**Candidates for treatment with nitisinone should meet ALL the following criteria:** • Diagnosis of hereditary tyrosinemia type 1 as confirmed by laboratory or genetic testing. • Patient has elevated urinary or plasma succinylacetone (SA) levels OR a mutation in the fumarylacetoacetate hydrolase (FAH) gene. • Prescribed by or in consultation with a provider who specializes in the treatment of inherited metabolic disorder/genetic diseases. • Documented use as an adjunct to dietary restriction of tyrosine and phenylalanine • For non-preferred products (e.g., brand name Orfadin capsules, Orfadin suspension, or Nityr tablets) patient had a documented trial and failure to generic nitisinone capsule. a. For patients unable to swallow capsules, nitisinone capsules maybe opened and contents suspended in a small quantity of water, formula, or apples sauce and administered immediately. Initial Approval: 12 months Continued Approval: 12 months. Continued approval for treatment with nitisinone should meet ALL of the criteria above in addition to the criteria below: • Member has documentation of positive clinical response and/or stabilization of disease (e.g., decrease in urinary/plasma succinylacetaone and alpha-1-microglobulin levels)
Orgovyx (Relugolix)	**Candidates for treatment with Orgovyx should meet ALL the following criteria:** • Prescribed by **Medical** Oncologist, Radiation Oncologist or Urologist • Age ≥ 18 years • Documented diagnosis of advanced prostate cancer • Patient has relative contraindications or have trialed and failed at least 1 year of continuous androgen deprivation therapy with leuprolide (Eligard or Lupron) OR Firmagon (Degarelix)

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ Relative contraindication: Patient with history of major cardiovascular events • Documentation of 1 of the following: ○ Evidence of biochemical (PSA) or clinical relapse after local primary intervention with curative intent ○ Newly diagnosed hormone-sensitive metastatic disease ○ Advanced localized disease unlikely to be cured by local primary intervention with curative intent Initial Approval: 12 months Continued Approval: 12 months. Confirm patient meets all above criteria. In addition, patient does not show evidence of progressive disease while on Orgovyx therapy. Ordering: • Orgovyx is available via Specialty Pharmacy: ASD Healthcare
Opfolda (Miglustat)	**Candidates for treatment with Opfolda should meet ALL the following criteria:** • Diagnosis of late-onset Pompe disease • Patient weighs 40 kg or more • Prescribed by or in consultation with a specialist in genetic medicine • Prescribed in combination with cipaglucosidase alfa (Pombiliti) • If female of childbearing potential, baseline negative pregnancy test Approval period: 6 months Continued approval: 1 year • Documented beneficial effect from therapy during specialist follow up in the last 6 months
Oriahnn (Elagolix, Estradiol, and Norethindrone; Elagolix)	**Candidates for treatment with Oriahnn should meet ALL the following criteria:** • Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) • Prescribed by an OB/GYN or reproductive endocrinologist • Age ≥ 18 years AND premenopausal • Documented minimum three-month trial, intolerance OR contraindication to **ALL** of the following (use of drugs below can occur simultaneously): ○ One combined oral contraceptive ○ One progestin therapy (Depo-Provera, IUD, progestin only pill) ○ Tranexamic acid (i.e., Lysteda) ○ Lupron Depot Reasons for Non-coverage: • Current or history of thrombotic or thromboembolic disorders • Patient at high risk or thrombotic events, (i.e., age ≥ 35 years with current nicotine use, uncontrolled hypertension)

Drug	Prior Authorization Criteria
	• Pregnancy • Known osteoporosis • Undiagnosed abnormal uterine bleeding • Current or history of breast cancer or other hormonally sensitive malignancies (i.e., mutations with BRCA malignancies) • Known hepatic impairment or disease • Concomitant use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine, gemfibrozil) Initial Approval: 6 months Continued Approval**:** 6 months (maximum approval of 24 months). Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, continue approval if the following: • Documented positive clinical response (i.e., clinically significant improvement in fibroid-induced heavy menstrual bleeding defined as at least 50% reduction in menstrual blood loss from baseline to the final month (6 months). • Treatment has not exceeded a total of 24 months

Orilissa
(Elagolix)
	Candidates for treatment with Orilissa should meet ALL the following criteria:
	
	• Diagnosis of moderate to severe pain associated with endometriosis
	• Prescribed by an OB/GYN or a Reproductive Endocrinologist
	• Age ≥ 18 years AND premenopausal
	• Documented minimum three-month trial, intolerance OR contraindication to the following
	  ○ One combined oral contraceptive (unless contraindication) **AND**
	  ○ One progestin-only therapy (MPA, Levonorgestrel-releasing IUD, progestin only pill)
	• For 200 mg BID: Patient must have coexisting condition of dyspareunia
	
	Reasons for Non-coverage:
	
	• Pregnancy
	• Known Osteoporosis
	• Severe Hepatic Impairment (Child-Pugh C)
	• Concomitant use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine, gemfibrozil)
	• Previously completed 24 months of treatment with Oriahnn, Myfembree or Orilissa
	
	Initial approval: 6 months
	
	***NOTE:** the 200 mg BID dosing will be authorized for 6 months only
	
	Continued approval (for DAILY DOSE ONLY): 1 year. Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, continue approval if documented positive clinical response (e.g., improvement in pain) AND treatment has not exceeded a total of 24 months
	
	***NOTE:** The 200 mg BID dosing should not be reauthorized for continued therapy

Drug	Prior Authorization Criteria

Orkambi
(Lumacaftor and Ivacaftor)
	Candidates for treatment with Orkambi should meet ALL the following criteria:
	
	• Patient is at least 1 year of age
	• Prescribed by a Pulmonologist
	• Patient has a documented diagnosis of cystic fibrosis
	• Documented homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
	• Documentation of baseline ALT, AST, and bilirubin provided
	• Baseline ophthalmic examination results are provided in pediatric patients
	• Patient is **NOT** taking contraindicated medications such as:
	  ○ Anti-infectives: rifampin or rifabutin
	  ○ Seizure Medications: Phenobarbital, carbamazepine or phenytoin
	  ○ Sedatives/Anxiolytics: triazolam or midazolam
	  ○ Immunosuppressants: cyclosporine, everolimus, sirolimus, or tacrolimus
	  ○ Herbal supplement: St. John's Wort
	
	Initial Approval: 6 months
	
	Continued Approval: 6 months. Confirm patient meets all above coverage criteria without reason for non-coverage. In addition, continue approval if the following criteria are met:
	
	• Adherence to quarterly clinic visits
	• The prescribing physician determines that the patient is tolerating lumacaftor/ivacaftor therapy and has achieved a clinically meaningful indicator of response in at least one of the following parameters:
	  ○ Improvement of percent predicted FEV_1 from baseline
	  ○ Pulmonary exacerbations
	  ○ Body mass index
	
	Ordering Information:
	
	Orkambi is available through the KP Specialty Pharmacy. If approved for coverage, prescribers must complete the KP-SP Orkambi Order Form and fax it to the KP-Specialty Pharmacy (1-650-301-5790).

Orladeyo (Berotralstat)	**Candidates for treatment with Orladeyo should meet ALL of the following criteria:** • Prescribed by an allergist or immunologist • **For request of Orladeyo pellets:** Age is 2-11 years • **For request of Orladeyo capsules:** Age ≥ 12 years • A diagnosis of **one** of the following: ▪ Type I hereditary angioedema (HAE) with documented C4 level below the lower limit of normal as defined by the laboratory performing the test

Drug	Prior Authorization Criteria
	AND C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test ▪ Type II HAE with documented C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test with documentation provided • Patient has documented intolerance, trial, failure, or contraindication to Takhzyro AND Haegarda for HAE prophylaxis. • Orladeyo is NOT being used in combination with other products indicated for **prophylaxis** against HAE attacks (e.g., Takhzyro, Cinzyre, Haegarda). ▪ Note: Orladeyo has not been studied in combination with other prophylactic therapies for HAE, and combination therapy for long-term prophylactic use is not recommended. Individuals may use other medications, including Cinryze, for on-demand treatment of acute HAE attacks, and for short-term (procedural) prophylaxis Reasons for Non-coverage: • Treatment of angioedema acute attacks in adult and adolescent patients with HAE Initial Approval: 12 months Continued Approval: 12 Months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, approval will be based on clinical documentation of functional improvement, a decrease in frequency of HAE attacks, and an improvement in severity and duration of attacks. Ordering information: • Available via Specialty Pharmacy: Optime Care (https://www.optimecare.com/)
Orlynvah (Sulopenem etzadroxil-probenecid)	**Candidates for treatment with Orlynvah (sulopenem etzadroxil-probenecid) should meet ALL of the following criteria:** • Prescribed by adult primary care physicians, urologists, gynecologists, infectious disease specialists • Diagnosed with uncomplicated urinary tract infection (uUTI) • Patient is female AND age ≥ 18 years • Patient has limited or no alternative ORAL antibacterial treatment options • Documented culture demonstrating uUTI is caused by a bacteria with sensitivity to sulopenem or ertapenem AND resistance or contraindication to all alternatives (e.g.,Pivya [pivmecillinam], trimethoprim-sulfamethoxazole [TMP-SMX], nitrofurantoin, fosfomycin, penicillins [e.g., amoxicillin-clavulanate], cephalosporins [e.g., cephalexin], fluoroquinolones [e.g., ciprofloxacin]) Reasons for Non-coverage: • Known blood dyscrasias (e.g., anemia, leukopenia, thrombocytopenia, hemophilia, etc.) • Known uric acid kidney stones

Drug	Prior Authorization Criteria
	• Concomitant use with ketorolac tromethamine or ketoprofen • CrCl < 15 ml/min or hemodialysis Approval: 5 days (one treatment course)

Orserdu (Elacestrant)	**Candidates for treatment with Orserdu should meet ALL the following criteria:**
	• Prescribed by an oncologist
	• Age ≥ 18 years
	• Diagnosis of advanced or metastatic estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, ESR1-mutated breast cancer
	• Documented disease progression after treatment with of BOTH of the following:
	  ○ At least one line of endocrine therapy (examples include fulvestrant, anastrozole, exemestane, and letrozole)
	  ○ At least one CDK4/6 inhibitor (examples include ribociclib, abemaciclib, and palbociclib)
	• For female patients, patient meets ONE of the following:
	  ○ Patient is post-menopausal
	  ○ Patient is pre/perimenopausal **AND** is prescribed a concurrent gonadotropin-releasing hormone (GnRH) agonist (e.g., leuprolide, goserelin (Zoladex), triptorelin (Trelstar), etc) **OR** has had surgical bilateral oophorectomy or ovarian irradiation
	
	Initial Approval: 12 months with quantity limited to 30 tablets per 30 days
	
	Continued Approval: 12 months with quantity limited to 30 tablets per 30 days. Continue approval if the following criteria is met:
	• Patient continues to meet the above criteria
	• No evidence of unacceptable toxicity or disease progression

Ortikos (Budesonide)	**Candidates for treatment with Ortikos should meet ALL the following criteria**: • Prescribed by Gastroenterologist • Diagnosis of Crohn's disease • Age ≥ 8 years • Documented trial of prednisone or documented failure, intolerance or contraindication • Documented trial of generic budesonide 3 mg or documented failure, intolerance, or contraindication Initial Approval: 12 weeks Continued Approval: One additional 8 week course if prescriber deems medically necessary for recurring episodes of active disease Reasons for Non-coverage:

Drug	Prior Authorization Criteria
	• Ulcerative Colitis • Pregnancy
Otarmeni (Lunsotogene parvec-cwha)	**Candidates for treatment with Otarmeni (lunsotogene parvec-cwha) should meet ALL the following criteria:** • Prescribed by geneticist, audiologist, or otolaryngologist/neurotologist (ENT) • Age ≥ 10 months • Diagnosis of severe-to-profound or profound sensorineural hearing loss (defined as inability to detect any frequency **< 90 dB HL**) • Confirmation of biallelic, pathogenic or likely pathogenic *OTOF* variants • Patient has NOT had a prior cochlear implant in the affected ear • Patient must demonstrate preserved outer hair cell (OHC) function via otoacoustic emissions (OAE) test • Patient must receive meningitis-related and age-appropriate vaccinations at least 1 month prior to the first corticosteroid dose Approval Period: One time approval (one full course of treatment) • **Please approve for inpatient administration only** Note: KP members will be referred to external facilities that are certified to administer lunsotogene parvec-cwha

Otezla
(Apremilast)
	Candidates for treatment with Otezla should meet ALL the following criteria PLUS the individual disease state criteria below:
	
	• Prescriber is a Rheumatologist or Dermatologist
	
	Diagnosis of psoriatic arthritis:
	
	• Patient is 6 years of age or older and weighs at least 20kg
	• Patient has a documented inadequate response, intolerance, or contraindication to all of the following:
	  ○ 1 conventional synthetic DMARD (unless documented axial or severe disease (e.g., dactylitis, multiple (>/=5) joint involvement, erosive disease, or functional limitation)
	  ▪ methotrexate
	  ▪ leflunomide
	  ▪ sulfasalazine
	  ○ 1 TNF inhibitor
	  ▪ Infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade)
	  ▪ Adalimumab product (Amjevita [preferred], Humira)
	  ▪ Others: Golimumab (Simponi), Certolizumab (Cimzia)
	  ○ 1 IL-17 inhibitor

Drug	Prior Authorization Criteria
	▪ Secukinumab (Cosentyx) ▪ Others: Ixekizumab (Taltz) ○ Tofacitinib (Xeljanz) • Patient has a documented inadequate response, intolerance, or contraindication the following (unless documented axial disease): ○ Ustekinumab product (Yesintek [preferred], Stelara) <u>Diagnosis of plaque psoriasis</u>: • Documented moderate-to-severe plaque psoriasis • Patient is 6 years of age or older • Patient has a documented inadequate response, intolerance, or contraindication to each of the following: ○ 1 TNF inhibitor (unless patient is less than 18 years old) ▪ Infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade) ▪ Adalimumab product (Amjevita [preferred], Humira) ▪ Others: Golimumab (Simponi), Certolizumab (Cimzia) ○ Ustekinumab product (Yesintek [preferred], Stelara) ○ 1 IL-17 inhibitor ▪ Secukinumab (Cosentyx) ▪ Others: Ixekizumab (Taltz) • If patient has been treated with a biologic drug for psoriasis in the past 6 months, proceed to initial approval. For all other patients, confirm additional criteria are met: ○ >10% Body Surface Area affected (Unless palmar-plantar involvement is severe) • Inadequate response (of at least a 3-month trial), intolerance or contraindication to Phototherapy (PUVA, UVB with coal tar or dithranol, UVB standard or narrow-band, or home UVB) <u>excluding</u> patients with: ○ Involvement of sensitive areas (e.g. hands, feet, face, body folds or genitals) ○ Concomitant use of medications that cause photosensitivity ○ History of a photosensitivity disorder (e.g. Lupus, Dermatomyositis, Porphyria, Xeroderma pigmentosum) ○ History of melanoma or abnormal moles or multiple non-melanoma skin cancers ○ Pediatric patient is developmentally unable to stand in light unit by him/herself ○ **NOTE: Light box trial required unless member has a High Deductible Health Plan** <u>Diagnosis of Hidradenitis Suppurativa:</u> • Documented moderate-to-severe hidradenitis suppurativa • Patient is 12 years of age or older • Patient has a documented inadequate response, intolerance or contraindication to one of the following: ○ Adalimumab product (Amjevita [preferred], Humira) ○ Infliximab product (infliximab-dyyb/Inflectra [preferred], Remicade) • For patients who have NOT been treated with a biologic for hidradenitis suppurativa in the past 6 months, confirm the following additional criteria:

Drug	Prior Authorization Criteria
	○ Documented inadequate response, intolerance, or contraindication to all of the following: ▪ Topical clindamycin 1% solution/lotion/gel (minimum of 12 weeks) ▪ Intralesional corticosteroids (minimum of 4 weeks) ▪ Oral antibiotics (e.g., doxycycline, tetracycline, clindamycin +/- rifampin, erythromycin) (minimum of 10 weeks) <u>Diagnosis of Behçet's disease:</u> • Patient has active oral ulcers or other mucocutaneous involvement • Patient is 18 years of age or older • Documented failure or clinically significant adverse effects to ALL of the following therapies (of at least a 1-month trial), unless contraindicated or clinical reason to avoid treatment ○ Colchicine ○ Systemic corticosteroids ○ Azathioprine ○ Tumor necrosis factor inhibitors (e.g., adalimumab or infliximab products) <u>Initial Approval:</u> 6 months <u>Continued Approval</u>: 12 months if the following criteria are met: <u>For new members who were initiated on apremilast (Otezla) outside of KPGA:</u> Confirm patient meets the full criteria above for approval. <u>For existing members who have previously met the full criteria above:</u> documented adequate response to therapy during specialist follow up in the last 12 months
Oxervate (Cenegermin-bkbj)	**Candidates for treatment with Oxervate should meet ALL the following criteria:** • Documented diagnosis of moderate to severe neurotrophic keratitis • Prescribed by an Ophthalmologist • Age ≥ 2 years • History of failure of ALL the following non-surgical options: ○ OTC artificial tear products, gels or lubricant ointments ○ Therapeutic Contact Lenses ○ Autologous Serum eye drops (unless contraindicated) • Not a candidate for surgical therapies <u>Approval:</u> • One 8- week authorization • **Approve for member to fill via the outpatient pharmacy benefit only**
Oxlumo (Lumasiran)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** **Candidates for treatment with Oxlumo should meet ALL the following criteria:**

Drug	Prior Authorization Criteria

	• Prescribed by nephrologists, pediatric nephrologists, urologists, and pediatric urologists
	• Documented diagnosis of primary hyperoxaluria type 1 (PH1) with confirmed AGXT mutation.
	• Diagnosis is confirmed by both of the following:
	  ○ Elevated urinary oxalate excretion, AND
	  ○ Elevated plasma oxalate concentration
	• Age ≥ 4 months
	• Documentation that the patient has made efforts to increase daily fluid intake
	• Concurrent use of pyridoxine OR previous trial of at least 3 months of pyridoxine with no significant improvement observed (e.g.,<30% reduction in urine oxalate concentration after at least 3 months of therapy).
	
	Reasons for Non-coverage:
	• eGFR < 30 mL/min/1.73 m2
	• Diagnosed with primary hyperoxaluria type 2 (PH2) or type 3 (PH3)
	• History of kidney or liver transplant
	• Clinical evidence of systemic oxalosis
	• Pregnant or breast-feeding women
	
	Initial Approval: 6 months.
	
	Continued Approval: 12 months. Continue approval if the following criteria are met without reasons for Non-coverage or criteria for discontinuation listed below:
	• Documentation that the patient is tolerating therapy and there was an improvement in urinary oxalate excretion from baseline.
	
	Criteria for discontinuation:
	• No improvement of clinical symptoms or manifestations of PH1 after 3 to 6 months of treatment
	• Patient is post liver transplant (in consultation with transplant team)
	• Intolerance to medication
	• Non-adherence to medication, recommended diet and lifestyle measures, or follow-up labs and assessments
	Dosing and Administration:
	• Per product labeling Oxlumo is intended for subcutaneous use and should be administered by a healthcare professional.
	• Less than 10 kg: Loading dose of 6 mg/kg once monthly for 3 doses. Maintenance dose begins 1 month after last loading dose of 3mg/kg once monthly.
	• 10kg – 19 kg: Loading dose of 6 mg/kg once monthly for 3 doses. Maintenance dose begins 1 month after last loading dose of 6mg/kg every 3 months (quarterly).
	• ≥ 20 kg: Loading dose of 3 mg/kg once monthly for 3 doses. Maintenance dose begins 1 month after last loading dose of 3mg/kg every 3 months (quarterly).

Padcev (Enfortumab vedotin-ejfv)	**Candidates for treatment with Padcev should meet ALL of the following criteria:** • Prescribed by an Oncologist • Age ≥ 18 years • Diagnosed with **Bladder cancer, muscle invasive, neoadjuvant and adjuvant therapy:**

Drug	Prior Authorization Criteria
	○ Treatment (in combination with pembrolizumab **or** pembrolizumab/berahyaluronidase) of muscle-invasive bladder cancer as neoadjuvant treatment and then continued as adjuvant treatment following cystectomy in adults who are ineligible for cisplatin-containing chemotherapy. **OR** • Diagnosed with **locally advanced or metastatic urothelial cancer** ○ Documented previous treatment with a programmed death receptor-1 (PD-1) (i.e., nivolumab, pembrolizumab, etc.) or programmed death-ligand 1 (PD-L1) inhibitor (i.e., atezolizumab, avelumab, durvalumab, etc.) **AND** Documented previous treatment with platinum-containing chemotherapy (i.e., DDMVAC, gemcitabine with either cisplatin or carboplatin), **OR** are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy Initial Approval**:** 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Approve for administration ONLY in KPGA infusion center, absent director level approval.** Reason for Non-coverage: Moderate or severe hepatic impairment Continued Approval: 12 months if patient continues to meet all coverage criteria above without reason for Non-coverage and all the following criteria: • Documented continued clinical benefit in Padcev therapy as demonstrated by tumor response or lack of disease progression • Absence of unacceptable toxicity (i.e., diabetic ketoacidosis, severe skin reactions, etc.) • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Approve for administration ONLY in KPGA infusion center, absent director level approval.** Dosing • 1.25 mg/kg IV (maximum dose: 125 mg) on days 1, 8, and 15, every 28 days until disease progression or unacceptable toxicity
Palforzia (Peanut Allergen Powder)	**Candidates for treatment with Palforzia should meet ALL the following criteria:** • Prescribing physician is an Allergist. • Patient is being started on the Initial Dose Escalation (IDE) phase of Palforzia, patient must be aged 1 through 17 years. • Diagnostic confirmation of peanut allergy by documentation of ONE of the following (also refer to algorithm below): ○ For patients who have undergone a supervised oral food challenge (OFC) with peanut protein with a documented reaction to a dose of ≤100 mg peanut protein

Drug	Prior Authorization Criteria
	with documented signs and symptoms consistent with an IgE-mediated reaction to peanut: ▪ Positive skin prick test (wheal diameter ≥3mm) or peanut-specific immunoglobulin E (≥0.35 kUA/L) within the past 24 months. **OR** ○ For patients who have NOT undergone a supervised OFC with peanut protein: ▪ Positive skin prick test (wheal diameter ≥8 mm) or peanut-specific immunoglobulin E (≥14 kUA/L) within the past 24 months. • Documented clinical history of an allergic reaction to peanut. • Documentation/Provider attestation that Palforzia will be used in conjunction with a peanut avoidance diet. • Documented written informed consent from adult subjects or written informed consent from parent/guardian for minor subjects with additional assent from minor subjects age ≥7 years. • Documentation/ Provider attestation that patient is willing to take a product that contains peanut protein and patient/parent/guardian agrees to adhere to drug therapy, follow-up visits, and monitoring requirements. • Prescriber verifies that the patient has an epinephrine auto-injector and instructs patient and parent/guardian that they should have it available for immediate use at all times. • Prescriber, health care setting, and patient or parent/guardian must meet manufacturer's Risk Evaluation and Mitigation Strategy (REMS) requirements (https://www.palforziarems.com/#Main). <u>Reasons for Non-coverage:</u> • History of cardiovascular disease, including uncontrolled or inadequately controlled hypertension. • History of severe or life-threatening episode of anaphylaxis or anaphylactic shock within the past 60 days. • History of chronic disease (other than asthma, atopic dermatitis, or allergic rhinitis) that is, or is at significant risk of becoming unstable or requiring a change in chronic therapeutic regimen. • History of eosinophilic esophagitis (EoE), other eosinophilic gastrointestinal (GI) disease, gastroesophageal reflux disease (GERD), symptoms of dysphagia (e.g., difficulty swallowing, food "getting stuck"), or recurrent GI symptoms of undiagnosed etiology. • Current participation in any other interventional study or in the "build-up phase" of immunotherapy to another allergen (i.e., has not reached maintenance dosing). • Concurrent peanut specific immunotherapy (e.g., Viaskin Peanut). • Patients with asthma if they meet 1 or more of the following: ○ Presence of clinical characteristics consistent with severe asthma as described in Table 1. ○ Inhaled corticosteroid dosing of >500 mcg/day fluticasone or equivalent (refer to Tables 2 and 3) ○ For patients age ≥ 6 years and able to perform spirometry: forced expiratory volume in one second (FEV_1) <80% of predicted, or ratio of FEV_1 to forced vital capacity (FEV_1/FVC) <75% of predicted, with or without controller medications

Drug	Prior Authorization Criteria
	○ Hospitalization for asthma within one year prior to screening. ○ Emergency room (ER) visit for asthma within six months prior to screening

Table 1: Evaluation of Asthma†

Classification	Symptoms	Nighttime awakenings	Lung Function	Interference with normal activity	Short-acting beta-agonist use
Intermittent (Step 1)	≤2 days per week	≤2x/month	Normal FEV_1 between exacerbations FEV_1 >80% predicted FEV_1/FVC normal*	None	≤2 days/week
Mild Persistent (Step 2)	>2 days per week but not daily	3-4x/month	FEV_1 ≥80% predicted FEV_1/FVC normal*	Minor limitation	>2 days/week but not >1x/day
Moderate Persistent (Step 3 or 4)	Daily	>1x/week but not nightly	FEV_1 ≥60% but <80% predicted FEV_1/FVC reduced 5%*	Some limitation	Daily
Severe Persistent (Step 5 or 6)	Throughout the day	Often 7x/week	FEV_1 <60% predicted FEV_1/FVC reduced >5%*	Extremely limited	Several times per day

†Asthma severity in the PALISADE study was assessed using the NHLBI classification published August 28, 2007 as described in Table 1.

*Normal FEV_1/FVC: 8-19 years = 85%; 20-39 years = 80

Drug	Prior Authorization Criteria

Table 2: Estimated comparative daily dosages for selected inhaled corticosteroids for long-term asthma control for children <12 years

	4 years of age			5-11 years		
Daily dose*	**Low**	**Medium**	**High**	**Low**	**Medium**	**High**
Medication						
beclomethasone MDI (QVAR Redihaler)	N/A	N/A	N/A	80-160 mcg	>160-320 mcg	>320 mcg
40 mcg/puff				1-2 puffs 2x/day	¶	
80 mcg/puff				1 puff 2x/day	2 puffs 2x/day	≥3 puffs 2x/day
budesonide DPI (Pulmicort Flexhaler)	N/A	N/A	N/A	180-360 mcg	>360-720 mcg	>720 mcg
90 mcg/inh				1-2 inh 2x/day	3-4 inhs 2x/day	
180 mcg/inh					2 inhs 2x/day	≥3 inhs 2x/day
ciclesonide MDI (Alvesco)	N/A	N/A	N/A	80-160 mcg	>160-320 mcg	>320 mcg
80 mcg/puff				1-2 puffs/day	2 puffs 2x/day	¶
160 mcg/puff				1 puff/day	1 puff 2x/day	≥2 puffs 2x/day
Fluticasone DPI (Flovent Diskus)	N/A	N/A	N/A	100-200 mcg	>200-400 mcg	>400 mcg
50 mcg/inh				1-2 inhalations 2x/day	3-4 inhalations 2x/day	
100 mcg/inh				1 inhalation 2x/day	2 inhalations 2x/day	>2 inhalations 2x/day
250 mcg/inh						1 inhalation 2x/day
fluticasone MDI (Flovent HFA)	176 mcg	>176-352 mcg	>352 mcg	88-176 mcg	>176-352 mcg	>352 mcg
44 mcg/puff	2 puffs 2x/day	¶		1-2 puffs 2x/day	¶	
110 mcg/puff		1 puff 2x/day	≥2 puffs 2x/day		1 puff 2x/day	≥2 puffs 2x/day
mometasone MDI (Asmanex HFA)	N/A	N/A	N/A	100 mcg	200-300 mcg	>300 mcg
50 mcg/puff				1 puff 2x/day	2 to 3 puffs 2x/day	
100 mcg/puff					1 puff 2x/day	≥2 puffs 2x/day
200 mcg/puff						≥1 puff 2x/day
mometasone DPI (Asmanex Twisthaler)	N/A	N/A	N/A	110 mcg	220-440 mcg	>440 mcg
110 mcg/inh				1 inh/day	1-2 inhs 2x/day	¶
220 mcg/inh					1-2 inhs/day	≥3 inh divided in 2 doses

Abbreviations: DPI = dry powder inhaler; inh(s) = inhalation(s); MDI = metered dose inhaler

*Some doses may be outside package labeling, especially in the high-dose range; ¶Select alternative preparation with higher mcg/puff to improve convenience

Drug	Prior Authorization Criteria

Table 3: Estimated comparative daily dosages for selected inhaled corticosteroids for long-term asthma control for patients ≥12 years of age

	≥12 years		
Daily Dose*	**Low**	**Medium**	**High**
Medication			
beclomethasone HFA (QVAR Redihaler)	80-240 mcg	>240-480 mcg	>480 mcg
40 mcg/puff	¶	¶	
80 mcg/puff	1 puff am, 2 puffs pm	2-3 puffs 2x/day	≥4 puffs 2x/day
budesonide DPI (Pulmicort Flexhaler)	180-540 mcg	>540-1,080 mcg	>1,080 mcg
90 mcg/inh	1-3 inhs 2x/day		
180 mcg/inh	1 inh am, 2 inhs pm	2-3 inhs 2x/day	≥4 inhs 2x/day
ciclesonide MDI (Alvesco)	160-320 mcg	>320-640 mcg	>640 mcg
80 mcg/puff	1-2 puffs 2x/day	¶	
160 mcg/puff		2 puffs 2x/day	≥3 puffs 2x/day
Fluticasone DPI (Flovent Diskus)	100-300 mcg	>300-500 mcg	>500 mcg
50 mcg/inh	1-3 inhalations 2x/day		
100 mcg/inh		2 inhalations 2x/day	≥3 inhalations 2x/day
250 mcg/inh		1 inhalation 2x/day	≥2 inhalations 2x/day
fluticasone MDI (Flovent HFA)	88-264 mcg	>264-440 mcg	>440 mcg
44 mcg/puff	¶		
110 mcg/puff	1 puff 2x/day	2 puffs 2x/day	¶
220 mcg/puff		1 puff 2x/day	≥2 puffs 2x/day
mometasone MDI (Asmanex HFA)	200 mcg	400 mcg	>400 mcg
100 mcg/puff	1 puff 2x/day	2 puffs 2x/day	
200 mcg/puff		1 puff 2x/day	≥3 puffs divided in 2 doses
mometasone DPI (Asmanex Twisthaler)	110-220 mcg	>220-440 mcg	>440 mcg
110 mcg/inh	1-2 inhs pm	2 inhs 2x/day	¶
220 mcg/inh	1 inh pm	1 inh 2x/day or 2 inhs pm	≥3 inhs divided in 2 doses

Abbreviations: DPI = dry powder inhaler; inh(s) = inhalation(s); MDI = metered dose inhaler
*Some doses may be outside package labeling, especially in the high-dose range
¶Select alternative preparation with higher mcg/puff to improve convenience

- History of corticosteroid use (intravenous, intramuscular or oral administration) in any of the following manners:
  - Daily oral corticosteroid dosing for asthma >1 month during the past year
  - Burst oral corticosteroid course for asthma in the past three months
  - Two or more burst oral corticosteroid courses (≥3 days each) for asthma in the past year.
- Pregnancy or lactation.
- Use of beta-blockers (oral), angiotensin-converting enzyme (ACE) inhibitors, angiotensin-receptor blockers (ARB) or calcium channel blockers.
- Medical conditions that may decrease a patient's ability to survive anaphylaxis including, but not limited to, compromised lung function and severe mast cell disorder.
- Inability to discontinue antihistamines 5 half-lives before the initial day of escalation, skin prick testing, or screening oral challenge testing.
- Lack of available palatable vehicle food to which the subject is not allergic.
- Use of omalizumab or any other biologic or non-biologic immunomodulatory therapy (not including corticosteroids).

Initial approval period: 12 months.

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Initial Dose Escalation: Approve one-time initial dose escalation to be administered in office** • **Up-dosing: Approve for member to fill via outpatient pharmacy benefit only** • **Maintenance Dosing: Approve for member to fill via outpatient pharmacy benefit only** Criteria for Discontinuation: Treatment should be discontinued if any of the following is met: • Patient is unable to tolerate doses up to and including the 3 mg dose during the IDE. • Frequent dose-related (or even delayed) minor to moderate GI complaints/side effects that are not tolerated by the patient or family. Repeated problems with itchy mouth/throat. • Any serious or severe allergy-type reaction related to dosing. • Patients with suspected EoE or recurrent asthma exacerbations/persistent loss of asthma control. • Patients or family who are unable to comply with the daily dosing requirements, follow-up clinic visits, and monitoring requirements. Continued Approval Period: 1 year. Patient must meet ALL criteria listed above and does not meet any of the criteria for discontinuation. In addition, patient must meet ALL the following: • Mitigation of allergic reaction to accidental peanut exposure (if exposure occurs) • Patient is tolerating therapy and is adherent to the dosing protocol • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Maintenance Dosing: Approve for member to fill via outpatient pharmacy benefit only**

Palsonify
(Paltusotine)
	Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval
	
	Candidates for treatment with Palsonify (paltusotine) should meet ALL the following criteria:
	
	• Age ≥ 18 years of age
	• Documented diagnosis of acromegaly confirmed by one of the following:
	  • Elevated serum insulin growth factor 1 (IGF-1) levels which are above the age and gender-adjusted normal range at time of diagnosis **-OR-**
	  • Serum GH level > 1 ng/mL after a 2-hour oral glucose tolerance test at time of diagnosis
	• Prescribed by Endocrinology
	• Documented inadequate response to or not a candidate for surgery or radiation for the management of acromegaly
	• Documented inadequate treatment response after **therapeutic trial to ALL the following** unless patient is not a candidate or intolerance/contraindication:
	  • Sandostatin (octreotide) **OR** Somatuline (lanreotide)
	  • Cabergoline

Drug	Prior Authorization Criteria
	• Somavert (pegvisomant) with or without concomitant somatostatin receptor ligand therapy (octreotide, lanreotide, or pasireotide) Reasons for Non-Coverage: • History of hypersensitivity to paltusotine or any of its components • History of pituitary surgery within 24 weeks Initial Approval: 6 months. **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** Continued Approval: 12 months. Confirm patients meets all above criteria and meets the following: • Continues to follow with endocrinology team and visit in the past 12 months • Documentation of positive clinical response to Palsonify therapy (e.g., improvement in clinical symptoms or serum IGF-1 level has decreased from baseline) Ordering Information: • Palsonify is available through the McKesson Biologics Specialty Pharmacy in Cary, NC . Fax the Palsonify Enrollment Form to CrinetiCare (844-276-3299). The Palsonify Enrollment Form can be found on the Palsonify website.
Palynziq (Pegvaliase-pqpz)	**Candidates for treatment with Palynziq should meet ALL of the following criteria:** • Age ≥ 18 years • Confirmed Classical Phenylketonuria (PKU) (defined as having 2 mutations which are associated with classical PKU, or Phenylalanine (Phe) level greater than 1200 micromol/L. • Pre-treatment baseline Phe level above 600 micromol/L, on existing management • Patient consents to a patient-physician agreement to adhere to treatment requirements (including follow-up appointments, labs, dietician consults, maintaining a diet diary, and for those with pregnancy potential, use of adequate contraception. • If on sapropterin (Kuvan), sapropterin should be discontinued prior to initiation of pegvaliase-pqpz. • Patient and Prescriber must be enrolled in the Palynziq REMS program Reasons for Non-coverage: • Pregnancy or lactating women • Intent to become pregnant or pregnancy potential without use of adequate birth control. • Pediatric Patients • Phe level controlled below 600 micromol/L while taking sapropterin and Phe-restricted diet. Initial Approval**:** 6 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** ○ Initial Dose: **approve one-time subcutaneous dose to be given in office**

Drug	Prior Authorization Criteria
	○ Maintenance: **approve for member to fill via the outpatient pharmacy benefit only** Reasons for Discontinuation: • Intolerance to medication • Non-adherence to medication, diet diary, or follow-up labs and assessments • Pregnancy is diagnosed or patient is breastfeeding • Phe remains above 600 micromol/L after 16 weeks on the maximum 60mg dose unless prescriber documents rationale for continued treatment. Continued Approval: 12 months if continue to meet all coverage criteria, without reason for Non-coverage, with documented reduction in blood phe concentration to less than or equal to 600 micromol/L and adherence to medication, diet diary, and follow-up labs and assessments (see above). • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** ○ Maintenance: **approve for member to fill via the outpatient pharmacy benefit only** Dosing: Induction: • The initial dose should be administered under the supervision of a healthcare provider to monitor the patient closely in case of anaphylaxis. • The recommended initial dosage is 2.5 mg subcutaneously once weekly for 4 weeks Titration: • Titrate the dosage in a stepwise manner over at least 5 weeks, based on tolerability, to achieve a daily dosage of 20 mg Maintenance: • Maintain dosage at 20 mg daily for 24 weeks • Consider increasing to maximum dosage of 60 mg daily if patient has not achieved Phe ≤ 600 micromol/L while on 40 mg daily • Reduce the dosage and/or modify dietary protein and phenylalanine intake, as needed, to maintain Phe below 600 micromol/L at minimum (below 360 micromol/L preferred) and above 30 micromol/L. • Individualize treatment to the lowest effective and tolerated dosage. Ordering Information: • Palynziq is OUTSOURCED to Accredo Specialty Pharmacy at 866-759-1557 or www.accredo.com.
Panretin (Alitretinoin)	**Candidates for treatment with Panretin (alitretinoin) topical gel should meet ALL the following criteria:** • Prescribed by a by a specialist in the area of practice related to the patient's diagnosis (e.g., dermatologist, oncologist, or infectious disease specialist) • Patient has a diagnosis of cutaneous lesions in HIV-related Kaposi's Sarcoma • Patient has <10 new Kaposi's Sarcoma lesions in the prior month • Patient has a documented therapeutic failure or intolerance to cryotherapy

Drug	Prior Authorization Criteria
	Reasons for Non-coverage: • Use for cosmetic conditions • Patient is receiving systemic therapy for Kaposi's Sarcoma (e.g., >10 new lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary Kaposi Sarcoma, or symptomatic visceral involvement) Initial Approval: 18 weeks Continued Approval: 6 month. Continue approval based on documentation of positive clinical response to therapy. • Effectiveness of use beyond 96 weeks has not been established.

Papzimeos (Zopapogene imadenovec)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	
	Candidates for treatment with Papzimeos (zopapogene imadenovec) should meet ALL the following criteria:
	
	• Prescribed by hematologist/oncologist, otolaryngologist, pulmonologist, or specialist knowledgeable in the treatment of recurrent respiratory papillomatosis
	• Age ≥ 18 years old
	• Diagnosis of recurrent respiratory papillomatosis confirmed by biopsy
	• Documented human papillomavirus (HPV) serotype 6 or 11
	• Patient has received 3 or more surgical debulking of present visible laryngotracheal papillomas within 12 months prior to treatment
	• Patient will undergo surgical debulking prior to first dose of treatment to remove laryngotracheal papilloma
	• Documented adequate trial, intolerance, and/or contraindication to ALL of the following therapies:
	  ○ HPV vaccine
	  ○ Intralesional cidofovir
	  ○ Systemic bevacizumab
	
	Approval Period: One time approval of one treatment course (total 4 doses)
	• **Please approve for back-office administration only**
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**

Parathyroid Hormone Analogs: Forteo	For osteoporosis: • Age ≥ 18 years • Documented diagnosis of osteoporosis • Prescribed by endocrinology or rheumatology

Drug	Prior Authorization Criteria

(Teriparatide) [Preferred]
 	
Tymlos (Abaloparatide)
	• History of very high-risk osteoporotic fracture documented by **one of the following:**
	  ○ Major fracture such as hip, spine, or pelvis in the past 12 months
	  ○ T-score ≤ -3.5
	  ▪ If either apply, initial anabolic therapy is appropriate→ Proceed to Forteo Approval. If patient does not meet criteria for very high-risk of osteoporotic fracture, proceed with criteria below:
	• Documented inadequate response (trial of at least 12 months) or intolerance/contraindication to each of the following:
	  ○ At least 1 oral bisphosphonate (e.g., alendronate, ibandronate, risedronate).
	  ▪ Example of inadequate response = fracture on bisphosphonate.
	  ○ At least 1 IV bisphosphonate (e.g., zoledronic acid) or documented clinical reason for avoiding IV bisphosphonate
	  ○ At least 1 denosumab product (e.g., Stoboclo [preferred], Prolia)
	• Patient should NOT be on any other therapy for osteoporosis (Prolia, bisphosphonates, etc.).
	• Documentation of lab values within normal limits (WNL) in the past 6 months for the following: Parathyroid hormone (PTH), Calcium, Serum Creatinine (SCr), and Vitamin D.
	• For Tymlos: Documented trial and failure of teriparatide (Forteo).
	
	<u>Initial Approval</u>: 24 months. KP pharmacies will dispense BRAND Forteo as the preferred product.
	
	<u>Continued Approval</u>: Total duration of therapy cannot exceed 24 months. Approve for a total of 24 months of treatment. Document start date and duration of therapy.
	
	<u>For new members who were initiated on parathyroid hormone analogs (Forteo, Tymlos) outside of KPGA</u>:
	
	Approve Forteo if all the following are met:
	• Documented Endocrinology or Rheumatology visit in the past 6 months and considered to be stable on current therapy
	• KP pharmacies will dispense BRAND Forteo as the preferred treatment.
	
	If request is for Tymlos, must switch to Forteo unless documentation of failure, contraindication or intolerance to preferred therapy.
	
	<u>For chronic hypoparathyroidism</u>:
	• Prescribed by an endocrinologist
	• Diagnosed with chronic hypoparathyroidism (HP) of postsurgical, autoimmune, genetic, or idiopathic origins based on hypocalcemia in the setting of inappropriately low serum PTH levels
	• Documented adequate trial of max tolerated doses of conventional therapy: activated vitamin D (e.g., calcitriol) and calcium for at least 3 months with inadequate response

Drug	Prior Authorization Criteria
	○ Elemental calcium at ≥ 600 mg daily ○ Calcitriol ≥ 0.5 ug/day • Documented (within last 4 weeks) serum 25 (OH) vitamin D in normal range (20-80 ng/mL) and albumin adjusted serum calcium > 7.8 mg/dL • Documented PTH is not elevated (>77 pg/mL) within the last six months **Initial Approval: 6 months** **Continued Approval: 12 months. Continued approval for the treatment with Forteo should meet ALL the criteria above and provider attestation of a positive response per criteria below:** • Documentation of a recent albumin-corrected serum calcium in the normal reference range or just below the normal reference range (~8–9 mg/dL) Independence from conventional therapy (e.g., patient no longer requires active vitamin D or of calcium) *The cumulative use of parathyroid hormone analogs for more than 2 years during a patient's lifetime is NOT recommended.
PCSK-9 Inhibitors: **Repatha** (Evolocumab) [Preferred] **Praluent** (Alirocumab)	**Candidates for treatment with PCSK-9 Inhibitors should meet ALL the following criteria:** • Prescribed by cardiologist or endocrinologist • Documented diagnosis of atherosclerotic cardiovascular vascular disease **(ASCVD)*** OR familial hypercholesterolemia • Documentation of the appropriate LDL for the treatment indication ○ HeFH/HoFH (familial): LDL >100 (age ≥ 10 years) ○ Not high risk ASCVD: LDL >70 (age 40 to 75 years) ○ Very high risk ASCVD: LDL >55 (age 40 to 75 years) • Documented adequate trial of maximally tolerated statin (at least 3 months) or intolerance or contraindication, **must meet one of the following**: ○ Currently prescribed high intensity statin (atorvastatin 40 or 80 mg OR rosuvastatin 20 or 40 mg). Check MRAR∞ ○ Currently prescribed maximally tolerated statin AND ezetimibe 10 mg. Check MRAR∞ ○ Previously prescribed atorvastatin, rosuvastatin, and 1 additional statin, including an attempted alternative dosing regimen (e.g., every-other day, once or twice weekly). Check med hx when available. ○ Provider attestation and documentation that patient unable to take statin due to **one of the following:** ▪ History of CPK >10xULN or rhabdomyolysis attributed to a statin and not explained by a drug interaction, fall or prolonged immobility ▪ Acute liver failure or decompensated cirrhosis; nursing female, pregnancy, or plans to become pregnant; hypersensitivity reaction

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	▪ Liver disease as unexplained aminotransferase values >3 times above upper normal range confirmed on repeat testing • Documented adequate trial, intolerance or contraindication to ezetimibe unless patient requires >25% LDL reduction • NOT given in combination with another PCSK9 inhibitor or Juxtapid (lomitapide), or LDL apheresis • For Praluent, the patient must have a documented contraindication to, an allergy to, a history of adverse events to, or tried and failed an appropriate dose of evolocumab (Repatha) • Patient receiving maximally tolerated statin therapy (PCSK9 inhibitors are only indicated as adjunct to diet and maximally tolerated statin therapy. Monotherapy with PCSK9 may be considered for secondary prevention if the patient has tried/failed or is intolerant to statins + ezetimibe[†] and is defined as being at **very high risk**** for a recurrent ASCVD event.) *Clinical ASCVD includes: Acute coronary syndrome: Myocardial infarction, Stable or unstable angina, Coronary or other arterial revascularization procedure (such as PTCA, CABG), Transient ischemic attack (TIA), Peripheral arterial disease presumed to be of atherosclerotic origin, Findings from CT angiogram or catheterization consistent with clinical ASCVD **Very High risk defined per 2018 AHA Blood Cholesterol Guidelines**:** Multiple ASCVD events OR one ASCVD event AND multiple very high-risk conditions. High risk conditions defined as: Age ≥ 65 years, heterozygous or homozygous familial hypercholesterolemia, history of prior coronary bypass surgery or percutaneous coronary intervention outside of the major ASCVD event, diabetes mellitus, HTN, eGFR 15-59 mL/min/1.72m^2, current smoker, LDL of ≥100 mg/dL, or congestive heart failure. ∞NOTE: [MRAR ≥ 80% for ≥ 3 months. If MRAR < 80%, reviewer can confirm adherence in the last 3 months based on medication sold dates found in Health Connect medication tab (e.g., 3 one month fills or one 90 day fills)] Initial Approval: 3 months. Patient must obtain LDL after 3 months of therapy. (This lab should be ordered when initiating therapy). • **Approve for member to fill via the outpatient pharmacy benefit only** Continued Approval: Indefinite. Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, continue approval if the following criteria are met based on 3-month LDL: • Documented LDL lowering by ≥30% or at designated LDL goal since starting PCSK9 therapy • Per 2018 AHA guidelines, if a patient has 2 consecutive LDL readings < 25, use clinical judgement on whether therapy should be continued with a PCSK9 Inhibitor. ○ **Approve for member to fill via the outpatient pharmacy benefit only** *Adherence can be reviewed via KPHC with the dot phrase **.mrar** For new members who were initiated on Repatha outside of KPGA: Approve Repatha indefinitely if patient is confirmed to be clinically stable on it by a Specialist in the last 6 months.

Drug	Prior Authorization Criteria
	For new members who were initiated on Praluent outside of KPGA: Approve Praluent if patient has tried and failed the preferred alternative Repatha, and is confirmed to be clinically stable on it by a Specialist in the last 6 months.

Pegfilgrastim Products
 	
Preferred:
Fulphila (Pegfilgrastim-jmdb) 6 mg/0.6 ml
 	
Non-Preferred Pegfilgrastim Products (listed by order of preference):
 	
Nyvepria (Pegfilgrastim-apgf) 6mg/0.6ml
 	
Udenyca (Pegfilgrastim-cbqv) 6 mg/0.6 mL
 	
Stimufend (Pegfilgrastim-fpgk) 6 mg/0.6 mL
 	
Fylnetra (Pegfilgrastim-pbbk) 6 mg/0.6 mL
 	
Ziextenso (Pegfilgrastim-bmez) 6mg/0.6ml
 	
Neulasta and Neulasta Onpro (Pegfilgrastim) 6mg/0.6ml
	Non-preferred products pegfilgrastim products will only be considered for use after a trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction) to KP's preferred therapy, pegfilgrastim-jmdb (Fulphila).
	
	Pediatric patients < 18 years of age should meet ALL of the following criteria:
	• Prescribed by Hematology or Oncology or Pediatric Hematology/Oncology
	• Inadequate response, intolerance and/or contraindication to pegfilgrastim-jmdb (Fulphila) AND pegfilgrastim-apgf (Nyvepria) prior to non-preferred product approval.
	
	Adult patients ≥ 18 years of age should meet ALL of the following criteria:
	• Prescribed by Hematology or Oncology
	• Patient has **ONE** of the following:
	  ○ Treatment failure on Filkri (filgrastim-laha) or other filgrastim biosimilar product (e.g., subtherapeutic ANC despite treatment with Filkri (filgrastim-laha) or filgrastim biosimilar product) for 7 to 10 days
	  ○ Intolerance, allergic reaction, or contraindication to Filkri (filgrastim-laha) **AND** at least one additional filgrastim product (e.g., Granix (tbo-filgrastim), Nivestym (filgrstim-aafi),Releuko (filgrastim-ayow), Zarxio (filgrastim-sndz), Neupogen (filgrastim), etc)
	  ○ Expected duration of G-CSF therapy to exceed 13 days
	  i. The commonly accepted treatment regimens are inpatient lymphoma regimens (e.g., R-EPOCH, CHOEP, (R)ICE).
	• Inadequate response, intolerance and/or contraindication to pegfilgrastim-jmdb (Fulphila) AND pegfilgrastim-apgf (Nyvepria) AND pegfilgrastim-cbqv (Udenyca) prior to other non-preferred product approval.
	
	NOTE: Filkri (filgrastim-laha) is KP's preferred G-CSF product and is available on the formulary. Other filgrastim biosimilar products (e.g., Granix (tbo-filgrastim), Nivestym (filgrastim-aafi), Zarxio (filgrastim-sndz) and Releuko (filgrastim-ayow) are non-formulary/non-preferred and request for these products can be sent to the Pharmacy Consult Service for review.
	
	Initial Approval: 12 months.
	• **For patients ≥45 kg: approve for administration via the outpatient pharmacy benefit ONLY.**
	• **For patients <45 kg who are unable to self-administer product:**
	  ○ If patient is ≥18 years of age, approve for back-office administration at KP facility ONLY.
	  ○ If patient is <18 years of age, may be approved for back-office administration at non-KP facility.
	
	Continued Approval: 12 months if patient meets the following:
	• Patient meets all above coverage criteria
	• Patient has documented improvement and requires continued treatment

Drug	Prior Authorization Criteria
	• **For patients ≥45 kg: approve for administration via the outpatient pharmacy benefit ONLY.** Do not approve for back-office administration for any patients weighing ≥45 kg. • **For patients <45 kg who are unable to self-administer product:** o If patient is >13 years of age, approve for back-office administration at KP facility ONLY. o If patient is <13 years of age, may be approved for back-office administration at non-KP facility. Pediatric patients weighing < 45 kg dosage and administration: • < 10 kg, administer 0.1 mg/kg • 10-20 kg: 1.5 mg/0.15 mL • 21-30 kg: 2.5 mg/0.25 mL • 31-44 kg: 4 mg/0.4 mL
Pemazyre (Pemigatinib)	**Candidates for Pemazyre should meet ALL the following criteria:** Diagnosis of cholangiocarcinoma: • Prescribed by an oncologist. • Age ≥ 18 years • Patient has a diagnosis of unresectable, locally advanced, or metastatic cholangiocarcinoma. • Tumor has fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement. • Patient has received at least ONE prior first-line treatment. o Examples of prior treatment regimens include, but are not limited to the following: • gemcitabine + cisplatin or oxaliplatin • 5-flurouracil or capecitabine + cisplatin or oxaliplatin • gemcitabine + nab-paclitaxel • gemcitabine + capecitabine • gemcitabine + nab-paclitaxel + cisplatin • 5-fluorouracil; gemcitabine • pembrolizumab • entrectinib • larotrectinib Diagnosis of Myeloid/Lymphoid Neoplasms: • Prescribed by an oncologist. • Age ≥ 18 years • Patient has a diagnosis myeloid, lymphoid, or mixed lineage neoplasm. • Disease has presence of a FGFR1 rearrangement. Initial Approval: 12 months with a quantity limit of 30 tablets per 30 days. Continued Approval: 12 months with a quantity limit of 30 tablets per 30 days. For continued approval for treatment with Pemazyre, patient should meet ALL the following criteria: • Patient continues to meet the above criteria.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. <u>For new members who were initiated on Pemazyre outside of KPGA:</u> • Prescribed by an oncologist. • Age ≥ 18 years • Diagnosis of an unresectable, locally advanced, or metastatic cholangiocarcinoma with a FGFR2 fusion or rearrangement OR myeloid, lymphoid, or mixed lineage neoplasm with a FGFR1 rearrangement • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. • Quantity limit of 30 tablets per 30 days.

Pemgarda
(Pemivibart)
	Candidates for treatment with Pemgarda (pemivibart) should meet ALL of the following criteria:
	
	• Age ≥ 12 years and weight ≥ 40 kg
	• Patient has completed a confirmatory negative COVID-19 test with office lab
	• Prescribed as pre-exposure prophylaxis (PrEP) of COVID-19 in patients who meet 1 of the following parameters:
	  ○ Have moderate to severe immune compromise due to certain medical conditions AND are unlikely to mount an adequate immune response to COVID-19 vaccination **OR**
	  ○ Have received certain immunosuppressive medications or treatments AND are unlikely to mount an adequate immune response to COVID-19 vaccination
	  ▪ Examples of medical conditions or treatments:
	  ➢ Active treatment for solid tumor and hematologic malignancies
	  ➢ Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia)
	  ➢ Receipt of solid-organ transplant or an islet transplant and taking immunosuppressive therapy
	  ➢ Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppressive therapy)
	  ➢ Moderate or severe primary immunodeficiency (e.g., common variable immunodeficiency disease, severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome)
	  ➢ Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
	  ➢ Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely

Drug	Prior Authorization Criteria
	immunosuppressive, and biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents) Reasons for Non-coverage: • Currently infected with SARS-CoV2 • Known recent exposure to an individual infected with SARS-CoV-2 • Patient received COVID-19 vaccine within last 2 weeks • Patient unable remain in office 2 hours post infusion for anaphylactic monitoring Initial Approval: 2 months Continued Approval: 6 months Dosing and Administration: • Administer only in settings with immediate access to medications to treat hypersensitivity reactions (eg, anaphylaxis) and the ability to activate the emergency medical system as necessary. • Patient must be monitored at least 2 hours post infusion, for hypersensitivity / anaphylactic reactions • Must be infused over a minimum of 60 minutes • IV: 4.5 g as a single dose; may repeat dose every 3 months

Phesgo (Pertuzumab, Trastuzumab, and Hyaluronidase)	**Candidates for Phesgo should meet ALL of the following criteria**:
	
	• Diagnosis of HER2-positive breast cancer
	• Prescribed by an oncologist
	• Age ≥ 18 years
	• Patient meets one of the following criteria:
	  ○ Prescribed as combination therapy with chemotherapy for the neoadjuvant treatment of adult patients with HER2- positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer **OR**
	  ○ Prescribed for use in combination with chemotherapy for the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence **OR**
	  ○ Prescribed for use in combination with docetaxel for the treatment of adult patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.
	• Request meets one of the following (a or b):
	  ○ Dose does not exceed an initial dose of 1,200 mg pertuzumab, 600 mg trastuzumab, and 30,000 units hyaluronidase (one single-dose vial), followed by 600 mg pertuzumab, 600 mg trastuzumab, and 20,000 units hyaluronidase (one single-dose vial) every three weeks **OR**
	  ○ Dose is supported by practice guideline or peer-reviewed literature for the relevant off label use (prescriber must submit supporting evidence).
	
	Reasons for Non-coverage:
	• Cardiomyopathy

Drug	Prior Authorization Criteria
	• Pregnancy Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Phesgo is administered in office ONLY** Continued Approval: 12 months. Confirm patient meets all above criteria. In addition, continue approval if no evidence of unacceptable toxicity or disease progression while on the current regimen. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Phesgo is administered in office ONLY** Dosing and Administration: • For SubQ use only • Administer initial dose subcutaneously over ~8 minutes; administer maintenance dose over ~5 minutes. • Doses should be administered by a health care professional. • Breast cancer, early, neoadjuvant treatment, HER2+: o Initial loading dose: Pertuzumab 1,200 mg/trastuzumab 600 mg/hyaluronidase 30,000 units initially, followed 3 weeks later by maintenance dosing. o Maintenance dosing: Pertuzumab 600 mg/trastuzumab 600 mg/hyaluronidase 20,000 units once every 3 weeks. Following surgery, continue pertuzumab/trastuzumab/hyaluronidase to complete 1 year of treatment (up to 18 cycles) or until disease progression or unacceptable toxicity, whichever occurs first. • Breast cancer, early, adjuvant treatment, HER2+: o Initial loading dose: Pertuzumab 1,200 mg/trastuzumab 600 mg/hyaluronidase 30,000 units initially, followed 3 weeks later by maintenance dosing. o Maintenance dosing: Pertuzumab 600 mg/trastuzumab 600 mg/hyaluronidase 20,000 units once every 3 weeks for a total of 1 year (up to 18 cycles) or until disease progression or unacceptable toxicity, whichever occurs first. • Breast cancer, metastatic, HER2+: o Initial loading dose: Pertuzumab 1,200 mg/trastuzumab 600 mg/hyaluronidase 30,000 units initially, followed 3 weeks later by maintenance dosing. o Maintenance dosing: Pertuzumab 600 mg/trastuzumab 600 mg/hyaluronidase 20,000 units once every 3 weeks; continue pertuzumab/trastuzumab/hyaluronidase until disease progression or unacceptable toxicity, whichever occurs first.
Phyrago (Dasatinib)	**Candidate for treatment with Sprycel for hematologic/oncologic indications should meet ALL the following criteria:** • Prescribed by a hematologist/oncologist; AND

Drug	Prior Authorization Criteria

	• Requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines; AND
	• Patient has a diagnosis of one of the following:
	  ▪ Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)
	  ○ Age ≥ 1 year
	  ○ Confirmed by molecular testing by the detection of the Ph chromosome or BCR-ABL gene prior to initiation of therapy
	  ○ If the patient has had prior therapy with a TKI then ONE of the following requirements must be met:
	  • Resistance to prior therapy with TKI
	  ▪ T315I mutation negative
	  • Toxicity or intolerance to prior therapy with a TKI
	  ▪ Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
	  ○ Age ≥ 1 year
	  ○ Confirmed by molecular testing by the detection of the Ph chromosome or BCR-ABL gene prior to initiation of therapy
	  ○ If the patient has had prior therapy with a TKI then ONE of the following requirements must be met:
	  • Resistance to prior therapy with TKI
	  ▪ T315I mutation negative
	  • Toxicity or intolerance to prior therapy with a TKI
	• Patient has tried generic dasatinib and had an intolerance or allergic reaction that is likely due to **inactive** components of the generic medication and cannot be explained by other clinical or lifestyle factors **OR**
	• Patient is taking proton pump inhibitor or H2 blocker in combination with Dasatinib which is known to reduce the dasatinib absorption and efficacy.
	
	<u>Reasons for Non-coverage:</u>
	• T315I mutation positive
	
	<u>Initial Approval Period:</u> 1 year
	
	<u>Continued Approval</u>: 1 year if ALL the following are met:
	• Member continues to meet the above criteria AND
	• Continues to be seen by a hematologist/oncologist AND
	• Member is responding positively to therapy as defined by stabilization of disease/lack of disease progression or decrease in size of tumor or tumor spread AND
	• Absence of unacceptable toxicity from the drug AND
	• NO dual therapy with another tyrosine kinase inhibitor

PiaSky (Crovalimab-akkz)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** **Candidates for treatment with PiaSky (Crovalimab-akkz) should meet ALL the following criteria:**

Drug	Prior Authorization Criteria

	• Prescribed by a specialist in the area of practice related to the patient's diagnosis (e.g., hematologist, oncologist, immunologist, or genetic specialist)
	• Age ≥ 13 years
	• Patient weighs ≥ 40 kg
	• Diagnosed with paroxysmal nocturnal hemoglobinuria (PNH) as confirmed by both of the following:
	  ○ Flow cytometry analysis confirming presence of PNH clones
	  ○ Laboratory results, signs, and/or symptoms attributed to PNH (e.g.,LDH >1.5 × ULN, Hb <10 g/dL, abdominal pain, anemia, dyspnea, extreme fatigue, unexplained/unusual thrombosis, etc.)
	• Completed or updated meningococcal vaccine at least 2 weeks prior to start of therapy
	• The patient has tried and failed Epysqli (eculizumab-aagh) or Ultomoris (ravulizumab-cwvz) or Soliris as evidenced by hemoglobin levels < 10.5 g/dL directly following at least 3 months of stable dosing
	• PiaSky will be used as monotherapy and patient is not receiving therapy with another complement inhibitor for the treatment of PNH (Empaveli, Epysqli, Soliris, Ultomiris, Fabhalta, Voydeya)
	
	<u>Reasons for Non-coverage:</u>
	• Unresolved serious Neisseria meningitidis infection
	• Lactation
	• Not vaccinated against Neisseria meningitidis, unless risk of treatment delay outweighs infection risk
	
	<u>Initial Approval:</u> 6 months
	• Approve for back-office administration by a healthcare provider ONLY
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	<u>Continued Approval:</u> 12 months. Continue approval based on adherence to specialist follow-up appointments and documentation of positive clinical response to therapy.
	• Approve for back-office administration by a healthcare provider ONLY
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	<u>Dosing and Administration:</u>
	• The recommended dosage regimen consists of one loading dose administered by intravenous (IV) infusion (on Day 1), followed by four additional weekly loading doses administered by subcutaneous (SUBQ) injection (on Days 2, 8, 15, and 22).
	• The maintenance dose starts on Day 29 and is then administered every 4 weeks by subcutaneous injection. Administer doses based on the patient's actual body weight, as shown in Table 1.

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>
Table 1 PIASKY Dosage Regimen Based on Body Weight
<table>
<tr><th>Body Weight</th><th>≥ 40 kg to < 100 kg</th><th>≥ 100 kg</th></tr>
<tr><td>Loading Dose</td><td></td><td></td></tr>
<tr><td>Day 1</td><td>1,000 mg (IV)</td><td>1,500 mg (IV)</td></tr>
<tr><td>Day 2, 8, 15, 22</td><td>340 mg (SUBQ)</td><td>340 mg (SUBQ)</td></tr>
<tr><td>Maintenance Dose</td><td></td><td></td></tr>
<tr><td>Day 29 and Q4W[a] thereafter</td><td>680 mg (SUBQ)</td><td>1,020 mg (SUBQ)</td></tr>
</table>
IV = intravenous, SUBQ = subcutaneous
[a] Q4W=every 4 weeks
* Table copied from piasky_prescribing.pdf (gene.com)

Ordering Information:
PIASKY is available only through a restricted program under a REMS called PIASKY REMS. Further information is available at www.PIASKYREMS.com or 1-866-4My-Skyy (469-7599).
</td></tr>
<tr><td>Piqray
(Alpelisib)</td><td>
PLEASE NOTE: Alpelisib is also marketed as Vijoice. If prescribed Vijoice, please refer to Vijoice's criteria

Coverage for treatment with Piqray should meet ALL the following criteria:

Prescribed by an oncologist
Age ≥ 18 years
The patient is a postmenopausal female or a male
The patient has advanced or metastatic breast cancer
The patient has HR-positive disease
The patient has HER2-negative disease
The patient has PIK3CA-mutated breast cancer detected by a FDA approved test
The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, tamoxifen)
Used in combination with fulvestrant

Approval period:

Initial approval: 12 months
Continued Approval: 12 months if the patient does not show evidence of progressive disease while on Piqray therapy.

</td></tr>
<tr><td>Pombiliti
(Cipaglucosidase alfa)</td><td>
Candidates for treatment with Pombiliti should meet ALL the following criteria:

Diagnosis of late-onset Pompe disease confirmed by enzyme assay demonstrating a deficiency of acid alpha-glucosidase enzyme activity or by genetic testing
Age ≥18 years
Patient weighs ≥40 kg
Prescribed by or in consultation with a specialist in genetic medicine, neurologist, a metabolic disorder sub-specialist, or physician who specializes in the treatment of lysosomal storage disorders

</td></tr>
</table>

Drug	Prior Authorization Criteria
	• Patient has not demonstrated an improvement in objective measures (e.g., forced vital capacity (FVC) or six-minute walking test) on current enzyme replacement therapy with alglucosidase alfa (Lumizyme) or avalglucosidase alfa (Nexviazyme) • Prescribed in combination with miglustat (Opfolda) • If female of childbearing potential, baseline negative pregnancy test Approval period: 6 months. Approve for KP clinic/back-office administration OR KP home infusion program ONLY. **Do not approve for administration outside of KP facilities.** • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approva (excluding Pharmacy Consult Service)l.** Continued approval: 1 year. Approve for KP clinic/back-office administration OR KP home infusion program ONLY. **Do not approve for administration outside of KP facilities.** • Documented beneficial effect from therapy during specialist follow up in the last 6 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
Ponvory (Ponesimod)	**Candidates for treatment with Ponvory should meet ALL the following criteria**: Ponvory should be reserved for treatment of patients with relapsing forms of multiple sclerosis exhibiting high-disease activity or prognostic factors for early progression to secondary progressive multiple sclerosis. • Documented diagnosis of relapsing-remitting multiple sclerosis (RRMS) or active secondary progressive multiple sclerosis (active SPMS) • Prescribed by a neurologist • Ponvory is prescribed for use as monotherapy for treatment of MS • Documented baseline CBC with differential, ophthalmologic exam, LFT, serum bilirubin and EKG • For females of childbearing age (12-50 years), a baseline negative pregnancy test within the past month AND either a prescription for birth control (IUD or other contraceptive) or documentation of the patient declining contraception and being counseled of the potential risk of pregnancy • Documented trial and intolerance to fingolimod (Gilenya) that is expected to be reduced with ponesimod (Ponvory) • Documented clinical barrier, therapeutic failure, or intolerance to rituximab product (Riabni is the preferred product if rituximab has never been tried) Reasons for Non-coverage: Ponvory should NOT be used in patients with ANY of the following: • Unstable angina within the last 6 months. • Concomitant Class Ia or Class III anti-arrhythmic drugs (beta-blockers, diltiazem, verapamil, quinidine, disopyramide, procainamide, amiodarone, dofetilide, ibutilide, dronedarone,

Drug	Prior Authorization Criteria
	sotalol) and no cardiologist consult prior to initiation of ponesimod. Heart failure, class III/IV within the last 6 months. • Decompensated heart failure requiring hospitalization within the last 6 months. • Mobitz type II second-degree or third-degree atrioventricular block (history or current) unless the patient has a functional pacemaker. • Myocardial infarction within the last 6 months. • QTc interval at baseline 500 milliseconds or greater and no cardiologist consult prior to initiation of ponesimod. • Sick-sinus syndrome (history or current) unless the patient has a functional pacemaker • Resting Heart rate less than 50 bpm on baseline electrocardiogram and no cardiologist consult prior to initiation of ponesimod. • Irregular heartbeat. • Stroke within the last 6 months • TIA within the last 6 months • Opportunistic infection • Macular edema or significant risk factors for macular edema (diabetes or uveitis) unless documentation that benefit of Ponvory outweighs risk. • Pregnancy or lactation. • Concomitant beta-blockers • Uncontrolled systemic arterial hypertension. Initial Approval Period: 1 year Continued Approval: 1 year. Continued approval for treatment with Ponvory should meet ALL the following criteria: For new members who were initiated on Ponvory outside of KPGA: Approve Ponvory if • Patient has had a visit with a KPGA MS Specialist (*please note: Dual Choice and Tricare members may see either a KPGA or an external MS Specialist) • Patient has tried and failed the preferred alternatives rituximab AND fingolimod (Gilenya) • Patient is confirmed to be stable on the therapy and safety screenings have been ordered or completed For existing members who have previously met the full criteria above: • Documented beneficial effect from therapy during Neurology follow up • Documentation of at least one examination of the fundus of the eye or optical coherence tomography imaging test after therapy initiation (recommended 3-4 months after therapy initiation)
Prevymis (Letermovir)	**Candidates for Prevymis should meet ALL of the following criteria:** **Criteria for prophylaxis of CMV for allogenic hematopoietic stem cell transplant:**

Drug	Prior Authorization Criteria
	• Prescribed by an Infectious Disease specialist, Hematologist, Oncologist, or Transplant Specialist. • Age ≥ 18 years • Patient has received, or is scheduled to receive, an allogeneic hematopoietic stem cell transplant (HSCT). • Patient is CMV-seropositive [R+] • Initiated between Day 0 and Day 28 post-transplantation Reasons for Non-coverage: • Treatment of CMV • Preemptive therapy for CMV reactivation • Patient is CMV-seronegative [R-] • Severe hepatic impairment (Child-Pugh class C) • Concomitant use of pimozide or ergot alkaloid • Concomitant use of pitavastatin or simvastatin when also used with cyclosporine Initial Approval: One-time approval for 4 months **Criteria for prophylaxis of CMV in adult kidney transplant recipients:** • Prescribed by Nephrologist, Infectious Disease or Transplant Specialist • Age ≥ 18 years • Patient has received, or is scheduled to receive, a primary or secondary allograft kidney from a CMV IgG seropositive (D+) donor. • Patient is CMV-seronegative • Initiated between Day 0 and Day 7 post-kidney transplant Reasons for Non-coverage: • Treatment of CMV infection • Preemptive therapy for CMV reactivation • Severe hepatic impairment (Child-Pugh class C) • Concomitant use of pimozide or ergot alkaloid • Concomitant use of pitavastatin or simvastatin when also used with cyclosporine Initial Approval: One-time approval for 7 months Dosing and administration: **Prophylaxis of CMV for allogenic hematopoietic stem cell transplant:** • The recommended dose is 480 mg orally or IV infusion over 1 hour once daily beginning between day 0 and 28 after transplantation (before or after engraftment) and continue through day 100 • Switch from IV to oral as soon as possible; may switch routes without dosage adjustment • Coadministration with cyclosporine:

Drug	Prior Authorization Criteria
	• If cyclosporine is initiated after starting letermovir, decrease the next letermovir dose to 240 mg once daily • If cyclosporine is discontinued after starting letermovir, increase the next letermovir dose to 480 mg once daily • If cyclosporine is interrupted due to high cyclosporine levels, no dose adjustment of letermovir is needed **Prophylaxis of CMV in adult kidney transplant recipients:** • The recommended dose is 480 mg administered once daily orally or as an IV infusion over 1 hour through 200 days post-transplant • Coadministration with cyclosporine: • If cyclosporine is initiated after starting letermovir, decrease the next letermovir dose to 240 mg once daily • If cyclosporine is discontinued after starting letermovir, increase the next letermovir dose to 480 mg once daily • If cyclosporine is interrupted due to high cyclosporine levels, no dose adjustment of letermovir is needed Monitoring: • Patients should be observed for hypersensitivity reactions during the infusion and for approximately 60 minutes after administration for signs/symptoms of anaphylaxis • Monitor for CMV reactivation
Procysbi (Delayed-Release Cysteamine)	**Candidates for treatment with Procysbi should meet ALL the following criteria:** • Document diagnosis of nephropathic cystinosis • Age ≥ 6 years • Documented inadequate response or unable to tolerate Cystagon (immediate-release cysteamine) Reasons for Non-coverage: • Hypersensitivity to penicillamine Initial Approval: 12 months. Maximum dosage approved should be restricted to 1.95 grams/ m2/day. Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, continue approval based on review of compliance to therapy and documentation of evidence of response to therapy
Provenge (Sipuleucel-T)	**Candidates for treatment with Provenge should meet ALL of the following criteria**:

Drug	Prior Authorization Criteria

	Prescriber should be enrolled in the Dendreon ON Call Program: (877) 556-3737. Representatives can be reached at (877) 336-3736 to answer general questions, Monday-Friday from 8:00a-8:00pm (ET) and 24 hours per day in the event of a product related health emergency
	
	• Histological documentation of adenocarcinoma of the prostate without evidence of neuroendocrine or small cell features
	• Patient must be asymptomatic or minimally symptomatic, without cancer-related bone pain or use of opioid analgesics for cancer pain
	• Must have Progressive androgen independent prostate cancer.
	  ○ Current (i.e., within past 6 months) and continuing evidence of disease progression while on medical castration or after surgical castration demonstrated by:
	  ▪ PSA progression[a] OR
	  ▪ progression of measurable disease[b] OR
	  ▪ progression of non-measurable disease[c]
	• Must have metastatic disease as evidenced by:
	  ○ soft tissue metastases on CT of abdomen/pelvis within 6 months OR bony metastases on bone scan within 6 months AND
	  ○ no known lung, liver, or brain metastases, malignant pleural effusions, or malignant ascites
	• Life expectancy of at least 6 months
	• Testosterone < 50 ng/dL achieved via medical or surgical castration
	  ○ Medical Castration (Lupron or Zoladex) has occurred and has been continued for at least 3 months OR
	  ○ Surgical (orchiectomy) castration must have occurred at least 3 months prior
	• No known pathologic long-bone fractures, imminent pathologic long-bone fracture (cortical erosion on radiography > 50%) or spinal cord compression.
	• No requirement for systemic immunosuppressive therapy (e.g., corticosteroids) for any reason
	• **None** of the following may occur within 28 days prior to Provenge:
	  ○ Surgery
	  ○ External beam radiation therapy
	  ○ Treatment with chemotherapy
	  ○ Treatment with other investigational products
	  ○ Treatment with other systemic therapy for prostate cancer (except for medication castration with Lupron or Zoladex)
	  ○ Treatment with 5-α-reductase inhibitors (e.g., finasteride [Proscar], dutasteride [Avodart])
	  ○ Treatment with high dose calcitriol [1,25(OH)2VitD] (i.e., > 0.5 μg/day)
	  ○ Treatment with ketoconazole
	  ○ Treatment with PC-SPES (or PC-SPEC) or Saw Palmetto
	  ○ Treatment with megestrol acetate (Megace), diethylstilbesterol (DES), or cyproterone acetate

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ Treatment with non-steroidal antiandrogens (e.g., flutamide, nilutamide or bicalutamide) ○ No change (initiation or discontinuation) in bisphosphonate therapy ○ No systemic corticosteroids ▪ Use of inhaled, intranasal, intra-articular, and topical steroids is acceptable, as is a short course (i.e., < 1 day) of corticosteroids to prevent a reaction to the IV contrast used for CT scans ○ No use of narcotics for cancer related pain ○ Average weekly pain score of ≥ 4 (measured by the Visual Analogue Scale (VAS))14 days prior to treatment initiation • The following lab values must be demonstrated prior to therapy initiation: ○ White blood cell (WBC) > 2,500 cells/µL ○ Neutrophils > 1,000 cells/µL ○ Platelets > 100,000 cells/µL ○ Hemoglobin (HgB) > 9.0 g/dL ○ Creatinine < 2.0 mg/dL ○ Total Bilirubin < 2 x upper limit of normal (ULN) ○ Aspartate transferase (AST) < 2.5 x ULN ○ Alanine transferase (ALT) < 2.5 x ULN ○ Serum PSA > 5.0 ng/mL Notes: • **PSA Progression:** Two consecutive PSA values, at least 14 days apart, each > 5.0 ng/mL and > 50% above the minimum PSA observed during castration therapy or above the pre-treatment value if there was no response. • **Measurable disease:** > 50% increase in the sum of the cross products of all measurable lesions or the development of any new lesions. The change will be measured against the best response to castration therapy or against the pre-castration measurements if there was no response. • **Non-measurable disease:** ○ **Soft tissue disease**: The appearance of 1 or more new lesions, and/or unequivocal worsening of non-measurable disease when compared to imaging studies acquired during castration therapy or against the pre-castration studies if there was no response. ○ **Bone disease:** Appearance of 2 or more new areas of abnormal uptake on bone scan when compared to imaging studies acquired during castration therapy or against the pre-castration studies if there was no response. Increased uptake of pre-existing lesions on bone scan does not constitute progression. Approval Duration: Up to 3 doses (one course of treatment) • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.**

Drug	Prior Authorization Criteria
	Ordering information: ○ Provenge is provided only through specified KP treatment sites with training and coordination handled by Dendreon. For more information and to fill out the Kaiser Provenge Enrollment Form, visit http://kpnet.kp.org/kphealthconnect/deploy/prod/ac/provenge.htm.
Pyrukynd (Mitapivat)	**Candidates for Pyrukynd should meet ALL of the following criteria**: • Age ≥ 18 years • Diagnosis of hemolytic anemia due to pyruvate deficiency • Prescribed by or in consultation with a nephrologist or hematologist • Documented hemoglobin level is currently ≤10 mg/dL • Documented concomitant use of folic acid daily • If receiving regular transfusions, documentation of both of the following: ○ A minimum of 6 transfusion episodes in the 12-month period prior to treatment • If not receiving regular transfusions, documentation of the following: ○ No more than 4 transfusions in the 12-month period prior to treatment and no transfusions in the 3-month period prior to treatment Reasons for Non-coverage: • Member is homozygous for the R479H mutation or 2 non-missense mutations (without the presence of another missense mutation), in the PKLR gene • Moderate or severe hepatic impairment • Coadministration with strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, posaconazole, voriconazole, clarithromycin) • Coadministration with strong CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, phenytoin, carbamazepine, St. John's Wort) • Concomitant use of hematopoietic-stimulating agents Initial Approval: 6 months Continued Approval: 12 months. Continue if the following criteria are met: • For patients receiving regular transfusions at baseline: must document greater than or equal to a 33% reduction in RBC units transfused compared to baseline • For patients not receiving regular transfusions at baseline: must document greater than or equal to a 1.5 g/dL increase in Hb from baseline
Qalsody (Tofersen)	**Candidates for treatment with Qalsody should meet ALL the following criteria:** • Prescribed by a Neurologist • Age ≥ 18 years • Documented diagnosis of amyotrophic lateral sclerosis (ALS) with mutation in the superoxide dismutase 1 (SOD1) gene • Documented forced vital capacity (FVC) of 50% or higher within 2 months prior to treatment

Drug	Prior Authorization Criteria
	Reasons for Non-coverage: • Patient has tracheostomy • Current hepatitis B or HIV infection • Patient enrolled in hospice Initial Approval Period: 12 months Continued Approval Period: 12 months if patient meets ALL the initial criteria above and documentation of clinical benefit of treatment. Dosing and Administration: • Intrathecal administration • Recommended dose: 100 milligrams (15 mL) per administration • Initiate QALSODY treatment with 3 loading doses administered at 14-day intervals. A maintenance dose should be administered once every 28 days thereafter

Qbrexza
(Glycopyrronium)
	Candidates for treatment with Qbrexza should meet ALL the following criteria:
	
	• Age ≥ 9 years
	• There is documentation that the axillary hyperhidrosis is severe, intractable and disabling
	• Documented inadequate response, intolerance or contraindication to the following therapies:
	  ○ For members aged < 18 years:
	  ▪ At least 3 months of topical aluminum chloride (e.g., OTC Hypercare, Drysol Rx)
	  ○ For members aged ≥ 18 years:
	  ▪ At least 3 months of topical aluminum chloride (e.g., OTC Hypercare, Drysol Rx)
	  ▪ At least 3 months of oral glycopyrrolate (e.g., Robinul)
	  ▪ At least 6 months of Botox (QRM)
	
	Initial Approval: 3 months
	
	Continued Approval: 6 months. Confirm patient meets all above criteria. In addition, continue approval if patient has documented clinically significant benefit from medication as defined by the Provider.

Qinlock (Ripretinib)	**Candidates for Qinlock should meet ALL the following criteria:** • Prescribed by an oncologist. • Age ≥ 18 years • Patient has a diagnosis of advanced, unresectable, recurrent, or metastatic gastrointestinal stromal tumor (GIST) • Patient has a documented treatment failure or intolerance to **three or more** kinase inhibitors, including imatinib (Gleevec), sunitinib (Sutent) AND regorafenib (Stivarga)

Drug	Prior Authorization Criteria
	Initial Approval: 12 months with a quantity limit of 90 tablets per 30 days. Continued Approval: 12 months with a quantity limit of 90 tablets per 30 days. For continued approval for treatment with Qinlock, patient should meet ALL the following criteria: • Patient continues to meet the above criteria. • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. For new members who were initiated on Qinlock outside of KPGA: Patient should meet ALL the following criteria: • Prescribed by an oncologist. • Age ≥ 18 years • Patient has a diagnosis of advanced GIST. • Patient has a documented treatment failure or intolerance to **three or more** kinase inhibitors, including imatinib (Gleevec), sunitinib (Sutent) AND regorafenib (Stivarga) • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. • Quantity limit of 90 tablets per 30 days

Qulipta
(Atogepant)
	Candidates for treatment with Qulipta should meet ALL the following criteria:
	
	• Age ≥ 18 years
	• Prescribed for the preventative treatment of episodic migraine or chronic migraine
	• Prescribed by a Neurologist or provider in the Department of Neurology who specializes in headache management
	• Documented compliance with a headache diary for at least 1 month prior to initiation
	• Documented adequate trial of 3 preventative agents with strong evidence for migraine (e.g., tricyclic antidepressant, beta-blocker, topiramate, valproate, serotonin-norepinephrine reuptake inhibitor, ACE-inhibitor or angiotensin-receptor blocker)
	• Documentation of one of the following:
	  ○ Trial and failure of 2 CGRP injectable medications (i.e Ajovy [KP preferred product], Emgality, Aimovig, Vyepti)
	  ○ Patient is unable to master self-injection technique and lacks a caregiver who can perform injections
	  ○ Patient has a history of persistent or severe injection site reactions not responsive to conservative measures while on injectable agents
	
	Initial Approval: 6 months.
	
	• Qulipta 60 mg tablets ONLY have been approved for tablet splitting.
	• Please request conversion and approve Qulipta 60 mg ½ tablet daily (30 mg) for patients requiring Qulipta 30 mg per day ONLY, unless patient is unable or unwilling to split tablets.
	• Quantity limit:
	  ○ For Qulipta 60 mg ½ tablet daily: QRM reviewer to approve 15 tablets per 30 days
	  ○ For Qulipta 30 mg or 60 mg: QRM reviewer to approve 30 tablets per 30 days

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	Continued approval: 12 months. Continue approval if the following criteria are met:
	
	• For new members who were initiated on Qulipta outside of KPGA, approve Qulipta if patient has previously tried and failed three or more preventive migraine therapies including at least one CGRP injectable medications (Ajovy is the KP preferred CGRP injectable).
	• Documented beneficial effect and tolerance of the medication.
	• Quantity limit:
	  ○ For Qulipta 60 mg ½ tablet daily: QRM reviewer to approve 15 tablets per 30 days
	  ○ For Qulipta 30 mg or 60 mg: QRM reviewer to approve 30 tablets per 30 days

Radicava ORS (Edaravone)	**Candidates for treatment with Radicava should meet ALL the following criteria:** • Prescribed by a Neurologist • Diagnosis of clinical ALS • ALS Functional Rating Scale-Revised (ALSFRS-R) score* of 2 points or better on each of the 12 items within the past two months • Duration of 2 years or less from onset of first symptom • Forced vital capacity (%FVC) ≥80% within past two months • Prior or current use of riluzole • For Radicava IV infusion: Patient willing/able to have a tunneled catheter long-term Reasons for Non-coverage: • Score of < 3 on ALSFRS-R for dyspnea, orthopnea, or respiratory insufficiency Initial approval: 6 months Continued approval: 12 months. Continue approval based on adherence to follow-up assessments and documented ALSFRS-R, and % FVC in the medical Record Treatment may be discontinued for any of the following: • Non-adherence to follow-up assessments • Patient is requiring a tracheotomy or non-invasive ventilation all day • %FVC < 50% and blood gas $PaCO_2$ > 45 mm Hg • Significant clinical decline based on ALSFRS-R and/or %FVC • Patient requiring hospice care *ALSFRS-R: A standardized scale from 0 (worst) to 48 (best). The ALSFRS-R scale consists of 12 questions that evaluate the fine motor, gross motor, bulbar, and respiratory function of patients with ALS (speech, salivation, swallowing, handwriting, cutting food, dressing/hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, and respiratory insufficiency). Each item is scored from 0 (no ability) to 4 (normal), with higher scores representing greater functional ability.
Ravicti (Glycerol phenylbutyrate)	**Candidates for treatment with Ravicti should meet ALL the following criteria:**

Drug	Prior Authorization Criteria
	• Documented diagnosis of urea cycle disorder • Age ≥ 2 years • Inadequate response to ONE of the following: dietary protein restriction or amino acid supplementation • Must be used with dietary protein restriction • Documented inadequate response or unable to tolerate Buphenyl (sodium phenylbutyrate) Reasons for Non-coverage: • Known hypersensitivity to phenylbutyrate • Being used for treatment of acute hyperammonemia in patients with urea cycle disorders Initial Approval: 12 months Continued Approval: 24 months. Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, continue approval if there is documented evidence of response to therapy and patient is actively on dietary protein restriction. Ordering information: Ravicti is available through the KP Specialty Pharmacy. Prescribers must complete the **Ravicti Drug Order Form** and fax it to KP-Specialty Pharmacy (1-650-301-5790).

Reblozyl
(Luspatercept-aamt)
	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	Candidates for treatment with Reblozyl should meet ALL the following criteria:
	• Prescribed by a hematologist
	• Age ≥ 18 years
	• Documented diagnosis of beta thalassemia or hemoglobin E/beta thalassemia (beta thalassemia with mutation and/or multiplication of alpha globin is allowed)
	  ○ Patient is receiving regular transfusions (defined as: 6-20 RBC units in the 24 weeks prior to treatment initiation and no transfusion-free period for ≥35 days during that period)
	OR
	• Documented diagnosis of anemia due to myelodysplastic syndromes with ring sideroblasts or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis
	  ○ Failing an erythropoiesis-stimulating agent and requiring 2 or more RBC units over 8 weeks
	• Documentation that a trial of luspatercept-aamt is warranted to reduce the burden of transfusions and transfusion-related iron overload
	
	Reasons for Non-coverage: Reblozyl should NOT be used in patients with any of the following:
	• Diagnosis of Hemoglobin S/β-thalassemia or alpha (α)-thalassemia (e.g., Hemoglobin H)
	• If female patient is pregnant or lactating
	• Patient has uncontrolled hypertension

Drug	Prior Authorization Criteria
	• Major surgery within the prior 4 weeks Initial Approval Period: 12 months. Approve for back-office administration ONLY. Preferred administration with KP. Criteria for Discontinuation: • No clinically meaningful decrease in transfusions after 9 weeks (3 doses) on maximum recommended dose • Intolerance to luspatercept-aamt • Non-adherence to luspatercept-aamt or follow-up labs and assessments • Patient becomes pregnant or is breastfeeding • Approved for back-office administration ONLY. Preferred administration with KP. Continued Approval Period: 12 months if patient does not meet any criteria for discontinuation listed above.
Rebyota (Fecal microbiota, live-jslm) ****Note:** **Rebyota is floor stock for GI Anesthesiology. QRM review is not required if ordered by TSPMG GI clinician for that department.**	**Candidates for Rebyota should meet ALL of the following criteria**: • Prescribed by an Infectious Disease Specialist or Gastroenterologist • Age ≥ 18 years • Documented diagnosis of recurrent *C. difficile* infection (CDI) • Documentation of at least 2 recurrent episodes of severe CDI (≥3 total CDI episodes) • Positive stool test for *C. difficile* toxin within 30 days before QRM/PA request • Rebyota-naïve patients must have documented treatment with ≥3 antibiotic courses (including vancomycin and fidaxomicin), unless contraindication or intolerance • Rebyota will be administered within 24 to 72 hours of completing antibiotic treatment for the current CDI episode • Rebyota will not be used in combination with Vowst Initial Approval: 8 weeks for 1 lifetime treatment only • Approve for administration at a KP facility only • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: Not applicable. Rebyota is intended as a one-time treatment. Dosing and Administration: • Rectal administration by a healthcare provider • A single dose of Rebyota is 150 mL

Drug	Prior Authorization Criteria
Redemplo (Plozasiran)	**Candidates for treatment with Redemplo (plozasiran) should meet ALL of the following criteria:** • Prescribed by an endocrinologist, geneticist, or cardiologist • Patient is 18 years of age or older • Documented diagnosis with familial chylomicronemia syndrome (FCS) based on genetic testing • Fasting triglyceride (TG) level >/= 880 mg/dL in the past 1 month prior to starting therapy • Documented history of pancreatitis in past 10 years • Documentation that Redemplo (plozasiran) will be used as an adjunct therapy to diet • Documented trial of Tryngolza (olezarsen) or documented failure, intolerance or contraindication Reasons for Non-coverage: • Active pancreatitis • Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 2.0 × upper limit of normal (ULN) • Total bilirubin > ULN unless due to Gilbert's syndrome Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reason for Non-coverage. • In addition, documentation of at least 30% reduction in TG levels since starting therapy. • At subsequent approvals, must maintain >40% reduction in TGs from baseline. Ordering Information: Redemplo is available via Vanscoy Rare Specialty Pharmacy. Visit KPSP using this link, SPIP_REDEMPLO_20260413 or call 1-844-REDEMPLO (1-844-733-3675),

Relistor
(Methylnaltrexone)
	Candidates for treatment with Relistor should meet ALL the following criteria:
	
	• Prescribed by oncologist, hospice/palliative care, gastroenterologist, or pain management specialist
	• Diagnosis of opioid induced constipation and an active opioid prescription
	• Age ≥18 years
	• Patient has failed a trial of **at least 4-weeks** or has an intolerance or contraindication to scheduled dosing of the following medications:
	  ○ ONE osmotic laxative: Polyethylene glycol (Miralax) OR Lactulose
	  AND
	  ○ ONE stimulant laxative: Senna OR Bisacodyl (oral or rectal)
	  ○ Lubiprostone (Amitiza)
	  ○ Naloxegol (Movantik)
	  ○ Naldemedine (Symproic)

Drug	Prior Authorization Criteria
	• If request for the injectable, must document the following: Unable to tolerate or documented intolerance/contraindication to **all the agents listed above AND oral Relistor tablets.** Reasons for Non-coverage: • Known or suspected mechanical GI obstruction and at increased risk of recurrent obstruction Initial Approval: 3 months Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reason for Non-coverage.

RET Inhibitors:
 	
Preferred:
Retevmo
(Selpercatinib)
 	
Non-Preferred:
Gavreto
(Pralsetinib)
	Candidates for treatment with Gavreto or Retevmo should meet ALL the following criteria:
	
	For diagnosis of non-small cell lung cancer (NSCLC)**:**
	• Documented diagnosis of metastatic RET fusion-positive NSCLC, as detected by a FDA approved test
	• Age ≥ 18 years
	• Prescribed by a hematologist/oncologist
	• For Gavreto, patient has a documented treatment failure, contraindication, or intolerance to KP's preferred therapy, Retevmo.
	
	For diagnosis of medullary thyroid cancer (MTC) **(For Retevmo Only)**:
	• Documented diagnosis of advanced or metastatic RET-mutant MTC that requires systemic therapy
	• Age ≥ 2 years
	• Prescribed by a hematologist/oncologist
	
	For diagnosis of thyroid cancer:
	• Documented diagnosis of advanced or metastatic RET fusion-positive thyroid cancer that requires systemic therapy
	• Patient has ONE of the following:
	  ○ For Retevmo: Age ≥ 2 years
	  ○ For Gavreto: Age ≥ 12 years
	• Prescribed by a hematologist/oncologist
	• The disease is radioactive iodine-refractory (if radioactive iodine is appropriate)
	• For Gavreto, patient has a documented treatment failure, contraindication, or intolerance to KP's preferred therapy, Retevmo.
	
	For diagnosis all other solid tumors **(For Retevmo Only)**:
	• Documented diagnosis of advanced or metastatic RET fusion-positive solid tumor, as detected by an FDA-approved test
	• Patient has progressed on or following prior systemic therapy OR has no satisfactory alternative treatment options
	• Age ≥ 2 years

Drug	Prior Authorization Criteria
	• Prescribed by a hematologist/oncologist Reasons for Non-coverage: • Uncontrolled hypertension (i.e ≥140/90, blood pressure should be optimized prior to initiating Gavreto or Retevmo) Initial Approval: 12 Months Continued Approval: 12 months if the patient has experienced any of the following: • Patient continues to meet the above criteria; AND • Patient does not show evidence of progressive disease while on Gavreto or Retevmo therapy • Absence of unacceptable toxicity from the drug (i.e hepatotoxicity, hemorrhagic events, QT interval prolongation, recurrent interstitial lung disease/pneumonitis)

Preferred:
Lenalidomide
(generic Revlimid)
(NOTE: available on the formulary/no PA required)
 	
Non-Preferred:
Revlimid
(lenalidomide)
	Lenalidomide (generic Revlimid) is the preferred product at KP and is available on the formulary without prior authorization.
	
	Candidates for BRAND Revlimid should meet ALL the following criteria:
	• Prescribed by a hematologist or oncologist.
	• Diagnosis of ONE of the following:
	  ○ Follicular lymphoma
	  ○ Mantle cell lymphoma
	  ○ Marginal zone lymphoma
	  ○ Multiple myeloma
	  ○ Myelodysplastic syndrome
	  ○ B-cell lymphoma
	  ○ Castleman disease
	  ○ Chronic lymphocytic leukemia
	  ○ Histiocytic neoplasms
	  ○ Hodgkin lymphoma
	  ○ Kaposi sarcoma
	  ○ Myelofibrosis
	  ○ Primary central nervous system lymphoma
	  ○ POEMS Syndrome
	  ○ Small lymphocytic leukemia
	  ○ Systemic light chain amyloidosis
	  ○ T-cell lymphoma
	• Patient has a documented trial of lenalidomide (generic Revlimid) and experienced an adverse reaction that cannot be explained by other clinical or lifestyle factors and may be due to the **inactive components** of the product.
	  ○ **DO not approve** for coverage/use if documented treatment failure or intolerance is to the authorized generic (AG) lenalidomide by Teva. Lenalidomide AG is identical in composition of both active and inactive ingredients as brand Revlimid.

Drug	Prior Authorization Criteria
	○ **Do not approve for coverage** if the request for coverage of brand Revlimid is based upon the physician's and/or member's unwillingness to change to a preferred alternative. Patient will need to meet the full criteria for coverage. Initial Approval: 12 months Continued Approval: 12 months. For continued approval for treatment with brand Revlimid, patient should meet ALL the following criteria: • Patient continues to meet the above criteria. • Patient is responding positively to therapy based on stabilization of disease or no disease progression Ordering Information: • Patient must be registered in the RevAssist Program prior to filling first prescription. Provider authorization number can be obtained by calling 1-888-423-5436. • Lenalidomide is delivered directly to the patient through the KP Specialty Pharmacy. If approved for coverage, prescribers must complete the KPSP Lenalidomide Order Form and fax it to the KP Specialty Pharmacy at 1-650-301-5790.
Revuforj (Revumenib)	**Candidates for treatment with Revuforj (revumenib) should meet ALL the following criteria:** • Prescribed by a hematologist/oncologist • Age ≥ 1 year • Patient diagnosed with relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation **OR** relapsed or refractory acute myeloid leukemia with susceptible nucleophosmin 1 (NPM1) mutation with no satisfactory alternative treatment options. Reasons for Non-coverage: • Pregnant • Lactation Initial Approval: 12 months Continued Approval: 12 months. Patient continues to meet all criteria above and does not show evidence of progressive disease while on Revuforj therapy.
Rezdiffra (Resmetirom)	**Candidates for treatment with Rezdiffra (resmetirom) should meet ALL the following criteria:** • Prescribed by a hepatologist or gastroenterologist • Age ≥ 18 years • Patient diagnosed with noncirrhotic metabolic or nonalcoholic steatohepatitis (MASH or NASH) confirmed by **ONE** of the following: ○ History of a liver biopsy in the past 2 years if no change in body weight of > 5% post biopsy. If change in body weight > 5% then re-evaluation to grade and stage MASH is required. ○ Transient elastography (e.g., Fibroscan) if no change in body weight of > 5% in the past

Drug	Prior Authorization Criteria
	in the 12 months. If change in body > 5% then re-evaluation to grade and stage NASH is required. • Diagnosis is consistent with advanced liver fibrosis consistent with stages F2 or F3 • Prescriber documents and patient agrees to alcohol avoidance. PETH lab test (POPETH) completed with baseline labs and is < 20. • For patients with a BMI ≥ 27kg/m^2, inability to achieve the target weight-loss goal of ≥ 10% from baseline after lifestyle interventions and a 3-month trial of at least **TWO** of the following oral medications, unless documented contraindication or intolerance. *This requirement is not applicable if BMI < 27 kg/m²*: ○ Phentermine** ○ Qsymia (phentermine/topiramate ER) ** or separate prescriptions taken concomitantly ○ Contrave (naltrexone/bupropion) or separate prescriptions taken concomitantly ○ Orlistat (common formulation include Alli, Xenical) ○ If patient achieves a weight reduction of ≥ 5% or greater, then re-evaluation to grade and stage MASH is required **Note: Maintained on a stimulant medication for **ADHD** is a contraindication to phentermine use. Phentermine contraindicated with uncontrolled HTN (blood pressure >140/90 mmHg on 2 or more appropriately dose adjusted HTN meds), hx of ASCVD, hyperthyroidism, glaucoma, agitated states, hx of drug abuse. If phentermine/Qsymia is contraindicated, patients aged 18 or older must trial Contrave (or separate prescriptions) and Orlistat unless contraindication or intolerance. • For patients with a BMI ≥ 27kg/m^2, documented inadequate response (of at least a 12-month trial), intolerance or contraindication to semaglutide (titrated to target weekly dose). *This requirement is not applicable if BMI < 27 kg/m².* • If concurrent diagnosis of Type 2 Diabetes Mellitus, all the following are required: ○ A1C at goal in the past 3 months (see below) ▪ Documented A1c < 7% **OR** ▪ Documented A1C < 8% if age ≥ 65 years OR age 18-64 years with dementia, blindness, lower extremity amputation, CKD 4/5, ESRD, cardiomyopathy/CHF, cardiovascular disease (e.g., MI, CABG, percutaneous coronary intervention, angina, thoracoabdominal aneurysm, carotid stenosis, renal atherosclerosis, peripheral vascular disease) ○ Currently receiving statin unless documented contraindication or intolerance • DO NOT cover if the following are documented: ○ Serum alanine aminotransferase (ALT) >250 U/L ○ Documented Child-Pugh Class B or C ○ Concomitant use with a GLP-1RA for treatment of NASH/MASH ○ Regular use of drugs historically associated with metabolic dysfunction-associated fatty liver disease (MAFLD) due to concern for drug-induced fatty liver (e.g., amiodarone, methotrexate, systemic glucocorticoids at greater than 5 mg/day, tamoxifen, estrogens at doses greater than those used for hormone replacement or contraception, anabolic steroids (except testosterone replacement) and valproic acid) ○ Thyroid disease as defined by: ▪ Active hyperthyroidism, or ▪ Untreated clinical hypothyroidism defined by thyroid stimulating hormone (TSH) >7 IU/L with symptoms of hypothyroidism or >10 IU/L without symptoms, ▪ Note: Patients who have had a thyroidectomy and are on replacement thyroxine doses >75 µg per day

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	Initial Approval: 6 months
	
	First Continued Approval:
	
	For existing members who previously met the full criteria for initial 6-month approval above:
	• Has patient completed a repeat elastography (i.e., Fibroscan)
	  ○ If yes, go to #2
	  ○ If no, patient does NOT meet criteria. GI follow up required
	• Does Fibroscan show an improvement in liver stiffness measure (LSM): kPA has decreased from baseline
	  ○ If yes, go to #3
	  ○ If no, patient does NOT meet criteria
	• Does Fibroscan show an improvement in controlled attenuation parameter (CAP): CAP has decreased from baseline
	  ○ If yes, go to #4
	  ○ If no, patient does not meet criteria
	• Patient has all the following:
	  ○ No fibrosis stage F4 or liver cirrhosis
	  ○ If diagnosis of T2DM patient continues to maintain A1c goal
	  ○ Provider documentation of continued abstinence from alcohol
	  ○ Patient does not meet any of the above reasons for non-coverage
	  ○ If yes, continue to approval for 12 months
	
	Continued Approval: 12 months (after first 12-month approval). Confirm patient meets all above **initial** coverage criteria without reasons for non-coverage or criteria for discontinuation. In addition, **ONE** of the following must be met:
	
	• NAFLD Activity Score (NAS) has decreased by at least 2 points from baseline
	• Reduction in fibrosis stage from baseline (prior to staging therapy for MASH)

Rezlidhia (Olutasidenib)	**Candidates for treatment with olutasidenib should meet ALL the following criteria:** • Prescribed by an oncologist • Age ≥ 18 years • Diagnosed relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation (e.g., R132C, R132H, R132G, R132S, R132L) as detected by an FDA-approved test. ○ Information on FDA-approved tests for the detection of IDH1 mutations in AML is available at http://www.fda.gov/CompanionDiagnostics Reasons for Non-Coverage: • Pregnancy or lactation • Severe hepatic impairment (total bilirubin >3 times ULN with any AST)

Drug	Prior Authorization Criteria
	• Severe renal impairment (CrCl <30 mL/min) • Patients on dialysis Initial Approval Period: 12 months Continued Approval Period: 12 months if patient meets ALL the initial criteria above and patient does not show evidence of progressive disease on olutasidenib therapy.

Rezurock
(Belumosudil)
	Candidates for Rezurock should meet ALL of the following criteria:
	
	• Prescribed by Hematologist/ Oncologist or transplant specialist
	• Age ≥12 years
	• Diagnosis of chronic graft-versus-host disease (cGVHD)
	• Failed ≥2 previous lines of systemic therapy for treatment of cGVHD including failure or intolerance of ruxolitinib (Jakafi) at up to maximally indicated doses
	  ○ Examples of failed conventional systemic treatments for cGVHD
	  ▪ Corticosteroids: methylprednisolone
	  ▪ Calcineurin inhibitors: cyclosporine, tacrolimus, sirolimus
	  ▪ Other therapies: mycophenolate mofetil, axatilimab, ibrutinib
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. Continued approval for treatment with Rezurock should meet ALL the following criteria:
	
	For new members who were initiated outside of KPGA:
	
	• Hematologist or oncologist visit
	• The patient is confirmed stable on therapy, and safety screenings have been ordered or completed
	• The patient has tried and failed ruxolitinib
	
	For existing members who have previously met the full criteria above:
	• Documented beneficial effect during Hematologist/Oncologist visit

Rezzayo (Rezafungin)	**Candidates for treatment with Rezzayo should meet ALL the following criteria:** • Age ≥ 18 years • Prescribed by an Infectious Disease specialist • Diagnosed with candidemia or invasive candidiasis • Documented reason patient is unable to take oral azole antifungal • Documentation that patient is unable receive daily infusions Reasons for Non-Coverage: • Known hypersensitivity to rezafungin or other echinocandins

Drug	Prior Authorization Criteria
	• Documented failure to other echinocandins or as demonstrated by antifungal susceptibility testing (i.e., caspofungin, micafungin, anidulafungin) • Documented intolerance to other echinocandins (i.e., caspofungin, micafungin, anidulafungin) Approval Period: 30 days. One time course of 4 weekly doses. Dosage and Administration: • Administer REZZAYO by intravenous infusion over approximately one hour (~250 mL/h) • Administration by healthcare professional

Rhapsido (Remibrutinib)	**Candidates for Rhapsido should meet ALL of the following criteria**:
	
	• Prescribed by an allergist, dermatologist, or immunologist
	• Age ≥ 18 years
	• Documented diagnosis of chronic spontaneous urticaria (CSU)
	• Patient experiences hives or angioedema on most days of the week for ≥ 6 weeks
	• Documented inadequate response (to a minimum 4 week trial), intolerance, or contraindication to 1 of the following options:
	  ○ A second generation H1-antihistamine (e.g., loratadine, cetirizine, fexofenadine) given at four times the standard FDA-approved **OR**
	  ○ Two second generation H1-antihistamines given in combination (e.g., fexofenadine 180mg daily in the AM plus cetirizine 10-20mg daily at bedtime)
	• Inadequate response, intolerance, or contraindication to at least ONE of the following therapies:
	  ○ Dupixent (dupilumab)
	  ○ Xolair (omalizumab)
	• Not taken in combination with another systemic biologic (e.g., Dupixent [dupilumab], Xolair [omalizumab], Cinqair [reslizumab], Nucala[mepolizumab], Tezspire [Tezepelumab]) for the treatment of chronic spontaneous urticaria
	
	Initial approval: 6 months with quantity limited to 60 tablets per 30 days
	
	Continued approval: 12 months. Continue approval if the following criteria are met:
	
	For new members who were initiated outside of KPGA: Confirm patient meets all above coverage criteria without reasons for non-coverage.
	
	• Quantity limit: 60 tablets per 30 days
	
	For existing members who have previously met the criteria: Documented clinically significant benefit from the medication during specialist follow up in the last 12 months.
	
	• Quantity limit: 60 tablets per 30 days

Drug	Prior Authorization Criteria

Rhopressa (Netarsudil)
 	
Rocklatan (Netarsudil and Latanoprost)
	Candidates for treatment with Rhopressa/Rocklatan should meet ALL the following criteria:
	
	• Documented diagnosis of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension
	• Prescribed by an ophthalmologist or optometrist
	• Patient is 18 years and older
	• Documented inadequate response, intolerance or contraindication to the following:
	  ○ Prostaglandin analogs (e.g., latanoprost etc.)
	  ▪ If intolerance: at least 2 ophthalmic prostaglandin analogs OR
	  ▪ If inadequate response or contraindication: at least one ophthalmic prostaglandin analogs AND
	  ○ At least one ophthalmic beta-blocker (e.g., timolol etc.) AND
	  ○ At least one alpha-2 adrenergic agonist (e.g., brimonidine) AND
	  ○ At least one carbonic anhydrase inhibitor (e.g., dorzolamide)
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. Confirm patient meets all above criteria. In addition, continue approval if there is documented positive response to therapy.

Rinvoq (Upadacitinib)	**Candidates for treatment with Rinvoq should meet ALL the following criteria PLUS the individual disease state criteria below:**
	
	• Patient has had a negative interferon-gamma release assay test for TB Infection within the past 24 months or is positive for latent TB and has completed treatment in the past or is currently on treatment.
	• Medication is NOT being used in combination with another biologic medication [omalizumab (Xolair), rituximab (Rituxan), adalimumab (Amjevita, Humira), etc.], Janus kinase inhibitor [abrocitinib (Cibinqo), baricitinib (Olumiant), tofacitinib (Xeljanz)], or other potent immunosuppressants [azathioprine, cyclosporine].
	• Then follow the disease state specific criteria below, based on diagnosis:
	
	Diagnosis rheumatoid arthritis:
	• Prescriber is a rheumatologist
	• Age ≥ 18 years
	• Request is for Rinvoq 15mg ER daily
	• Documented contraindication, intolerance, or inadequate response to at least a 3-month trial of each of the following:
	  ○ 1 conventional synthetic DMARD:
	  i. methotrexate, sulfasalazine, leflunomide, OR hydroxychloroquine
	  ○ 1 TNF inhibitor:
	  i. Infliximab (Infliximab-dyyb/Inflectra [preferred], Remicade)
	  ii. Adalimumab (Amjevita [preferred], Humira)
	  iii. Others: Golimumab (Simponi), Certolizumab (Cimzia)
	  ○ 1 IL-6 inhibitor
	  i. Tocilizumab (Avtozma [preferred], Actemra), Kevzara (sarilumab)

Drug	Prior Authorization Criteria
	○ Tofacitinib Diagnosis of axial spondyloarthritis (ankylosing spondylitis or nonradiographic axial spondyloarthritis): • Prescriber is a rheumatologist • Age ≥ 18 years • Request is for Rinvoq 15mg ER daily • Documented contraindication, history of intolerance or inadequate response to at least a 3-month trial of each of the following: ○ 1 TNF inhibitor: i. Infliximab (Infliximab-dyyb/Inflectra [preferred], Remicade) ii. Adalimumab (Amjevita [preferred], Humira) iii. Others: Golimumab (Simponi), Certolizumab (Cimzia) ○ Cosentyx (secukinumab) ○ Tofacitinib Diagnosis of psoriatic arthritis: • Prescriber is a rheumatologist or dermatologist • Age 2 to 65 years AND weight ≥ 10kg • Request is for Rinvoq 15mg ER daily OR Rinvoq 1mg/ml oral solution (oral solution for pediatric patients only) • Documented contraindication, history of intolerance or inadequate response to at least a 3-month trial of each of the following: ○ 1 TNF inhibitor: i. Infliximab (Infliximab-dyyb/Inflectra [preferred], Remicade) ii. Adalimumab (Amjevita [preferred], Humira) iii. Others: Golimumab (Simponi), Certolizumab (Cimzia) ○ 1 IL-12/23 inhibitor (unless documented axial disease) i. Ustekinumab (Yesintek [preferred], Stelara) ○ 1 IL-17 inhibitor i. Secukinumab (Cosentyx), Ixekizumab (Taltz) ○ 1 IL-23 inhibitor i. Guselkumab (Tremfya), Risankizumab (Skyrizi) ○ Tofacitinib (for patients ≥ 40kg) Diagnosis of polyarticular juvenile idiopathic arthritis: • Prescriber is a rheumatologist • Age ≥ 2 years AND weight ≥ 10kg • Request is for Rinvoq 15mg ER daily OR Rinvoq 1mg/ml oral solution (oral solution for pediatric patients only) • Documented contraindication, intolerance or inadequate response to at least a 3-month trial of each of the following: ○ Methotrexate ○ Adalimumab product (Amjevita [preferred], Humira)

Drug	Prior Authorization Criteria
	○ Tocilizumab product (Avtozma [preferred]), Actemra) ○ Tofacitinib (for patients ≥ 40kg) Diagnosis of Giant Cell Arteritis: • Prescriber is a rheumatologist • Age ≥ 18 years • Request is for Rinvoq 15mg ER daily • Patient is unable to taper glucocorticoid treatment without disease relapse • Patient has documented contraindication, history of intolerance, or inadequate response to tocilizumab (Avtozma [preferred], Actemra). Diagnosis of Atopic Dermatitis: • Prescribed by a dermatologist • Age ≥ 12 years and weight ≥ 40 kg • Request is for Rinvoq 15mg ER daily or 30mg ER daily • Documented diagnosis of moderate-to-severe atopic dermatitis (BSA > 10%) • Documented inadequate response, intolerance, or contraindication to at least a 16-week trial of each of the following: ○ Dupixent (dupilumab) or Adbry (tralokinumab-ldrm) ○ Nemluvio (nemolizumab) Initial approval: 12 months Continued approval: 12 months. Continue approval if the following criteria are met: • For new members who were initiated on upadacitinib outside of KPGA: Patient must meet all above coverage criteria and have documented adequate response and tolerance of medication during specialist follow-up in the past 6 months. • For existing members who have previously met the full criteria above: documented adequate response and tolerance of medication during specialist follow up in the last 12 months. Diagnosis of ulcerative colitis (UC) • Age ≥ 18 years • Documented moderately to severely active ulcerative colitis • Prescribed by gastroenterologist • Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to the following: ○ Infliximab product (e.g., Inflectra [preferred]) ○ Ustekinumab product (e.g., Yesintek [preferred]) ○ Tofacitinib, preferred JAK-inhibitor Diagnosis of Crohn's Disease (CD) • Age ≥ 18 years • Documented moderately to severely active ulcerative colitis • Prescribed by gastroenterologist

Drug	Prior Authorization Criteria

	• Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to the following:
	  ○ Infliximab product (e.g., Inflectra [preferred])
	  ○ Adalimumab product (e.g., Amjevita [preferred])
	  ○ Ustekinumab product (e.g., Yesintek [preferred])
	  ○ Entyvio (vedolizumab) - trial not required in CD, if documentation of small bowel, perianal or fistulizing / penetrating disease
	
	Initial approval: 12 months (Note: For Rinvoq 45 mg tablets, approval should be limited to 12 weeks for Crohn's Disease induction and 8-16 weeks for Ulcerative Colitis induction)
	
	Continued approval for UC and CD: 12 months.
	
	For new members and existing members Documented clinical benefit (asymptomatic or in remission) from therapy, by a gastroenterology specialist within the past 12 months.

Rituxan (rituximab) NOTE: Prior authorization review is **NOT** required for rituximab biosimilar products for Commercial Benefits (e.g., Riabni [rixtuimab-arrx], Truxima [rituximab-abbs], Ruxience [rituximab-pvvr], etc.)	**Candidates for treatment with Rituxan should meet ALL the following criteria:** Rituxan (rituximab) will only be considered for use after trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction) to two rituximab biosimilars including KP's preferred therapy, Riabni (rituximab-arrx) AND the same intolerance, contraindication, or adverse event would not be expected to occur with Rituxan. NOTE: Prior authorization review is NOT required for rituximab biosimilar products for Commercial Benefits (e.g., Riabni [rixtuimab-arrx], Truxima [rituximab-abbs], Ruxience [rituximab-pvvr], etc.) Neurology, Nephrology and Rheumatology indications: • Documented diagnosis of multiple sclerosis, neuromyelitis optica (NMO), encephalitis, neurosarcoidosis, idiopathic CNS demyelinating disease, myasthenia gravis, rheumatoid arthritis, systemic lupus erythematosus, or nephrotic syndrome. • Patient switched from Rituxan (rituximab) to Riabni (rituximab-arrx) in the last 12 months AND • Documented rituximab antibody levels following the conversion AND • Patient has had loss or efficacy or intolerance to TWO biosimilar products including KP preferred product Riabni ○ Loss of efficacy to a rituximab product as evidenced by documentation of at least 2 infusions of the product and loss of efficacy confirmed by objective findings on physical exam or lab abnormalities Reasons for Non-coverage: • Patient has never been treated with Rituxan product. Initial approval: 6 months

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for administration ONLY in KPGA infusion center, absent director level approval** ○ Intolerance to rituximab product as evidenced by documentation of at least 2 infusions of the product and patient experienced Grade 2* or 3* side effects which persisted despite interventions to mitigate the occurrence of the side effects * Side Effect Grading, per Common Terminology Criteria for Adverse Events (CTCAE): • Grade 1: mild, asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated • Grade 2: moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living (preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.) • Grade 3: severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living (bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden) • Grade 4: life-threatening consequences; urgent intervention indicated • Grade 5: death related to adverse event Continued approval: 12 months. Continue approval if the following criteria are met For new members who were initiated on Rituxan outside of KPGA: patient must meet the full criteria above for approval of Rituxan. Note: If the physician's request for coverage of brand Rituxan is based upon the physician's and/or member's unwillingness to change to the preferred alternative, the request will be denied unless the member meets the full criteria. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for administration ONLY in KPGA infusion center, absent director level approval** For existing members who have previously met the full criteria above: documented adequate response and tolerance of medication during specialist follow up in the last 12 months. Resolution of the side effects that occurred with the biosimilar if that was the reason for switching back. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for administration ONLY in KPGA infusion center, absent director level approval** For Dermatology Indications: • Rituxan (rituximab) will only be considered for use after trial and failure (intolerance, allergic reaction, disease progression, infusion reaction) to two biosimilars including KP's preferred therapy, Riabni (rituximab-arrx) AND the same intolerance, contraindication, or adverse event would not be expected to occur with Rituxan.

Drug	Prior Authorization Criteria

	Pemphigus vulgaris, pemphigus foliaceus, or Bullous pemphigoid indication:
	
	• Prescribed by a dermatologist
	• Diagnosis of refractory Pemphigus vulgaris, pemphigus foliaceus or bullous pemphigoid as defined by trial and failure, intolerance, or contraindication to each of the following therapies
	  ○ High-potency topical corticosteroid (e.g., clobetasol propionate 0.05%) for at least 4 weeks
	  ○ Systemic corticosteroid (e.g., prednisone) with or without adjuvants (e.g., azathioprine, mycophenolate, methotrexate, doxycycline, dapsone) for at least 3 weeks
	
	CRITERIA FOR REFERENCE PRODUCT (RITUXAN) FOLLOWING BIOSIMILAR USE (RIABNI)
	• Patient was previously stable on the reference product for a duration of at least 2 infusions (not applicable for patients who are naïve to the reference product)
	• Patient has received at least 2 infusions of the TWO biosimilar products including KP preferred product Riabni with one of the following:
	  ○ Increased side effects or development of a new side effect not previously experienced with the reference product (not applicable for patients who are naïve to the reference product)
	  ○ Intolerance to a biosimilar product as evidenced by Grade 2 or 3 side effect(s) that persisted despite interventions to mitigate occurrence of side effect(s)
	  ○ Loss of efficacy to a biosimilar product confirmed by objective findings on physical exam and not due to the presence of rituximab antibodies
	
	Reasons for Non-coverage:
	• Patient has evidence of a severe infection
	• Patient has or has a history of progressive multifocal leukoencephalopathy (PML)
	
	Initial approval: 6 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	• **Approve for administration ONLY in KPGA infusion center, absent director level approval**
	
	Continued approval**:** 12 months. Confirm patient meets all above coverage criteria without reasons for non-coverage. In addition, continued approval for treatment with Rituxan should meet the following criteria:
	• Documentation of a clinical response as defined by an improvement in the formation of new blisters, healing of existing blisters, and control of pruritus.
	
	For new members who were initiated on Rituxan outside of KPGA: Approve Rituxan if patient meets the full coverage criteria above without reasons for non-coverage.
	
	Oncology Indications:

Drug	Prior Authorization Criteria

	CRITERIA FOR REFERENCE PRODUCT (RITUXAN) USE FOLLOWING BIOSIMILAR (RIABNI) USE:
	
	Patient was previously stable on the reference product for a duration of at least 3 infusions AND
	
	• Patient has received at least 2 infusions of the TWO biosimilar products including KP preferred product Ribani with one of the following:
	  ○ Increased side effects or development of a new side effect not previously experienced with the reference product
	  ○ Side effect(s) must be grade 2 or 3 persists despite interventions to mitigate occurrence of side effect(s)
	  ○ Loss of efficacy with biosimilar after objective findings on physical exam or lab abnormalities
	• Patient meets disease state specific criteria below
	
	SIDE EFFECT GRADING, PER COMMON TERMINOLOGY CRITERIA FOR ADVERSE EVENTS (CTCAE):
	
	• Grade 1: mild, asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
	• Grade 2: moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living
	• Grade 3: severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living
	• Grade 4: life-threatening consequences; urgent intervention indicated
	• Grade 5: death related to adverse event
	
	CRITERIA FOR APPROVAL OF RITUXIMAB PRODUCT (RIABNI IS THE PREFERED PRODUCT IF RITUXIMAB HAS NEVER BEEN TRIED) USE FOR ONCOLOGIC OR HEMATOLOGIC INDICATIONS:
	
	Use of rituximab products for Hematologic/Oncologic indications (all of the following must be met):
	
	• Prescribed by a hematologist/oncologist AND
	• The requested dose and frequency are within FDA-approved labeling AND
	• Paint has been screened for HBV infection (i.e., HBsAG and Anti-HBc) AND
	• Patient has a diagnosis of any ONE of the following (a to j):
	  ○ Non-Hodgkin's Lymphoma and ANY ONE of the following:
	  ▪ Rituximab product is prescribed as a single agent for any ONE of the following:
	  1. Diagnosis of non-progressing (including stable disease), low grade, CD-20 positive
	  2. Diagnosis of relapsed or refractory, low-grade or follicular, CD-20-positive B-cell NHL
	  3. Maintenance therapy for patients achieving a complete or partial response to chemotherapy
	  ▪ Rituximab product is prescribed in combination with cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP) OR other anthracycline based

Drug	Prior Authorization Criteria
	chemotherapy regimens for previously untreated diffuse large B-cell CD20-positive NHL ▪ Rituximab product is prescribed in combination with first line chemotherapy for previously untreated follicular, CD20-positive, B-cell NHL o Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL) and ANY ONE of the following: ▪ Patient has significant comorbidities unable to tolerate purine analogs 1. Prescribed as first line therapy AND 2. Prescribed with chlorambucil ▪ Patient is >65 years or <65 with significant comorbidities 1. Prescribed as first line therapy AND 2. Prescribed with chlorambucil OR bendamustine ▪ Patient is <65-year-old without significant comorbidities 1. Prescribed with fludarabine and cyclophosphamide OR 2. Prescribed with fludarabine, pentostatin and cyclophosphamide or bendamustine ▪ Patient has relapsed/refractory disease o Diagnosis of Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma (LPL) o Diagnosis of Hodgkin's lymphoma, nodular lymphocyte-predominant o Diagnosis of B-cell acute lymphoblastic leukemia (ALL) and ALL of the following: ▪ Patient is > 15 years AND ▪ Disease is Philadelphia chromosome negative AND ▪ Treatment is for induction/consolidation AND Prescribed in combination with an anthracycline, cyclophosphamide, and vincristine-based regimen OR ▪ Treatment is for relapsed/refractory disease and used as a component of MOpAD regimen (methotrexate, vincristine, pegaspargase, and dexamethasone) o Diagnosis of Central nervous system (CNS) cancers with ANY ONE of the following: ▪ Leptomeningeal metastases from lymphomas and rituximab product will be administered intrathecally ▪ Primary CNS lymphoma as ANY ONE of the following: 1. In combination with methotrexate-containing regimen as a component of induction therapy and/or consolidation therapy with a complete response (CR) or a complete response unconfirmed (CRu) to induction therapy 2. Relapsed or refractory disease and will receive rituximab product as a single agent or in combination with temozolomide or high-dose methotrexate o Diagnosis of Chronic graft-versus-host disease (cGVHD) if ALL of the following: ▪ Post allogeneic stem cell transplant (generally 3 or more months) AND ▪ Failed one or more previous lines of systemic therapy for the treatment of cGVHD (e.g., corticosteroids or immunosuppressants such as cyclosporine) AND ▪ Tried and had an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ibrutinib

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ Diagnosis of hemolytic anemia and ANY ONE of the following: ▪ Individual has warm-reactive disease refractory to or dependent on glucocorticoids ▪ Individual has cold agglutinin disease with symptomatic anemia, transfusion-dependence, and/or disabling circulatory symptoms ○ Management of Immunotherapy-Related Toxicities if individual is/has ALL of the following: ▪ Received therapy with an immune checkpoint inhibitor (e.g., cemiplimab, nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, ipilimumab, etc.) AND ▪ Diagnosis of non-viral encephalitis related to immunotherapy treatment AND ▪ Individual is ANY ONE of the following: 1. Autoimmune-encephalopathy-antibody positive OR 2. Refractory to methylprednisolone and/or IV immunoglobulin (IVIG) ○ Diagnosis of Thrombocytopenic purpura if ALL of the following: ▪ Individual previously failed or has a contraindication or intolerance to therapy with corticosteroids ▪ Increased risk for bleeding as indicated by platelet count (within the previous 28 days) less than 30 × 109/L (30,000/mm³) ▪ Diagnosis is ANY ONE of the following: 1. Primary thrombocytopenia 2. Idiopathic (Immune) thrombocytopenia purpura (ITP) 3. Evan's syndrome 4. Congenital and hereditary thrombocytopenic purpura 5. Thrombotic thrombocytopenic purpura in patients with ADAMTS13-deficiency **Solid Organ Transplant (i.e., heart, lung, liver, and kidney) :** • Prescribed by a Transplant Specialist for solid organ transplant including posttransplant proliferative disorder. • Patient has had loss of efficacy or intolerance to TWO biosimilar products including KP preferred product Riabni (rituximab-arrx) ○ Loss of efficacy to a rituximab product as evidenced by documentation of at least 2 infusions of the product and loss of efficacy confirmed by objective findings on physical exam or lab abnormalities ○ Intolerance to rituximab product as evidenced by documentation of at least 2 infusions of the product and patient experienced Grade 2* or 3* side effects which persisted despite interventions to mitigate the occurrence of the side effects <u>Initial approval period</u>: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for administration ONLY in KPGA infusion center, absent director level approval** <u>Continued approval for hematologic/oncologic indications:</u> • Member continues to meet the above criteria AND

Drug	Prior Authorization Criteria
	• Member is responding positively to therapy as defined by stabilization or disease or decrease in size of tumor or tumor spread • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for administration ONLY in KPGA infusion center, absent director level approval** <u>Reasons for Non-coverage:</u> • Non-FDA approved indications, which are not listed in these guidelines, unless there is sufficient documentation of efficacy and safety in the published literature (literature must be provided by the prescriber) • Patient has evidence of a severe infection • Patient has or has a history of PML

Rivfloza
(Nedosiran)
	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Candidates for Rivfloza (Nedosiran) should meet ALL the following criteria:
	
	• Prescribed by nephrologists, pediatric nephrologists, urologists, and pediatric urologists.
	• Documented diagnosis of primary hyperoxaluria type 1 (PH1) with confirmed *AGXT* mutation. Diagnosis is confirmed by ONE of the following:
	  ○ Molecular genetic testing
	  ○ Liver enzyme analysis of alanine: glyoxylate aminotransferase (AGT)
	• Kidney function with an eGFR ≥ 30 mL/min/1.73 m^2) in the past 1 month
	• Age ≥ 9 years
	• Documentation of concurrent use of high-dose pyridoxine (5 mg/kg in one or two divided doses daily) OR previous trial of at least 3 months of high-dose pyridoxine (5 mg/kg in one or two divided doses daily) with no significant improvement observed (e.g., <30% reduction in urine oxalate concentration after at least 3 months of therapy).
	• Trial of Oxlumo (Lumasiran) unless not indicated (e.g., age < 9 years, unable to return to clinic for Oxlumo injections)
	
	<u>Reasons for Non-coverage:</u>
	
	• eGFR < 30 mL/min/1.73 m^2
	• Diagnosed with primary hyperoxaluria type 2 (PH2) or type 3 (PH3)
	• History of kidney or liver transplant
	• Patient is currently on dialysis or anticipated requirements for dialysis
	• Taking RNAi therapy (e.g., Onpattro, Givlaari, Oxlumo, or Leqvio) concurrently
	
	<u>Initial Approval:</u> 6 months.
	
	• **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**

Drug	Prior Authorization Criteria
	○ For adults and adolescents aged ≥ 12 years, approve member to fill pre-filled syringe via the outpatient pharmacy benefit only ○ For pediatric patients aged 9-11 years who weigh ≥50 kg, approve member to fill pre-filled syringe via the outpatient pharmacy benefit only ○ For pediatric patients aged 9-11 years who weigh L 50 kg, approve member to fill vials via the outpatient pharmacy benefit if healthcare provider has provided instruction on how to prepare and inject. Continued Approval: 12 months. Continue approval if the patient meets all criteria above in addition to the following: • Documentation that the patient is tolerating therapy and there was a reduction in urinary or plasma oxalate levels from baseline. • **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** ○ For adults and adolescents aged ≥ 12 years, approve member to fill pre-filled syringe via the outpatient pharmacy benefit only ○ For pediatric patients aged 9-11 years who weigh ≥50 kg, approve member to fill pre-filled syringe via the outpatient pharmacy benefit only ○ For pediatric patients aged 9-11 years who weigh L 50 kg, approve member to fill vials via the outpatient pharmacy benefit if healthcare provider has provided instruction on how to prepare and inject. Dosing and Administration: • Rivfloza is a once-monthly therapy administered subcutaneously by a healthcare professional, caregiver or patient • For children aged 9 to 11 years ○ Weight ≥ 50 kg: 160 mg administered subcutaneously once monthly ○ Weight < 50 kg: 3.3 mg/kg administered subcutaneously once monthly, not to exceed 128 mg • For adults and adolescents aged ≥ 12 years ○ Weight ≥ 50 kg: 160 mg administered subcutaneously once monthly ○ Weight < 50 kg: 128 mg administered subcutaneously once monthly Ordering Information: Rivfloza is available through the NovoCare Program. If approved for coverage, prescribers must complete the Patient Enrollment Form here.
Rolvedon (Eflapegrastim)	**Candidates for Rolvedon should meet ALL the following criteria:** • Prescribed by hematology or oncology • Age ≥ 18 years • Expected duration of therapy exceeds 13 days • Inadequate response, intolerance and/or contraindication to ALL of the following: ○ Pegfilgrastim-jmdb (Fulphila) AND ○ Pegfilgrastim-apgf (Nyvepria) AND ○ Pegfilgrastim-cbqv (Udenyca) AND ○ Pegfilgrastim (Neulasta)

Drug	Prior Authorization Criteria
	Reasons for non-coverage: N/A Initial Approval: 12 months. If outpatient administration is not possible, approve for KP clinic/back-office administration or KP home infusion program only. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Continued Approval: 12 months if patient meets the following: • Patient meets all above coverage criteria. • Patient has documented improvement and requires continued treatment. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Adult dosage and administration: • Chemotherapy-induced neutropenia, prevention (non-myeloid malignancies): SUBQ: 13.2 mg once per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy. • Do not administer within the period from 14 days before to 24 hours after administration of cytotoxic chemotherapy.
Romvimza (Vimseltinib)	**Candidates for treatment with Romvimza (vimseltinib) should meet ALL of the following criteria:** • Prescribed by an oncologist • Age ≥ 18 years • Diagnosed with symptomatic tenosynovial giant cell tumor defined in the MOTION study as at least moderate pain or at least moderate stiffness, with a score of 4 or more on a 0–10 scale, where 10 represents the worst condition) • Measurable disease with ≥ 1 lesion, ≥ 2 cm in size • Documentation that patient's tumor cannot be surgically resected, as that may cause worsening functional limitation or severe morbidity Reasons for Non-coverage: • Pregnancy or lactation • Active liver or biliary disease including NASH or cirrhosis Initial Approval: 6 months Continued Approval: 12 months. For continued approval for treatment, patient should meet ALL the following criteria: • Documented positive response to Romvimza (e.g., active range of motion is stable or improved; tumor volume score is stable or improved; Patient-Reported Outcomes Measurement Information System-Physical Function (PROMIS-PF): stable or improved; Brief Pain Inventory (BPI)-30 Response: stable or improved)

Drug	Prior Authorization Criteria

Rozlytrek
(Entrectinib)
	Candidates for treatment with Rozlytrek should meet ALL the following criteria:
	
	• Prescribed by a Hematology-Oncology Specialist AND
	• Age ≥ 18 years AND has a diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS-1 positive as detected by an FDA-approved test OR
	• Age ≥ 1 month with solid tumors that has all of the following:
	  ○ have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, as detected by an FDA-approved test, without a known acquired resistance mutation AND
	  ○ are metastatic or where surgical resection is likely to result in severe morbidity AND
	  ○ has progressed following treatment or have no satisfactory alternative therapy
	
	Reasons for Non-coverage
	
	• Documentation of symptomatic heart failure, myocardial infarction, unstable angina, and coronary artery bypass graft in the last 3 months
	• Patient is pregnant
	• Patient is breastfeeding
	
	Initial Approval: 6 months
	
	Continued Approval: 12 months if patient continues to meet ALL the above criteria and is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.

Rubraca
(Rucaparib)
	Rucaparib (Rubraca®) will only be considered after trial and failure (e.g., intolerance, allergic reaction, disease progression) to KP's preferred PARP inhibitor, Lynparza® (olaparib), AND the same intolerance, contraindication, or adverse event would not be expected to occur with Rucaparib (Rubraca®).
	
	Candidate for treatment with Rubraca for oncologic indications should meet all the following:
	
	• Prescribed by a hematologist/oncologist OR Gynecologic Oncologist
	• Age ≥18 years
	• Patient has a diagnosis of ONE of the following:
	  ○ Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer
	  ▪ Used as maintenance treatment
	  ▪ Complete or partial response to platinum-based chemotherapy (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine, etc)
	  ○ Metastatic castrate-resistant prostate cancer
	  ▪ BRCA-positive mutation
	  ▪ Previously treated with androgen-receptor directed therapy and a taxane-based chemotherapy (unless patient is not medically fit for cytotoxic chemotherapy)

Drug	Prior Authorization Criteria
	• Examples of androgen-receptor therapy: abiraterone, flutamide, nilutamide, bicalutamide, enzalutamide, apalutamide, darolutamide • Examples of taxane-based chemotherapy: docetaxel, paclitaxel, etc Initial Approval Period: 12 months Continued Approval: 12 months. Patient should meet all the following: • Patient continues to meet the above criteria; AND • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread; AND • Absence of unacceptable toxicity from therapy (any ≥ grade 3 toxicity that does not improve with dose reduction and/or holding therapy)
Ruconest (C1 inhibitor (Recombinant))	**Candidates for treatment with Ruconest should meet ALL the following criteria:** • Diagnosis of acute attacks in adult and adolescent patients with hereditary angioedema (HAE). • Prescribed by an allergist. • Documented trial of Berinert ○ Trial not required if patient is pregnant. • Age ≥ 13 years Reasons for Non-coverage: • Routine prophylaxis against angioedema attacks in non-pregnant adolescent and adult patients with HAE • Being used in the treatment of HAE patients with laryngeal attacks Initial Approval: 12 months Continued Approval: 12 months or duration of pregnancy. Confirm patient meets all above coverage criteria without reason for non coverage. In addition, continue approval based on clinical documentation of functional improvement, a decrease in frequency of HAE attack, and an improvement in severity and duration of attacks. Dosing and Administration: • < 84 Kg: 50 IU per kg to be administered as a slow intravenous injection over approximately 5 minutes. • ≥ 84 Kg: 4200 U to be administered as a slow intravenous injection over approximately 5 minutes. • If the attack symptoms persist, an additional (second) dose can be administered at the recommended dose level. Do not exceed 4200 IU per dose. • No more than two doses should be administered within a 24 hour period.

Drug	Prior Authorization Criteria

Rukobia
(Fostemsavir)
	Candidates for treatment with Rukobia should meet ALL the following criteria:
	
	• Prescribed by an Infectious Disease Specialist or HIV Specialist
	• Age ≥ 18 years
	• Has a diagnosis of HIV-1 infection
	• Failing current antiretroviral (ARV) regimen for HIV documented by two consecutive HIV-1 RNA (viral load) of greater than 400 copies/mL within the past 6 months
	• Adherence of ≥ 80% adherence to HIV [MRAR ≥ 80%. If MRAR < 80%, reviewer can confirm adherence in the last 90 days based on medication sold dates found in Health Connect medication tab (e.g., 3 one month fills or one 90 day fill)]
	• Patient will maintain an optimized background therapy (OBT) with at least one highly active ARV medication (demonstrated by full viral sensitivity/susceptibility testing)
	• Has documented resistance, intolerable side effects or contraindications to at least one ARV medication in at least 2 different classes noted below:
	  ○ Protease Inhibitor (PI)
	  ○ Nucleoside reverse transcriptase inhibitor (NRTI)
	  ○ Non-nucleoside reverse transcriptase inhibitor (NNRTI)
	  ○ Integrase Inhibitors (INSTI)
	
	Reasons for Non-coverage:
	
	• Hypersensitivity to fostemsavir or any of its components
	• Co-administration with a strong CYP3A inducer (i.e., carbamazepine, phenytoin, phenobarbital, primidone, rifampin, rifabutin, St. John's wort)
	
	Initial Approval**:** 6 months
	
	Continued Approval**:** 12 months
	• Confirm patient meets all above coverage criteria without reasons for Non-coverage or criteria for discontinuation below
	• ≥ 80% adherence to therapy [MRAR ≥ 80%. If MRAR < 80%, reviewer can confirm adherence in the last 90 days based on medication sold dates found in Health Connect medication tab (e.g., 3 one month fills or one 90 day fill)]
	• Documented decreased viral load and increased CD4 count compared to baseline.
	• Patient continues an optimized background regimen with at least one highly active ARV medication
	
	For new members who were initiated on fostemsavir outside of KPGA, continue approval for 3 months if:
	• Infectious Disease Specialist or HIV Specialist visit is scheduled
	• Patient is taking at least one additional ARV medication

Drug	Prior Authorization Criteria
Rybrevant Faspro (Amivantamab and Hyaluronidase)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** **Candidates for treatment with Rybrevant Faspro (amivantamab and hyaluronidase) should meet ALL of the following criteria:** • Prescribed by an oncologist • Patient is 18 years of age or older • Diagnosed with locally advanced or metastatic non-small cell lung cancer (NSCLC) • <u>Patient meets ONE of the following:</u> o Documentation that patient has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations as detected by an FDA-approved test and meets ONE of the following: ▪ Rybrevant Faspro will be used in combination with lazertinib (Lazcluze) **OR** ▪ Rybrevant Faspro will be used in combination with carboplatin and pemetrexed AND the patient's disease has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (e.g., Tagrisso [osimertinib], Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib]) **OR** o Documentation that patient has epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, and meet ONE of the following: ▪ Rybrevant Faspro will be used in combination with carboplatin and pemetrexed **OR** ▪ Rybrevant Faspro will be used as a single agent and the patient's disease has progressed on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin) • Documented trial and failure (e.g., intolerance, allergic reaction, infusion reaction) or contraindication to Rybrevant (amivantamab) IV solution that would not be expected to occur with Rybrevant Faspro <u>Reasons for non-coverage:</u> • Pregnancy or lactation <u>Initial Approval:</u> 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** • **Approve for administration ONLY in KPGA infusion center, absent director level approval** <u>Continued Approval</u>: 12 months. Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, patient should meet the following: • No evidence of disease progression or unacceptable toxicity

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** • **Approve for administration ONLY in KPGA infusion center, absent director level approval**

Rydapt
(Midostaurin)
	Candidates for Rydapt should meet ALL the following criteria:
	• Prescribed by an oncologist.
	• Age ≥ 18 years
	• Patient has ONE of the following:
	  ○ Acute myeloid leukemia (AML) that is FLT3-mutation positive AND will be used in combination with standard induction and consolidation therapy (e.g., idarubicin and cytarabine)
	  ○ FGFR1 or FLT3-mutation positive myeloid or lymphoid neoplasms in chronic or blast phase with eosinophilia
	  ○ Aggressive systemic mastocytosis (ASM)
	  ○ Systemic mastocytosis associated with acute hematologic neoplasm (SM-AHN)
	  ○ Mast Cell Leukemia (MCL)
	
	<u>Initial Approval:</u> 12 months with a quantity limit for a maximum 240 tablets per 30 days.
	• For AML, approve a maximum quantity of 112 tablets per 28 days.
	• For all other indications, approve maximum quantity of 240 tablets per 30 days.
	
	<u>Continued Approval:</u> 12 months with a quantity limit of a maximum of 240 tablets for 30 days. For continued approval for treatment with Rydapt, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria.
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	• For AML, approve a maximum quantity of 112 tablets per 28 days.
	• For all other indications, approve maximum quantity of 240 tablets per 30 days.
	
	<u>For new members who were initiated on Rydapt outside of KPGA:</u> Patient should meet ALL the following criteria:
	• Prescribed by an oncologist.
	• Age ≥ 18 years
	• Patient has ONE of the following:
	  ○ Acute myeloid leukemia (AML) that is FLT3-mutation positive AND will be used in combination with standard induction and consolidation therapy (e.g., idarubicin and cytarabine)
	  ○ FGFR1 or FLT3-mutation positive myeloid or lymphoid neoplasms in chronic or blast phase with eosinophilia
	  ○ Aggressive systemic mastocytosis (ASM)
	  ○ Systemic mastocytosis associated with acute hematologic neoplasm (SM-AHN)
	  ○ Mast Cell Leukemia (MCL)
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	• For AML, approve a maximum quantity of 112 tablets per 28 days.

Drug	Prior Authorization Criteria
	• For all other indications, approve maximum quantity of 240 tablets per 30 days.

Ryoncil
(Remestemcel-L)
	Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval
	
	Candidates for treatment with Ryoncil (remestemcel-L) should meet ALL the following criteria:
	• Prescribed by hematologist/oncologist or transplant specialist
	• Age 2 months to 17 years
	• Diagnosed with acute graft versus host disease (aGvHD) AND
	  ○ Disease is steroid refractory, defined as progression within 3 days or no improvement within 7 consecutive days of treatment with methylprednisolone 2 mg/kg/day or equivalent
	• No known hypersensitivity to dimethyl sulfoxide (DMSO) or porcine and bovine proteins
	• Patient has a documented treatment failure or intolerance to Jakafi (ruxolitinib)
	
	Initial Approval: 8 infusions over 4 weeks
	• **NOTE:** If therapy was started inpatient, please confirm initiation date and number of infusions already administered. Only approve additional infusion to reach a maximum of 8 total infusions.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	
	Continued Approval: Approve for continued therapy when either of the following criteria is met:
	• If partial or mixed response to first course of treatment, approve for **4 additional infusions** over 4 weeks.
	  ○ **Partial response** is defined as organ improvement of at least one stage without worsening in any other organ as per International Blood and Marrow Transplantation Registry (IBMTR) Severity Index grading system
	  ○ **Mixed response** is defined as improvement of at least one evaluable organ with worsening in another organ as per IBMTR Severity Index grading system
	• If recurrence of GvHD after complete response, approve for **8 infusions** over 4 weeks.
	• **Please approve for back-office administration only**
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	
	Ordering Information:
	• Ryoncil is available through the MyMesoblast patient services support hub
	  ○ After QRM approval, prescribers must complete the Starter Form and fax it to MyMesoblast at **1-833-637-6008** to initiate the process
	  ○ To place an order, call the MyMesoblast patient services hub at **1-833-637-6007**. Ryoncil is shipped within 24-48 hours from time of order receipt.
	  ○ For additional information, refer to the manufacturer's website

Drug	Prior Authorization Criteria

Rystiggo
(Rozanolixizumab)
	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	Candidates for treatment with Rystiggo must meet ALL the following criteria:
	• Prescribed by or in consultation with a Neurologist with specialty in neuromuscular disorders
	• Diagnosis of generalized myasthenia gravis (gMG)
	• Patient is 18 years or older
	• Confirmed anti-acetylcholine receptor (AChR) antibody positive OR anti-muscle-specific tyrosine kinase (MuSK) antibody positive
	• If positive for anti-acetylcholine receptor (AChR), patient has tried and failed or has a contraindication to efgartigimod (Vyvgart) AND ravulizumab (Ultomiris) AND eculizumab-aagh (Epysqli)
	• No history of thymoma or thymic neoplasm OR patient has history of thymoma and has had a thymectomy that was completed over 3 months ago
	• Patient has a Myasthenia Gravis Activities of Daily Living (MG-ADL) scale score of 5 or higher
	• Patient is currently taking pyridostigmine for symptomatic management as prescribed unless there is a severe intolerance or contraindication
	• Trial of corticosteroid for at least 3 months and patient experienced inadequate disease control or patient has an intolerance or contraindication to corticosteroid therapy
	• Trial of at least one non-steroidal immunosuppressive therapy for the duration indicated:
	  ○ Azathioprine or mycophenolate for at least 12 months
	  ○ Rituximab or rituximab biosimilar for at least 12 months
	  ○ Other disease modifying therapy (e.g., cyclophosphamide, cyclosporine, tacrolimus, methotrexate) for at least 6 months
	• Patient has tried and failed or has a contraindication to chronic IV immune globulin (IVIG)
	
	<u>Reasons for Non-coverage:</u>
	• Patient is prescribed concomitant efgartigimod (Vyvgart) or monoclonal antibody therapy for myasthenia gravis such as Epysqli (eculizumab-aagh) or Ultomiris
	
	<u>Initial Approval:</u> 6 months
	• Approve for administration by a healthcare provider
	• **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	<u>Continued Approval:</u> 12 months
	• Approve for administration by a healthcare provider
	• **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	For new members who were initiated on rozanolixizumab (Rystiggo) outside of KPGA, approve if ALL the following criteria are met:
	• Patient has had a visit with a Neurologist with specialty in neuromuscular disorder to discuss consideration of chronic IVIG as an alternative treatment option

Drug	Prior Authorization Criteria
	• Patient has tried and failed a corticosteroid AND at least one non-steroidal immunosuppressive therapy as listed above • Patient confirmed to be stable on therapy by Neurologist For first renewal of rozanolixizumab: documented improvement of at least 2-points on the Myasthenia Gravis-Activities of Daily Living scale (MG-ADL) For subsequent renewals after first renewal: documented maintenance of stable MG-ADL score or documented beneficial effect from therapy during Neurology follow up in the last 12 months
Ryzneuta (Efbemalenograstim alfa)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Ryzneuta will only be considered for use after a trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction) to KP's preferred therapy, pegfilgrastim-jmdb (Fulphila) AND the same intolerance, contraindication, or adverse event would not be expected to occur with the non-preferred product. **Candidates for treatment with Ryzneuta (efbemalenograstim alfa) must meet ALL the following criteria:** • Prescribed by Hematology or Oncology • Inadequate response, intolerance and/or contraindication to ALL of the following **OR** expected duration of therapy exceed 13 days*: *The commonly accepted treatment regimens are inpatient lymphoma regimens (e.g., R-EPOCH, CHOEP, (R)ICE). a. Granix (tbo-filgrastim) b. Zarxio (filgrastim-sndz) c. Nivestym (filgrastim-aafi) • Inadequate response, intolerance and/or contraindication to pegfilgrastim-jmdb (Fulphila) AND pegfilgrastim-apgf (Nyvepria) AND pegfilgrastim-cbqv (Udenyca) <u>Reasons for non-coverage:</u> N/A <u>Initial Approval:</u> 12 months. Approve for KP clinic/back office administration or KP home infusion program only. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** <u>Continued Approval:</u> 12 months if patient meets the following: • Patient meets all above coverage criteria • Patient has documented improvement and requires continued treatment • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** <u>Dosage and administration:</u> SUBQ: 20 mg once per chemotherapy cycle. Administer ≥24 hours after cytotoxic chemotherapy. Do not administer within the period from 14 days before to <24 hours after administration of cytotoxic chemotherapy.
Saphnelo	**Candidates for treatment with Saphnelo should meet ALL the following criteria:**

Drug	Prior Authorization Criteria
(Anifrolumab)	Criteria for the diagnosis of systemic lupus erythematosus (SLE): • Prescribed by a Rheumatologist • Age ≥ 18 years • Patient has a diagnosis of moderate to severe SLE **without** severe active lupus nephritis or severe active central nervous system (neuropsychiatric) lupus. • Not used in combination with other biologics for SLE (e.g., Benlysta or rituximab). • Patient is on concomitant standard-of care with hydroxychloroquine unless contraindicated or intolerant • History of contraindication, intolerance or inadequate clinical response to at least one of the following: corticosteroid, methotrexate, azathioprine, or mycophenolate. • If the request is for Saphnelo IV and the prescriber is an external rheumatologist: Must have documented inadequate response, intolerance, or contraindication to Saphnelo subcutaneous prefilled syringe or pens. Initial Approval: 12 months • Saphnelo IV infusion: Approve for administration at a KP facility ONLY unless the member is seeing an external rheumatologist • **Saphnelo prefilled syringe or pens: Approve for member to fill via the outpatient pharmacy benefit only.** • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: 12 months For existing members who previously met the full criteria above: Approve if confirmed adequate tolerance and response to medication during Rheumatologist follow up in the last 12 months. • For Saphnelo IV infusion: approve for administration at a KP facility ONLY unless the member is seeing an external rheumatologist • For Saphnelo prefilled syringe or pens: Approve for member to fill via the outpatient pharmacy benefit only. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** For new members who were initiated on Saphnelo outside of KPGA: Approve if confirmed adequate tolerance and response to medication during Rheumatologist follow up in the last 12 months. • For Saphnelo IV infusion: Approve for administration at a KP facility ONLY unless the member is seeing an external rheumatologist • For Saphnelo pre-filled syringes or pens: Approve for member to fill via the outpatient pharmacy benefit

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
Scemblix (Asciminib)	• Scemblix will only be considered for use after a trial and failure (e.g., intolerance, allergic reaction, not achieving MMR (major molecular response) rate, or disease progression of KP's preferred therapies(e.g., imatinib or dasatinib) OR when there is a medical contraindication to the preferred product(e.g., imatinib or dasatinib) • Patient is T315I mutation positive and failed ponatinib therapy or when there is medical contraindication to ponatinib therapy **Candidates for treatment with Scemblix for hematologic/oncologic indications should meet ALL the following criteria:** • Prescribed by a hematologist/oncologist • Age ≥ 18 years • Documented diagnosis of ONE of the following: ○ Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) ○ Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) with the T315I mutation who failed ponatinib or when there is medical contraindication to ponatinib therapy. Reasons for Non-coverage: • Treatment of newly diagnosed chronic phase CML with positive T315I mutation who have NOT failed or do NOT have a medical contraindication to ponatinib Initial Approval: 12 months Continued Approval: 12 months. Patient should meet **ALL** of the following: • Member continues to meet the above criteria • Continues to be seen by a hematologist/oncologist • Member is responding positively to therapy as defined by stabilization of disease/lack of disease progression or decrease in size of tumor or tumor spread • Absence of unacceptable toxicity [e.g., pancreatic toxicity, myelosuppression, cardiovascular toxicity] from the drug • No dual therapy with another tyrosine kinase inhibitor
Sephience (Sepiapterin)	**Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval.** **Candidates for treatment with Sephience (sepiapterin) should meet ALL of the following criteria:** • Prescribed by or in consultation with a geneticist • Patient is 1 month of age or older

Drug	Prior Authorization Criteria
	• Diagnosed with phenylketonuria (PKY) with past medical history of at least two blood phenylalanine (Phe) measurements ≥600 µmol/L • Sephience will be used in conjunction with a phenylalanine (Phe)- restricted diet • Documented trial for at least 2 months or contraindication to sapropterin (Kuvan) **AND** pegvaliase (Palynziq) Reasons for Non-Coverage: • Hyperphenylalaninaemia due to pathogenic variants in *GCH1, PTS, QDPR, SPR, and PCBD1,* consistent with a diagnosis of primary BH_4 (tetrahydrobiopterin) deficiency • Concomitant treatment with sapropterin or pegvaliase Initial Approval: 4 weeks • **Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval.** Continued Approval: 12 months. For continued approval for treatment, patient should meet ALL the following criteria: • Reduction of blood phenylalanine levels by 30% from baseline level • **Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval.** Ordering Information: • Sephience is only available from Orsini Specialty Pharmacy or Optum Frontier Therapies • Prescriber should fax enrollment form to PTC Therapeutics (Getting Started on SEPHIENCE™ (sepiapterin))

Sickle Cell Disease (SCD) Gene Therapies
 	
Casgevy
(Exagamglogene autotemcel, exa-cel)
 	
Lyfgenia
(Lovotibeglogene autotemcel, lovo-cel)
	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval.**
	
	Candidates for treatment with Casgevy (exagamglogene autotemcel) or Lyfgenia (lovotibeglogene autotemcel) should meet ALL the following criteria:
	
	**Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).*
	
	• **MUST verify member's benefit information. If member's coverage is through Target, CLOSE the request.** Member must go through Aradigm for this therapy.
	• Prescribed by Hematology and Sickle Cell Disease Specialist
	• Patient meets age parameters below:
	  ○ For Casgevy: 12 to 25 years
	  ○ For Lyfgenia: 12 to 40 years
	• Documentation of severe SCD with ≥2 of the following events per year during the previous two years:
	  ○ Acute pain requiring medical facility visit and administration of pain medications (opioids or IV non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusions

Drug	Prior Authorization Criteria
	○ Acute chest syndrome, as indicated by the presence of a new pulmonary infiltrate associated with pneumonia-like symptoms, pain, or fever ○ Priapism lasting >2 hours ○ Splenic sequestration • Karnofsky performance status of ≥80 or Lansky performance status ≥80 (if < 16 years old) • Documentation that patient is medically eligible to undergo hematopoietic stem cell (HSC) transplant • Documentation that patient agrees to use effective contraception from start of mobilization through at least six months after gene therapy infusion • Documentation of failing hydroxyurea therapy at any point in the past (defined as >1 VOC or ≥1 acute coronary syndromes [ACS] after taking hydroxyurea for at least three months) OR • Documentation of intolerance to hydroxyurea (defined as inability to be maintained on an adequate dose of hydroxyurea due to marrow suppression or severe drug-induced toxicity [e.g., gastrointestinal distress, fatigue]) AND • Documentation of adequate trial of at least 3 months of L-glutamine <u>Reasons for Non-coverage:</u> • Positive for presence of HIV-1, HIV-2, hepatitis B, hepatitis C, human T-lymphotrophic virus-1 (HTLV-1) or HTLV-2, or untreated syphilis ○ Note: This reason for non-coverage does not apply to patients who have been vaccinated against hepatitis B who are negative for other markers of prior hepatitis B infection [e.g., negative for hepatitis B core antibody], or are positive for anti-hepatitis C antibody but have a negative hepatitis C viral load by quantitative polymerase chain reaction [qPCR] • Clinically significant or active bacterial, viral, fungal, or parasitic infection • Inadequate bone marrow function (defined as an absolute neutrophil count [ANC] of <1000/µL or 500/µL for patients on hydroxyurea treatment, or a platelet count <50,000/µL) • History of liver cirrhosis or clinically significant active liver dysfunction • Baseline estimated glomerular filtration rate (eGFR) <60 mL/min/1.73m^2 • Pregnancy or breastfeeding in a postpartum female • Prior HSC transplant or receipt of gene therapy • Baseline left ventricular ejection fraction (LVEF) <40% • Prior or current malignancy or myeloproliferative disorder, or a significant immunodeficiency disorder • Clinically significant pulmonary hypertension • Intolerance, contraindication, or sensitivity to plerixafor or busulfan • Prior anaphylactic reaction with excipients of products (e.g., dimethylsulfoxide [DMSO], dextran, etc) • Cardiac T2*<10 ms • Receipt of erythropoietin within the three months prior to bone marrow harvest • History of abnormal transcranial dopple (timed average mean maximum velocity [TAMMV]>200 cm/sec) for ages 12 to 16 years old • Casgevy ONLY: fetal hemoglobin (HbF) level >15%, irrespective of concomitant treatment with HbF-inducing treatments such as hydroxyurea • Documentation that patient is unable to comply with follow-up assessments and laboratory requirements

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Approval Period: ONE-TIME, SINGLE-DOSE INFUSION. Approve one-time intravenous dose given in facility/infusion clinic certified to administer Casgevy or Lyfgenia. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM of AAMD prior to providing QRM PA approval** Dosing and Administration: • To be administered at facilities that are certified to administer Casgevy or Lyfgenia • For intravenous use only • Patients must undergo HSC mobilization and apheresis to obtain CD34+ cells for Casgevy / Lyfgenia manufacturing • Dosing is based on body weight with a minimum recommended dose of $3x10^6$ CD34+ cells/kg • Casgevy: Full myeloablative conditioning must be administered between 48 hours and 7 days before infusion of Casgevy • Lyfgenia: Myeloablative conditioning must be administered before gene therapy infusion with a minimum of 48 hours of washout before Lyfgenia infusion
Siklos (Hydroxyurea)	**Candidates for treatment with Siklos should meet ALL the following criteria:** • Patient has a diagnosis of sickle cell anemia, with a history of recurrent moderate to severe painful crises • Age ≥ 2 years • Prescribed by Hematologist or provider that specialize in the treatment of sickle cell disease • Patient does NOT have a myeloproliferative disorder (for which Siklos is not approved) or other cancer • Patient is not currently pregnant • Documentation supports inability to use generic hydroxyurea (e.g., contraindications to the excipients in generic hydroxyurea) • Dose does not exceed 35 mg/kg per day based on weight Reasons for Non-coverage: • Previous hypersensitivity to hydroxyurea or any other component of its formulation Initial Approval: 6 months Continued Approval: 12 months. For continued approval for treatment with Siklos, patient should meet ALL the following criteria: For new members who were initiated on Siklos outside of KPGA: • Member must meet ALL criteria listed above AND • Patient is responding positively to therapy For existing members who previously met the full criteria above: • Patient is responding positively to therapy
Siliq (Brodalumab)	**Candidates for treatment with Siliq should meet ALL the following criteria:** Diagnosis of plaque psoriasis: • Prescribed by a dermatologist • Age 18 years or older

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	• Inadequate response (of at least a 3-month trial), intolerance and/or contraindication to ALL of the following:
	  ○ 1 TNF inhibitor (e.g., adalimumab (Amjevita [preferred], Humira), infliximab (Inflectra [preferred]))
	  ○ 1 IL/12-23 inhibitor (e.g., ustekinumab (Yesintek [preferred], Stelara))
	  ○ Preferred IL-17 inhibitor: Cosentyx (secukinumab)
	  ○ Tremfya
	  ○ Skyrizi
	• Prescribed the maintenance dose when transitioning from another biologic agent: Siliq 210 mg every 2 weeks. If loading dose is ordered, documented clinical rationale must be provided (e.g., actively flaring, BSA>50%, prior ER visit for psoriasis).
	• Not used in combination with another biologic or advanced small molecule (e.g., tofacitinib, upadacitinib, apremilast) for the same condition.
	
	Initial Approval: 12 months
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or PCS prior to providing QRM PA approval (excluding Pharmacy Consult Services).**
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	
	Continued Approval: 12 months. Continue approval if the following criteria are met:
	
	• For new members who were initiated outside of KPGA: Approve if patient meets all above coverage criteria and is confirmed to be clinically stable by a specialist during the last 6 months.
	• For existing members who have previously met the criteria: Documented clinically significant benefit from the medication during specialist follow up in the last 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or PCS prior to providing QRM PA approval (excluding Pharmacy Consult Services).**
	• **Approve for member to fill via the outpatient pharmacy benefit only**

Simponi **Simponi Aria** (Golimumab)	**Candidates for treatment with Simponi or Simponi Aria should meet ALL the following criteria PLUS the individual disease state criteria that follow:** • Patient has had a negative interferon-gamma release assay test for TB Infection within the past 24 months or is positive for latent TB and has completed treatment in the past or is currently on treatment • Medication is not being used in combination with another biologic or advanced small molecule (e.g., tofacitinib, upadacitinib, apremilast) for the same indication • Then follow the disease state specific criteria below, based on diagnosis: Diagnosis of rheumatoid arthritis, psoriatic arthritis or axial spondyloarthritis: • Prescriber is a Rheumatologist or Dermatologist • Age ≥ 18 years

Drug	Prior Authorization Criteria

	• Documented treatment failure, intolerance or contraindication to each of the following:
	  ○ 2 TNF inhibitors:
	  ▪ Infliximab product (Infliximab-dyyb/Inflectra [preferred])
	  ▪ Adalimumab product (Amjevita [preferred])
	  ▪ Others: Etanercept (Enbrel), certolizumab pegol (Cimzia)
	  ○ Tofacitinib (preferred)
	• Documented treatment failure, intolerance, or contraindication to each of the following options based on diagnosis:
	  ○ For Rheumatoid arthritis: tocilizumab product (Tyenne, Avtozma)
	  ○ For peripheral psoriatic arthritis: ustekinumab product (Yesintek [preferred]) AND secukinumab (Cosentyx)
	  ○ For axial psoriatic arthritis or axial spondyloarthritis: secukinumab (Cosentyx)
	  ▪ **For Simponi Aria (IV formulation):**
	  • Patients followed by internal rheumatology: Proceed to approval for Simponi Aria IV.
	  • Patients followed by external rheumatology: Prescriber must document previous failure, intolerance, or contraindication to Simponi SC.
	  ▪ **For Simponi SC (subcutaneous formulation)**:
	  • Patients followed by internal rheumatology: Prescriber must document reason patient is unable to receive Simponi Aria infusions (e.g., temporarily located outside of the KP network)
	  • Patients followed by external rheumatology: Proceed to approval for Simponi SC.
	
	Initial approval: 12 months
	• **For Simponi Aria IV: approve for administration at a KP facility only unless member is seeing an external rheumatologist. See Simponi Aria (IV) criteria above.**
	• **For Simponi SC: Approve for member to fill via the outpatient pharmacy benefit only.**
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Continued approval: 12 months if the following criteria are met:
	
	For new members who were initiated on Simponi outside of KPGA:
	• Patient has previously tried and failed 1 or more TNF inhibitors AND has a documented adequate response and tolerance to the medication during specialist follow-up in the past 6 months AND:
	  ○ New members seeing internal rheumatology
	  ▪ Approve continuation of Simponi Aria IV.
	  ▪ For Simponi SC, the prescriber must document reason patient is unable to receive Simponi Aria infusions (e.g., temporarily located outside of the KP network).
	  ○ New members seeing external rheumatology:
	  ▪ Approve continuation of Simponi SC.
	  ▪ For Simponi Aria IV, the prescriber must document previous failure, intolerance, or contraindication to Simponi SC.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	• **For Simponi Aria IV: approve for administration at a KP facility only unless member is seeing an external rheumatologist**
	• **For Simponi subcutaneous formulation: Approve for member to fill via the outpatient pharmacy benefit only.**
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	<u>For existing members who have previously met the full criteria above:</u>
	• Documented adequate response and tolerance of medication during specialist follow up in the last 12 months.
	  ○ Patients seeing internal rheumatology
	  ▪ Approve continuation of Simponi Aria IV.
	  ▪ For Simponi SC, the prescriber must document reason patient is unable to receive Simponi Aria infusions (e.g., temporarily located outside of the KP network).
	  ○ Patients seeing external rheumatology
	  ▪ Approve continuation of Simponi SC.
	  ▪ For Simponi Aria IV, the prescriber must document previous failure, intolerance, or contraindication to Simponi SC.
	• **For Simponi Aria IV: approve for administration at a KP facility only unless member is seeing an external rheumatologist**
	• **For Simponi subcutaneous formulation: Approve for member to fill via the outpatient pharmacy benefit only.**
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	<u>Diagnosis of polyarticular or psoriatic juvenile idiopathic arthritis (Simponi Aria IV ONLY):</u>
	
	• Age ≥ 2 years
	• Prescriber is a pediatric rheumatologist or dermatologist
	• Documented inadequate response, intolerance or contraindication to each of the following:
	  ○ Adalimumab (Amjevita [preferred], Humira) OR etanercept (Enbrel)
	  ○ Abatacept (Orencia)
	  ○ For polyarticular JIA: Tocilizumab product (Tyenne, Avtozma, Actemra) AND if weight <u>≥</u> 40 kg: Tofacitinib
	  ○ For psoriatic JIA without axial involvement: Secukinumab (Cosentyx) AND if age <u>≥</u> 6 years old: Ustekinumab product (Yesintek [preferred])
	
	<u>Initial approval</u>: 12 months
	
	• **For Simponi Aria IV: approve for administration internally or at a contracted facility for pediatric patients**
	• **For Simponi subcutaneous formulation: consider approval for member to fill via the outpatient pharmacy benefit only at discretion of QRM MD.**
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**

Drug	Prior Authorization Criteria
	Continued approval: 12 months if the following criteria are met: For new members who were initiated on Simponi outside of KPGA: • Patient has previously tried and failed 1 or more TNF inhibitors AND has a documented adequate response and tolerance to the medication during specialist follow-up in the past 6 months. • **For Simponi Aria IV: approve for administration internally or at a contracted facility for pediatric patients** • **For Simponi subcutaneous formulation: consider approval for member to fill via the outpatient pharmacy benefit only at discretion of QRM MD.** • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** For existing members who have previously met the full criteria above: • Documented adequate response and tolerance of medication during specialist follow up in the last 12 months. • **For Simponi Aria IV: approve for administration internally or at a contracted facility for pediatric patients** • **For Simponi subcutaneous formulation: consider approval for member to fill via the outpatient pharmacy benefit only at discretion of QRM MD.** • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** For the diagnosis of ulcerative colitis: • Prescribed by a gastroenterologist • Moderately to severely active ulcerative colitis • Inadequate response (after at least a 3-month trial) intolerance and/or contraindication to the following in the order of preference below: ○ Infliximab product (e.g., Infliximab-dyyb/Inflectra [preferred], Remicade) AND Adalimumab product (e.g., Amjevita [preferred], Humira) **(trial of both medications in any order)** followed by ○ Ustekinumab product (e.g., Yesintek [preferred], Stelara) ○ Entyvio (vedolizumab) ○ Tofacitinib the preferred JAK-inhibitor, or Rinvoq (upadacitinib) ○ Velsipity (etrasimod) • Negative test for hepatitis B within the past 24 months Continuation (patients new to KP currently on Simponi): • Prescribed by a gastroenterologist • Ulcerative colitis that is asymptomatic or in clinical remission Reasons for Non-coverage: • History of severe hypersensitivity to any anti-TNF inhibitor biologic • History of antibody formation to Simponi Initial approval period: 12 months

Drug	Prior Authorization Criteria

	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Continued approval: 12 months if patient is asymptomatic or in clinical remission
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Pediatric criteria for SIMPONI for the diagnosis of ulcerative colitis (UC): The pediatric patient (<18 years) must have a diagnosis of moderate to severe UC and meet all the following:
	
	**FDA indication for UC only, not FDA-approved for pediatric IBD conditions*
	
	• Prescribed by a gastroenterologist
	• Documented inadequate response with or loss of response, intolerance or contraindication to infliximab product (Infliximab-dyyb/Inflectra preferred)
	  ○ Provider should optimize dose, 5-10 mg/kg and consider dose interval change (q4 weeks)
	  ○ Adequate therapeutic trial of at least 2 infusions
	• Documented inadequate response with or loss of response, intolerance or contraindication to the following in the order of preference:
	  ○ Adalimumab product (Amjevita preferred)
	  ○ Ustekinumab product (Yesintek preferred)
	• Documented inadequate response with or loss of response, intolerance or contraindication to vedolizumab
	• Negative test for hepatitis B within the past 24 months
	
	Approval dose: Simponi 100 mg q4 weeks via the outpatient benefit only
	
	Initial approval: 12 months
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Continued approval: 12 months. Confirm patient meets above coverage criteria and patient is in clinical remission.
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**

Drug	Prior Authorization Criteria
	For new pediatric members who were initiated on Simponi outside of KP: approve medication if confirmed to be clinically stable as determined by specialist and last visit in the past 6 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**

Skyclarys
(Omaveloxolone)
	Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.
	Candidates for treatment with Skyclarys must meet ALL the following criteria:
	
	**Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).*
	
	• Patient is ≥ 16 years and ≤ 40 years of age
	• Prescribed by a neurologist, pediatric neurologist, or geneticist
	• Documented diagnosis of genetically confirmed Friedreich's ataxia
	• Modified Friedreich's Ataxia Rating Scale (mFARS) score ≥20 and ≤80
	• Left ventricular ejection fraction ≥40%
	• Documentation of patient agreement to practice medically acceptable methods of birth control
	
	Reasons for Non-coverage:
	• Diagnosis of pes cavus
	• Patient is non-ambulatory
	• Brain natriuretic peptide (BNP) level >200 pg/mL
	• History of clinically significant left-sided heart disease and/or clinically significant cardiac disease, with the exception of mild to moderate cardiomyopathy associated with Friedreich's ataxia, including but not limited to any of the following:
	  ○ Clinically significant congenital or acquired valvular disease
	  ○ Pericardial constriction
	  ○ Restrictive or congestive cardiomyopathy
	  ○ Symptomatic coronary disease (prior myocardial infarction, percutaneous coronary intervention, coronary artery bypass graft surgery, or angina)
	  ○ History of hospitalization for heart failure in the last five years
	  ○ Cardiac insufficiency, defined as New York Heart Association Class >2
	  ○ History of atrial fibrillation
	  ○ History of unstable arrhythmias
	• Known active fungal, bacterial, and/or viral infection, including human immunodeficiency virus (HIV) or hepatitis B or C virus
	• Known or suspected active drug or alcohol abuse
	• Severe hepatic impairment (Child-Pugh Class C)
	• Concomitant use with moderate or strong CYP3A4 inducers (e.g. carbamazepine, phenobarbital, phenytoin)
	• Pregnant or breastfeeding

Drug	Prior Authorization Criteria
	Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** Continued Approval: 12 months. Patient must meet all criteria above without reasons for non-coverage or criteria for discontinuation below. Confirm patient has documented positive response in an appointment with a specialist within 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** Criteria for discontinuation: • Increase in transaminase levels >5X ULN or >3X ULN with evidence of liver dysfunction (e.g., elevated bilirubin) • Becomes wheelchair bound or non-ambulatory • Intolerance to medication • Non-adherence to medication or follow-up labs and assessments • Pregnancy is diagnosed or woman is breastfeeding Ordering Information: • Skyclarys is only available through Biologics Specialty Pharmacy. Providers should submit the Reach Start Form at reach-start-form.pdf
Skyrizi (Risankizumab)	**Candidates for treatment with Skyrizi should meet ALL the following criteria:** • Not prescribed in combination with another biologic agent for the same indication or advanced small molecule (e.g., tofacitinib, upadacitinib) for the same indication • Then follow the disease state specific criteria below, based on diagnosis: Criteria for diagnosis of plaque psoriasis: • Documented moderate-to-severe plaque psoriasis • Prescribed by a dermatologist • Inadequate response (of at least a 3-month trial), intolerance and/or contraindication to each of the following: ○ 1 TNF inhibitor i. Preferred options: adalimumab (Amjevita [preferred], Humira), infliximab (Infliximab-dyyb/Inflectra [preferred]) ii. Others: etanercept (Enbrel), certolizumab (Cimzia) ○ 1 ustekinumab product (e.g., Yesintek [preferred], Stelara) ○ Cosentyx Prescribed the maintenance dose when transitioning to Skyrizi from another biologic agent: Skyrizi 150 mg every 12 weeks. If loading dose is ordered, documented clinical rationale must be provided (ie. actively flaring, BSA >50%, prior ER visits for psoriasis). Criteria for psoriatic arthritis (patient must meet ALL the following criteria):

Drug	Prior Authorization Criteria

	• Documented active psoriatic arthritis
	• Prescribed by a Rheumatologist
	• Inadequate response (of at least a 3-month trial), intolerance and/or contraindication to each of the following:
	  ○ 1 TNF inhibitor
	  i. Infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade)
	  ii. Adalimumab product (Amjevita [preferred], Humira)
	  iii. Others: Golimumab (Simponi), Certolizumab (Cimzia), Etanercept (Enbrel)
	  ○ 1 ustekinumab product unless patient has documented axial disease (Yestinek [preferred], Stelara)
	  ○ 1 IL-17 Inhibitor (e.g., Cosentyx (secukinumab), Bimzelx (bimekizumab))
	  ○ 1 IL-23 Inhibitor (e.g., Tremfya (guselkumab))
	  ○ 1 Janus Kinase (JAK) Inhibitor
	  i. Tofacitinib
	  ii. Others: Upadacitinib (Rinvoq)
	  ○ Abatacept (Orencia)
	
	Initial Approval: 12 months
	
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	
	Continued Approval: 12 months. Continue approval if the following criteria are met:
	
	• For new members who were initiated outside of KPGA: Documented clinically significant benefit during specialist follow-up in the last 6 months AND meets full criteria above.
	• For existing members who have previously met the criteria: Documented clinically significant benefit (adequate response or optimizing therapy to achieve adequate response) from the medication during specialist follow up in the last 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	
	Criteria for ulcerative colitis (UC):
	• Age ≥ 18 years
	• Prescribed by a gastroenterologist
	• Documented moderately to severely active ulcerative colitis (UC)
	• Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL the following:
	  ○ Infliximab product (e.g., Inflectra [preferred])
	  ○ Ustekinumab product (e.g., Yesintek [preferred])
	  ○ Tofacitinib (preferred JAK-inhibitor) OR Rinvoq (upadacitinib). If patient is pregnant, tofacitinib or Rinvoq trial is NOT required

Drug	Prior Authorization Criteria
	○ Tremfya (guselkumab) Criteria for Crohn's Disease (CD): • Age ≥ 18 years • Prescribed by a gastroenterologist • Documented moderately to severely active Crohn's Disease (CD) • Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL the following: ○ Infliximab product (e.g., Inflectra [preferred])* ○ Adalimumab product (e.g., Amjevita [preferred])* ○ Ustekinumab product (e.g., Yesintek [preferred]) ○ Entyvio (vedolizumab) – a trial is not required for CD, if documentation of small bowel, perianal or fistulizing / penetrating disease ○ Rinvoq (upadacitinib). If patient is pregnant, Rinvoq trial is NOT required ○ Tremfya (guselkumab) ○ *Patient must try/fail all of the agents listed above unless provider documents rationale why additional anti-TNF agent is inappropriate (i.e., primary or secondary non-response despite therapeutic drug level +/- presence of anti-drug antibodies or adverse effect requiring a different mechanism of action, member temporarily located outside of our KP network and cannot receive infusions) Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Induction:** Approve intravenous dose given in office at week 0, week 4 and week 8 ONLY • **Maintenance:** Approve for member to fill via the outpatient pharmacy benefit only • Quantity limit for Skyrizi = 360mg (2.4mL) per 8 weeks (NOTE: Provider may request an exception for this maintenance dose requirement when applicable by showing objective evidence for this maintenance dose requirement when applicable by showing objective evidence of disease progression or inadequate control justifying change in dose interval) Continued Approval: 12 months. • For new members and existing members Documented clinical benefit (asymptomatic or in remission) from therapy, by a gastroenterology specialist within the past 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Induction for Crohn Disease and ulcerative colitis:** approve intravenous dose of 600mg (for CD) or 1200mg (for UC) to be given in office at weeks 0,4, and 8 • **Maintenance for Crohn Disease and ulcerative colitis:** approve for member to fill via the outpatient pharmacy benefit only

Drug	Prior Authorization Criteria

Skysona (Elivaldogene autotemcel)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval**
	
	Candidates for treatment with Skysona should meet ALL the following criteria:
	
	**Prior to formal QRM review, MCMC review and endorsement required. Once endorsed by MCMC, case-specific information should be reviewed by an Interregional Consultative Panel.*
	
	• Males aged 4 to 17 years
	• Prescribed by Pediatric Neurology and Pediatric Hematology/Oncology Specialists
	• Diagnosis of active cerebral adrenoleukodystrophy (CALD) as defined by ALL of the following:
	  ○ Elevated very long chain fatty acids (VLCFA) values
	  ○ Active central nervous system (CNS) disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating BOTH:
	  ▪ Loes score between 0.5 and 9 (inclusive) on the 34-point scale
	  ▪ Gadolinium enhancement on MRI of demyelinating lesions
	• Neurologic Function Score (NFS) ≤1
	
	Reasons for Non-coverage:
	• Previous recipient of bone marrow transplant (BMT)
	
	Approval Period: ONE-TIME, SINGLE-DOSE INFUSION.
	
	Ordering Information:
	
	• Skysona is administered in select treatment centers nationwide
	• If patient obtains QRM approval, providers should fax completed enrollment form to My Bluebird Support (Program-Enrollment-Form.pdf)

SGLT-2 Inhibitors: **Preferred:** **Dapagliflozin (generic Farxiga) – No PA required** **Non-Preferred:** **Jardiance (Empagliflozin) [approve ½ tablets only]*** **Invokana** (Canagliflozin) [approve ½ tablets only]	**Candidates for treatment with non-preferred SGLT-2 Inhibitors should meet ALL the following criteria:** **Dapagliflozin (generic Farxiga) is the preferred SGLT-2 inhibitor for type 2 diabetes mellitus and does not require PA.** Non-preferred SGLT-2 inhibitors must be tried in the order listed on the left side of the document: If intolerance and/or contraindication to the preferred SGLT-2 (dapagliflozin), next empagliflozin (Jardiance) 25 mg ½ tab daily, then canagliflozin (Invokana) half tabs only if eGFR ≥ 60 ml/min. If request is for non-preferred Jardiance, patient has tried dapagliflozin (generic Farxiga) and had an intolerance or allergic reaction that is likely due to the inactive components of the dapagliflozin and cannot be explained by other clinical or lifestyle factors. • Empagliflozin (Jardiance), is the 2nd preferred option for ASCVD, HF, CKD and DM2 patients without compelling indications due to broad range of indications and cost (1/2 tab regimen). • Canagliflozin (Invokana), is the 3rd preferred option for ASCVD, CKD and DM2 patients without compelling indications due to broad range of indications and cost (1/2 tab regimen).

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

Invokana (Canagliflozin) [approve ½ tablets only]
 	
Steglatro (Ertugliflozin) (Indicated for DM2 only)
 	
Brenzavvy (Bexagliflozin) (Indicated for DM2 only)
 	
Inpefa (Sotagliflozin) [Indicated for HF ONLY]
 	
Non-Covered combination products (separate prescriptions required for ingredients in combination products):
 	
Dapagliflozin and metformin (generic Xigduo)
 	
Synjardy XR (Empagliflozin and metformin)
 	
Glyxambi (Empagliflozin and linagliptan)
 	
Invokamet XR
	Non-preferred whole tablets* can be approved if patient has an intolerance or adverse reaction to preferred dapagliflozin (Farxiga) whole tablets AND:
	• A1C within 0.2% of goal after 6 months on Jardiance 25 mg ½ table daily AND on optimized oral agents without insulin and without concurrent GLP-1 RA OR
	• A1C within 0.2% of goal after 6 months on Jardiance ½ tablet daily and on optimized oral agents and on weight-based insulin and without concurrent GLP-1 RA
	
	*For non-preferred whole tablets, whole tablets may be approved for patients who are unable to split tablets because of vision or manual dexterity issues or patient/prescriber request. If patient meets all other criteria, approve the prescribed whole tablet.
	
	<u>For non-preferred combination product:</u>
	• Patient must meet criteria for SGLT2 (below) AND
	• Separate prescriptions are required for ingredients in non-preferred combination products
	
	<u>Non-preferred SGLT2 Inhibitors coverage criteria for all new and current KP members WITH ASCVD, heart failure or CKD. Must meet ALL of the following criteria:</u>
	• Documented diagnosis of type 2 diabetes mellitus and age ≥ 10 years
	• Meet criteria for ASCVD, CKD or Heart Failure (HF) per criteria listed:
	  ○ For ASCVD: ASCVD defined as acute coronary syndromes, history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, carotid stenosis ≥50%, or symptomatic peripheral arterial disease presumed to be of atherosclerotic origin.
	  ○ For CKD: CKD defined as eGFR 30-59 ml/min and/or Urinary albumin-to-creatinine ratio, > 300
	  ○ For HF: New York Heart Association (NYHA) Heart Failure class II, III, or IV symptoms and an ejection fraction of ≤40%
	• Patient must be on the current medications for underlying condition:
	  ○ ASCVD:
	  ▪ Moderate to high-intensity statin therapy. If not on a statin, there must be a documented trial and intolerance of at least 3 different statins.
	  ▪ Aspirin or another antiplatelet. If not prescribed, prescriber should document rationale.
	  ▪ ACE inhibitor or angiotensin receptor blocker (ARB) therapy. If not prescribed, prescriber should document rationale.
	  ○ CKD:
	  ▪ ACE inhibitor or angiotensin receptor blocker (ARB) therapy, if not prescribed, prescriber should document rationale.
	  ○ Heart Failure:
	  ▪ ACE inhibitor or angiotensin receptor blocker (ARB) therapy, or angiotensin receptor-neprilysin inhibitor (ARNI) inhibitor, if not prescribed, prescriber should document rationale.
	  ▪ Beta-blocker, if not prescribed, prescriber should document rationale.
	• Documented failure, intolerance or contraindication to adequate therapeutic trial (>3 months) of dapagliflozin (Farxiga) 10 mg daily, next Jardiance (empagliflozin) 25 mg ½ tablet, next canagliflozin (Invokana) half tabs only if eGFR ≥ 60 ml/min.
	• Currently prescribed metformin [MRAR ≥ 80% for ≥ 3 months. If MRAR < 80%, reviewer

Drug	Prior Authorization Criteria
(Canagliflozin and metformin) **Segluromet** (Ertugliflozin and metformin) **Steglujan** (Ertugliflozin and sitagliptin) **Trijardy XR** (Empagliflozin, Linagliptin, and Metformin)	can confirm adherence in the last 90 days based on medication sold dates found in Health Connect medication tab (e.g., 3 one-month fills or one 90-day fill)] at maximum tolerated dose (optimal dose 1500 to 2000 mg daily), intolerance or contraindication ○ If GI intolerance on metformin IR, but no history of metformin SR, must complete trial of metformin SR 500 mg 1 tab daily for 7 days then metformin SR 500 mg 1 tab bid as tolerated unless not indicated. Initial approval period: 1 year. Continued approval: 1 year. Patient must all criteria above without reasons for Non-coverage. Non-preferred SGLT2 Inhibitors coverage criteria for current KP new start members WITHOUT ASCVD, CKD, or heart failure. Must meet ALL of the following criteria: • Documented diagnosis of type 2 diabetes mellitus and ≥ 10 years • A1C within 2% of goal in the past 3 months ○ A1C goal < 7% ○ A1C goal < 8% if: age ≥ 65 years OR age 18-64 years with: dementia, blindness, lower extremity amputation, CKD 4/5, ESRD, cardiomyopathy/CHF, cardiovascular disease (MI, CABG, percutaneous coronary intervention, angina, thoracoabdominal aneurysm, carotid stenosis, renal atherosclerosis, peripheral vascular disease) • Currently prescribed metformin [MRAR ≥ 80% for ≥ 3 months. If MRAR < 80%, reviewer can confirm adherence in the last 90 days based on medication sold dates found in Health Connect medication tab (e.g., 3 one-month fills or one 90-day fill)] at maximum tolerated dose (optimal dose 1500 to 2000 mg daily), intolerance or contraindication ○ If GI intolerance on metformin IR, but no history of metformin SR, must complete trial of metformin SR 500 mg 1 tab daily for 7 days then metformin SR 500mg 1 tab bid as tolerated unless not indicated • Documented failure, intolerance or contraindication to adequate therapeutic trial (>3 months) of dapagliflozin (Farxiga), next Jardiance (empagliflozin) half tabs, then canagliflozin (Invokana) half tabs only if eGFR ≥ 60 ml/min. • A1C >2% of designated goal and currently prescribed insulin: ○ Significant weight gain (≥ 5% increase in body weight after 6 months of starting a diabetes agent) OR ○ Optimal dose of insulin (per prescriber discretion) and A1C remains above goal Initial approval: 6 months. • Must obtain A1C after initiating therapy Continued approval: 1 year. • Patient must meet all criteria above without reasons for Non-coverage. In addition, patient must meet all following criteria: • Current A1C shows documented lowering of 0.5% from initial A1C or A1C now at goal. Non-preferred SGLT2 inhibitor coverage criteria for new members WITHOUT ASCVD, CKD, HF. Must meet ALL the following: • Documented diagnosis of type 2 diabetes mellitus and ≥ 10 years

Drug	Prior Authorization Criteria
	• Currently prescribed metformin at maximum tolerated dose (optimal dose 1500 to 2000 mg daily) or documented failure, intolerance or contraindication ○ If GI intolerance on metformin IR, but no history of metformin SR, must complete trial of metformin SR 500 mg 1 tab daily for 7 days then metformin SR 500mg 1 tab bid as tolerated unless not indicated • Documented failure, intolerance or contraindication to adequate therapeutic trial (>3 months) of dapagliflozin (Farxiga), next Jardiance (empagliflozin) half tabs, then canagliflozin (Invokana) half tabs only if eGFR ≥ 60 ml/min. • A1c ≤ 8% within 30 days Continued approval: 1 year. Patient must meet all criteria above without reasons for Non-coverage. Patient must also meet all criteria below: • A1c ≤ 8% Reasons for Non-coverage: • Type 1 diabetes mellitus • Severe renal impairment (eGFR < 30 ml/min) end-stage renal disease, or dialysis • For Brenzavvy: Severe hepatic impairment (Child-Pugh Score C) • Active bladder cancer for dapagliflozin **The criteria below are to be applied to only members WITHOUT diabetes:** The non-preferred SGLT2 inhibitor coverage criteria for new and current non-diabetic KP members with CKD. Must meet ALL the following criteria: • Age ≥ 18 years • CKD defined as eGFR 30-59 ml/min and/or Urinary albumin-to-creatinine ratio, > 300 • Prescribed maximum tolerated dose of ACE inhibitor OR angiotensin II receptor blockers and must be adherent [MRAR ≥ 80%. If MRAR < 80%, reviewer can confirm adherence in the last 90 days based on medication sold dates found in Health Connect medication tab (e.g., 3 one month fills or one 90 day fill)] or have a documented failure, intolerance or contraindication • Documented failure, intolerance or contraindication to adequate therapeutic trial (>3 months) of dapagliflozin (Farxiga), next empagliflozin (Jardiance) half tabs, then canagliflozin (Invokana) half tabs only if eGFR ≥ 60 ml/min. Initial approval: 6 months if the patient meets the following • Patient must have an eGFR checked at baseline and within 6 months Continued approval: 12 months • Patient must meet all criteria above without reasons for Non-coverage. Reasons for Non-coverage: • Diabetes (if diabetes present, refer to diabetes specific criteria) • Severe renal impairment (eGFR < 20 ml/min), dialysis, renal transplant • Fournier's gangrene • Pregnant or breastfeeding

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• Previous intolerance or contraindication to SGLT-2 inhibitors • Active or history of bladder cancer for dapagliflozin **Criteria below should be applied to diabetic and non-diabetic members:** <u>Non-preferred SGLT2 Inhibitor coverage criteria for all new and current KP members WITH heart failure with preserved ejection fraction (HFpEF). Must meet ALL of the following criteria:</u> • Must be prescribed by a Cardiology Provider • Diagnosis of Heart Failure with EF > 40% (other diagnosis' consistent with this can be identified in patient chart as "heart failure with preserved ejection fraction" or "diastolic heart failure") • New York Heart Association (NYHA) Heart Failure class II, III, or IV symptoms • Prescribed loop diuretic therapy • eGFR > 20 • Documented failure, intolerance or contraindication to adequate therapeutic trial (>3 months) of dapagliflozin (Farxiga, then Jardiance (empagliflozin) • For brand name Farxiga requests, must have a documented trial of/ or allergy/contraindication to generic dapagliflozin and a trial of the authorized generic dapagliflozin (Prasco Labs). If request is for non-preferred Farxiga, patient has tried dapagliflozin (generic Farxiga) and had an intolerance or allergic reaction that is likely due to the inactive components of the dapagliflozin and cannot be explained by other clinical or lifestyle factors. <u>Initial approval:</u> 6 months. • Patient must have eGFR checked at baseline and within 6 months <u>Continued approval:</u> 12 months: • Patient must meet all criteria above without reasons for Non-coverage <u>Reasons for Non-coverage:</u> • History of cardiac amyloidosis or hypertrophic obstructive cardiomyopathy • Pediatric patients (age < 18 years) • T1DM • eGFR < 20 mL/min/1.73 m^2 OR on dialysis • Fournier's gangrene • Pregnant or breastfeeding • Previous intolerance or contraindication to SGLT-2 inhibitors
Sofdra (Sofpironium)	**Candidates for treatment with Sofdra must meet ALL the following criteria:** 1. Age ≥ 9 years 2. Prescribed by dermatologist 3. Diagnosed with primary axillary hyperhidrosis (aHH) and symptoms of hyperhidrosis (HH) (e.g., focal, visible, excessive sweating) for ≥ 6 months that is severe, intractable, and disabling

Drug	Prior Authorization Criteria
	4. Documentation of at least **2** of the following criteria: a. Symptoms occur bilaterally b. Symptoms impair daily activities c. The patient has at least one episode per week d. Onset occurred prior to the patient turning 25 years of age e. The patient has a family history of primary axillary hyperhidrosis f. Symptoms do not occur during sleep 5. Documented inadequate response, intolerance or contraindication to ALL following therapies: a. For members aged < 18 years: i. At least 3 months of topical aluminum chloride (e.g., OTC Hypercare, RX Drysol) b. For members aged ≥ 18 years: i. At least 3 months of topical aluminum chloride (e.g., OTC Hypercare, RX Drysol) ii. At least 3 months of oral glycopyrrolate (e.g., Robinul) iii. At least 3 months of Qbrexza (glycopyrronium) iv. At least 6 months of Botox Reasons for Non-Coverage: • Medical conditions that can be exacerbated by the anticholinergic effect of SOFDRA (e.g., glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, Sjögren's syndrome) • Concurrent use with other topical anticholinergics indicated for primary axillary hyperhidrosis (e.g., Qbrexza [glycopyrronium tosylate]) Initial Approval: 2 months Continued Approval: 12 months. Continued approval for treatment with Sofdra (sofpironium) should meet ALL of the criteria above in addition to the criteria below: • Documented clinical benefit to treatment
Sohonos (Palovarotene)	**Candidates for treatment with Sohonos should meet ALL the following criteria:** • Prescribed by or in consultation with a geneticist • Patients is female AND age ≥ 8 years **OR** patient is male AND age ≥ 10 years • Patient is diagnosed with fibrodysplasia ossificans progressiva (FOP) with the *ACVR1* R206H mutation confirmed by genetic testing • Documented negative pregnancy test in patients of reproductive potential and attestation that the patient will use appropriate contraception methods at least 1 month before treatment, during treatment, and 1 month after the last dose.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Reasons for Non-coverage: • Pregnancy • Hypersensitivity to retinoids or any component of Sohonos Initial Approval Period: 12 months. Quantity limit of 30 day supply in 30 days. Continued Approval Period: 12 months if patient meets ALL the initial criteria above and the following: • Documentation that the patient continues to benefit from therapy • Documentation that the patient is tolerating therapy • Quantity limit of 30 day supply in 30 days. Ordering Information: • Sohonos is only available via Specialty Pharmacies. Information on ordering can be found at IPSEN CARES Specialty Pharmacy Flashcard.
Ekterly (Sebetralstat)	**Candidates for treatment with Ekterly should meet ALL the following criteria:** • Prescribed for acute treatment of hereditary angioedema (HAE) attacks • Prescriber must be an Allergist or Immunologist. • Age ≥ 12 years • Diagnosed with hereditary angioedema (HAE) confirmed by ONE of the following: a. C1 esterase inhibitor (C1-INH) antigenic level below the lower limit of normal; OR b. C1-INH functional level below the lower limit of normal; OR c. Normal C1-INH levels • Medication will NOT be used in combination with other products indicated for the acute treatment of HAE attacks (e.g., Berinert, Firazyr, Kalbitor, or Ruconest) Reasons for Non-coverage: • The patient had a trial of or contraindication to ONE of the following preferred agents: Kalbitor, Berinert, Ruconest, generic icatibant Initial Approval: 12 months Continued Approval: 12 months. Confirm patient meets all above criteria without reasons for Non-coverage. In addition, continue approval based on clinical documentation of functional improvement, a decrease in frequency of HAE attack, and an improvement in severity and duration of attacks.
Somatuline Depot (Lanreotide) **Preferred:**	**Candidates for Somatuline Depot should meet ALL the following criteria:** **For Somatuline Depot 60 mg and 90 mg dose:** • Prescribed by an endocrinologist OR oncologist. • Age ≥ 18 years

Drug	Prior Authorization Criteria

Lanreotide 120 mg/0.5 mL (Cipla 505(b)(2) product) **Available on the COM formulary - no PA required**	• Patient has a diagnosis of ONE of the following:
	  ○ Acromegaly AND patient has had an inadequate response to surgery and/or radiotherapy OR surgery and/or radiotherapy are NOT an option.
	  ○ Unresectable, well-or moderately-differentiated, locally advanced or metastatic Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)
	  ○ Carcinoid syndrome
	
	For Somatuline Depot 120 mg dose:
	• Prescribed by an endocrinologist OR oncologist.
	• Age ≥ 18 years
	• Patient has a diagnosis of ONE of the following:
	  ○ Acromegaly AND patient has had an inadequate response to surgery and/or radiotherapy OR surgery and/or radiotherapy are NOT an option.
	  ○ Unresectable, well-or moderately-differentiated, locally advanced or metastatic Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)
	  ○ Carcinoid syndrome
	  ○ Neuroendocrine tumors, including GI Tract, Lung, Thymus, Pancreas, and Pheochromocytoma/Paraganglioma AND used in ONE of the following:
	  • To treat unresectable primary gastrinoma
	  • Treatment of symptoms related to hormone hypersecretion and/or carcinoid syndrome
	  • Tumor control in patients with unresectable, locally advanced, and/or metastatic disease
	• Patient has tried Cipla lanreotide 505(b)(2) and had an intolerance or allergic reaction that is likely due to the **inactive** components (e.g., difference in dyes, fillers, preservatives, etc) of the generic medication and cannot be explained by other clinical or lifestyle factors.
	  ○ If the request for coverage of Somatuline Depot 120 mg is based upon disease progression or side effects due to the active ingredient lanreotide, the request will be denied unless the member meets the full criteria.
	  ○ If the request for coverage of Somatuline Depot 120 mg is based upon the physician's and/or members unwillingness to change to a preferred alternative, the request will be denied unless the member meets the full criteria.
	
	<u>Initial Approval:</u> 12 months.
	• Approve for KP clinic/back-office administration or KP home infusion program ONLY.
	
	<u>Continued Approval:</u> 12 months. For continued approval, patient meets ALL the following:
	• Patient continues to meet the above criteria.
	• Additional disease specific criteria:
	  ○ For acromegaly, patient has documented positive clinical response to therapy, such as reduction or normalization of IGF-1/GH level for same age and sex.
	  ○ For GEP-NETs, patient does not show evidence of disease progression while on therapy.
	  ○ For carcinoid syndrome, patient has documented positive clinical response to therapy.
	• Approve for KP clinic/back-office administration or KP home infusion program ONLY.

Drug	Prior Authorization Criteria
	Dosing and Administration: • Please refer to prescribing information for disease specific dosing. • For acromegaly: ○ Initial: 90 mg subcutaneously every 4 weeks for 3 months; after initial 3 months dose should be adjusted based on clinical response, growth hormone levels, and/or insulin like growth factor levels • For carcinoid syndrome: 120 mg subcutaneously every 4 weeks • **For Gastroenteropancreatic neuroendocrine tumors: 120 mg subcutaneously every 4 weeks until disease progression or unacceptable toxicity**
Somavert (Pegvisomant)	**Candidates for treatment with Somavert should meet ALL the following criteria:** • Documented diagnosis of acromegaly • Prescribed by an endocrinologist • Documented inadequate response or not a candidate for surgery or radiation for the management for acromegaly • Documented inadequate response or unable to tolerate Sandostatin® (octreotide) **OR** Somatuline® (lanreotide) if request is to use in combination with a somastatin receptor ligand (SRL) (i.e., sandostatin or somatuline). Patient must have documented trial of cabergoline in combination with SRL unless patient is not a candidate for cabergoline or intolerance/contraindication to cabergoline. Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Initial Loading Dose:** approve one-time initial loading dose given in office • **Maintenance:** approve for member to fill via the outpatient pharmacy benefit only Continued Approval: 12 months. Confirm patient meets all above criteria. In addition, continue approval if there is documented evidence of improvement in disease symptoms or stabilization of disease state and liver enzymes have been assessed and recommendation to continue treatment aligns with prescribing information for continuation of treatment based on results of liver tests • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Initial Loading Dose:** approve one-time initial loading dose given in office • **Maintenance:** approve for member to fill via the outpatient pharmacy benefit only Dosing and Administration • A loading dose of 40 mg of Somavert should be administered subcutaneously under physician supervision • Maintenance dose: 10 mg subcutaneously once daily • Doses may be adjusted by 5 mg increments in 4- to 6-week intervals based on IGF-I concentrations (maximum maintenance dose: 30 mg/day)

Drug	Prior Authorization Criteria
	• Somavert may be given in the thigh, buttocks, upper arm, or abdomen; the site of SC injections should be rotated daily to help prevent lipohypertrophy Monitoring: • GH-secreting tumor size • Serum glucose • Signs and symptoms of growth hormone deficiency • Serum IGF-I (every 4-6 weeks after initial dose and dosage change, every 6 months when normalized • Liver function tests at monthly intervals during the first 6 months of treatment, quarterly for the next 6 months, and then semi-annually for the next year Ordering Information: • Somavert is furnished by the KP Specialty Pharmacy (KP SP) in Daly City, California. Fax the Somavert Order Form to KP SP (650-301-5790). The Somavert Order Form can be found on the KP SP Website.

Soolantra
(Ivermectin)
	Candidates for treatment with Soolantra should meet ALL of the following criteria:
	
	• For topical treatment of rosacea with papules/pustules with erythema
	• Age ≥ 18 years
	• Prescribed by a dermatologist
	• Intolerant/contraindication or did not have an adequate response to ALL of the following alternatives after at least an 8-week course of therapy:
	  ○ Topical metronidazole 0.75%-1%
	  ○ One of the following topical antibiotics:
	  ○ Erythromycin or clindamycin phosphate +/- benzoyl peroxide
	  ○ Sulfacetamide-sulfur 10/5% cleanser
	  ○ Topical azelaic acid 15%
	  ○ One of the following oral antibiotics:
	  ▪ Doxycycline or azithromycin
	
	Initial Approval: 12 weeks with quantity limited to 45 grams per 30 days
	
	Continued approval: 1 year with quantity limited to 45 grams per 30 days. Confirm patient meets all above criteria. In addition, continue approval only if documented evidence of improvement in papules/pustules and/or erythema

Sotyktu (Deucravacitinib)	**Candidates for Sotyktu should meet ALL of the following criteria AND the individual disease state criteria below**: • Prescriber is a rheumatologist or dermatologist • Patient has had a negative interferon-gamma release assay test for TB infection within the past 24 months or is positive for latent TB and has completed treatment in the past or is currently on treatment • Should not be used concomitantly with biologic drugs (e.g., infliximab, adalimumab, ustekinumab, guselkumab, etc.), or other immunosuppressants (e.g. apremilast, tofacitinib, methotrexate). • Then follow the disease-state criteria below:

Drug	Prior Authorization Criteria

	Diagnosis of plaque psoriasis:
	• Patient is ≥ 18 years of age
	• Inadequate response (of at least a 3-month trial), intolerance and/or contraindication to each of the following:
	  ○ Adalimumab product (e.g. Amjevita [preferred]) OR infliximab product (e.g. Inflectra [preferred])
	  ○ Ustekinumab product (Yesintek [ustekinumab-kfce], Stelara)
	  ○ Cosentyx (secukinumab)
	  ○ Tremfya (guselkumab) or Skyrizi (risankizumab)
	• For patients who have NOT been treated with a biologic for psoriasis in the past 6 months, confirm the following additional criteria are met:
	  ○ >10% Body Surface Area Affected
	  ○ Inadequate response (of at least a 3-month trial), intolerance, or contraindication to Phototherapy (PUVA, UVB with coal tar or dithranol, UVB standard or narrow-band, or home UVB) excluding patients with:
	  ▪ Involvement of sensitive areas (e.g. hands, feet, face, body folds or genitals)
	  ▪ Concomitant use of medications that cause photosensitivity
	  ▪ History of a photosensitivity disorder (e.g. Lupus, Dermatomyositis, Porphyria, Xeroderma pigmentosum)
	  ▪ History of melanoma or abnormal moles
	  ▪ History of multiple non-melanoma skin cancers
	NOTE: light box trial required unless member has a High Deductible Health Plan
	
	Diagnosis of psoriatic arthritis:
	• Documented inadequate response, intolerance, or contraindication to each of the following:
	  ○ 1 conventional synthetic DMARD (unless documented axial disease or severe disease [e.g. dactylitis, multiple (>=5) joint involvement, erosive disease, or functional limitation]):
	  ▪ Methotrexate
	  ▪ Sulfasalazine
	  ▪ Leflunomide
	  ○ 1 TNF inhibitor:
	  ▪ Infliximab product (Infliximab-dyyb/Inflectra [preferred])
	  ▪ Adalimumab product (Amjevita [preferred], Humira)
	  ▪ Others: Golimumab (Simponi), Certolizumab (Cimzia), Etanercept (Enbrel)
	  ○ 1 ustekinumab product unless patient has documented axial disease (Yesintek [preferred], Stelara)
	  ○ 1 IL-17 Inhibitor (e.g. Cosentyx (secukinumab), Bimzelx (bimekizumab))
	  ○ 1 IL-23 Inhibitor (e.g. Tremfya (guselkumab), Skyrizi (risankizumab))
	  ○ 1 Janus Kinase (JAK) Inhibitor
	  ▪ Tofacitinib
	  ▪ Others: Upadacitinib (Rinvoq)
	  ○ Abatacept (Orencia)

Drug	Prior Authorization Criteria
	Initial approval: 6 months. Continued approval: 12 months. Continue approval if the following criteria are met: For new members who were initiated outside of KPGA: Approve if patient meets all above coverage criteria and is confirmed to be clinically stable by a specialist during the last 6 months. For existing members who have previously met the criteria: Documented clinically significant benefit from the medication during specialist follow up in the last 12 months.
Sovaldi (Sofosbuvir)	**Candidates for treatment with Sovaldi should meet ALL the following criteria:** Sovaldi is a non-preferred treatment agent at Kaiser Permanente. Please refer all requests to internal KP Hepatology or Infectious Disease.
Spevigo (Spesolimab-sbzo)	**Candidates for treatment with Spevigo should meet ALL the following criteria PLUS the individualized disease state criteria below:** • Prescribed by a dermatologist • Patient is 12 years of age or older and weighs at least 40kg • Patient is not taking Spevigo with another biologic treatment (ixekizumab [Taltz], bimekizumab [Bimzelx], risankizumab [Skyrizi], guselkumab [Tremfya], infliximab [Inflectra]) for the same indication • Then follow the disease state specific criteria below, based on diagnosis: Generalized Pustular Psoriasis **with Active Flare** (SPEVIGO IV): • Patient has a moderate to severe GPP flare based on one of the following: a. Presence of fresh pustules (new appearance or worsening pustules) b. At least 5% of body surface area (BSA) covered with erythema and the presence of pustules c. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate) d. GPPPGA pustulation sub-score of at least 2 (mild) • Patient has not received more than one Spevigo infusion for the current flare. Initial Approval: 6 weeks. Approve for a maximum of 2 infusions per flare. If the flare persists after the initial dose, a second dose may be administered 1 week later. • For patients 18 years of age and older, approve for administration at KP facility. • **Quantity Limit**: Spevigo 450 mg/7.5 mL: 4 vials per year. Each infusion is 2 vials. • **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** Continued Approval: 6 weeks. Continue approval if the following criteria are met: For new members who were initiated on Spevigo IV outside of KPGA:

Drug	Prior Authorization Criteria
	• Confirm patient meets all above coverage criteria AND that patient has not already received the maximum of 2 infusions for the current flare. Approve for up to 1 additional infusion in patients who received the first infusion prior to KP membership. • For patients 18 years of age and older, approve for administration at KP facility • **Quantity Limit**: Spevigo 450 mg/7.5 mL: 4 vials per year. Each infusion is 2 vials. • **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** <u>Generalized Pustular Psoriasis **with NO active flare** (SPEVIGO SC prefilled syringes):</u> • History of at least 2 GPP flares in the past • GPP Physician Global Assessment total score of 0 or 1 • Prescribed 300mg SQ every 4 weeks without a loading dose for patients who have recently completed treatment with IV Spevigo for an active flare <u>Initial Approval:</u> 3 months. In consultation with Chief of Dermatology • Approve for member to fill via the outpatient pharmacy benefit only • **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** <u>Continued Approval:</u> 12 months. Continue approval if the following criteria are met: <u>For new members who were initiated on Spevigo outside of KPGA:</u> • Confirm patient meets all above coverage criteria and is documented to be clinically stable on Spevigo by a specialist in the past 6 months. • Approve for member to fill via the outpatient pharmacy benefit only • **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** <u>For existing members who previously met the full criteria above:</u> • Documented clinically significant benefit from the medication during specialist follow up in the last 12 months. • Approve for member to fill via the outpatient pharmacy benefit only • **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.**
Spinraza (Nusinersen)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** **Candidates for treatment with Spinraza should meet ALL the following criteria:** **Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).* • Confirmed diagnosis of 5q-autosomal recessive SMA (spinal muscular atrophy) (biallelic deletions or mutations in the SMN1 gene); and • Two to four copies of SMN2 gene; and

Drug	Prior Authorization Criteria
	○ NOTE: For age <6 months, based on the strength of the current available data for onasemnogene abeparvovec-xioi (Zolgensma), KP consensus recommendation is to use onasemnogene abeparvovec as the preferred product for these patients. • Prescribed by Pediatric Neurology, Adult Neurology, or Physical Medicine and Rehabilitation • Must be administered by a provider capable of intrathecal medication administration • Baseline documentation in medical record: CBC, PT/PTT, urinalysis within 1 week prior to initiation • Baseline documentation in medical record: Motor function assessment, performed by a physical therapist is preferred: ○ For Infants: Hammersmith Infant Neurological Examination Section 2 (HINE-OR Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) ○ For Children (age ≥ 24 months), Adolescents, Adults: ▪ HFMSE and Revised Upper Limb Module (RULM) • Baseline documentation in medical record: Spine evaluation to assess ease of lumbar puncture entry or safety of creating lumbar puncture entry, AND risk assessment for procedure: objective respiratory testing: ○ Age ≥ 6 years: pulmonary function tests (PFTs); if PFTs are unsuccessful. obtain pulse oximetry and End-Tidal CO2 (ETCO2) measurements ○ Age < 6 years: pulse oximetry and End-Tidal CO2 (ETCO2) measurements. Also consider screening sleep studies in non-ambulatory, hypotonic infants and young children Reasons for Non-coverage: • Permanent invasive ventilation or tracheostomy • Dependent on invasive or non-invasive ventilation during waking hours each day to control hypercarbia, or development of hypercarbia without ventilatory support • Contraindication to lumbar puncture • Concurrent treatment with risdiplam (Evrysdi) • Prior or Planned treatment with gene therapy for SMA **Note: For patients >65 years with HFMSE <35, may have less benefit based on real-world data, therefore caution should be used Initial Approval: 12 Months **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Continued Approval: 12 Months. Confirm patient meets all above coverage criteria without reason for Non-coverage or criteria for discontinuation (see below). In addition, continue approval with documentation of follow-up assessments. **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Criteria for Discontinuation:

Drug	Prior Authorization Criteria
	• Risdiplam or other gene therapy for SMA is initiated • Non-adherence to follow-up assessments and/or medical treatment plan (e.g., nutrition, pulmonary, physical therapy) • No longer able to tolerate lumbar puncture • Permanent invasive ventilation or tracheostomy • Dependent on invasive or non-invasive ventilation during waking hours each day to control hypercarbia, or development of hypercarbia without ventilatory support • Loss of function or progressive weakness (physical and/or pulmonary) Recommended Dosing: • 12 mg (5 ml) intrathecally as room temperature bolus injection over 1-3 minutes after removing 5 ml of CSF. • Initiate with 4 loading doses; the first three loading doses should be administered at 14-day intervals; the 4th loading dose should be administered 30 days after the 3rd dose; a maintenance dose should be administered one every 4 months thereafter. Optional alternate (off-label) dosing regimen for later-onset SMA (symptom onset age> 6 months): Initiate with the first dose at Day 1 and subsequent doses at Day 30 (1 month), Day 90 (3 months), and Day 270 (9 months); a maintenance dose should be administered once every 6 months thereafter.
Spravato (Esketamine)	**Candidates for treatment with Spravato should meet ALL the following criteria:** Consult Behavioral Health QRM MD reviewers for review of medical necessity. MD reviewers will use IR criteria for reviews, Esketamine (Spravato) for Treatment-Resistant Depression (TRD) - Interregional | GA Clinical Library (kp.org). **Spravato is not approved for dispensing at outpatient pharmacies.**
Sprycel (Dasatinib)	**Candidate for treatment with Sprycel for hematologic/oncologic indications should meet ALL the following criteria:** • Prescribed by a hematologist/oncologist; AND • Requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines; AND • Patient has a diagnosis of one of the following: ▪ Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) ○ Age ≥ 1 year ○ Confirmed by molecular testing by the detection of the Ph chromosome or BCR-ABL gene prior to initiation of therapy ○ If the patient has had prior therapy with a TKI then ONE of the following requirements must be met: • Resistance to prior therapy with TKI ▪ T315I mutation negative • Toxicity or intolerance to prior therapy with a TKI

Drug	Prior Authorization Criteria
	▪ Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) ○ Age ≥ 1 year ○ Confirmed by molecular testing by the detection of the Ph chromosome or BCR-ABL gene prior to initiation of therapy ○ If the patient has had prior therapy with a TKI then ONE of the following requirements must be met: • Resistance to prior therapy with TKI ▪ T315I mutation negative • Toxicity or intolerance to prior therapy with a TKI ▪ Gastrointestinal Stromal Tumor (GIST) ○ Age ≥ 18 years ○ Disease progression after imatinib, sunitinib, AND regorafenib OR intolerance/contraindication to imatinib, sunitinib, AND regorafenib ○ PDGFRA D842V mutation • Patient has tried generic dasatinib and had an intolerance or allergic reaction that is likely due to **inactive** components of the generic medication and cannot be explained by other clinical or lifestyle factors. • If the request is for coverage of brand Sprycel: ▪ Do not approve for coverage/use if documented treatment failure or intolerance is to the authorized generic (AG) dasatinib by Prasco. Dasatinib AG is identical in composition of both active and inactive ingredients as brand Sprycel. ▪ Do not approve for coverage/use if request for coverage of brand Sprycel is based upon disease progression or side effects due to the active ingredients dasatinib. ▪ Do not approve for coverage/use if the physician's request for coverage of brand Sprycel is based upon the physician's and/or patient's unwillingness to change to a preferred alternative. Patient will need to meet the full criteria for coverage. <u>Reasons for Non-coverage:</u> • T315I mutation positive <u>Initial Approval Period:</u> 1 year <u>Continued Approval</u>: 1 year if ALL the following are met: • Member continues to meet the above criteria AND • Continues to be seen by a hematologist/oncologist AND • Member is responding positively to therapy as defined by stabilization of disease/lack of disease progression or decrease in size of tumor or tumor spread AND • Absence of unacceptable toxicity from the drug AND • NO dual therapy with another tyrosine kinase inhibitor
<u>Stimulants:</u>	**Candidates for treatment with dextroamphetamine and amphetamine (Mydayis), dextroamphetamine and amphetamine (Brand Adderall XR), methylphenidate extended-release**

Drug	Prior Authorization Criteria

Adderall XR (Dextroamphetamine and Amphetamine)
 	
Concerta (Methylphenidate)
 	
Jornay PM (Methylphenidate Extended-Release)
 	
Mydayis (Dextroamphetamine and Amphetamine)
 	
Quillichew ER (Methylphenidate Extended-Release)
 	
***QRM review is only required for the brand formulation**
	capsule (Jornay PM), methylphenidate extended-release chewable tablet (Quillichew), and methylphenidate (Brand Concerta) should meet ALL the following criteria:
	
	• Patient has a documented diagnosis of ADHD or narcolepsy confirmed by a sleep study
	• Age ≥ 6 years for dextroamphetamine and amphetamine (brand Adderall XR), methylphenidate extended-release capsule (Jornay PM), methylphenidate extended-release chewable tablet (Quillichew), and methylphenidate (brand Concerta) OR age ≥ 13 years for dextroamphetamine and amphetamine (Mydayis)
	• Patient has failed a trial of at least 4-weeks to or patient has experienced a clinically significant intolerance to:
	  ○ One formulary extended-release methylphenidate product or methylphenidate CD (methylphenidate CD capsules may be opened and sprinkled on applesauce if unable to swallow tablets or capsules) AND
	  ○ One formulary extended-release amphetamine product (capsules may be opened and sprinkled on applesauce if unable to swallow tablets or capsules) AND
	  ○ One formulary extended-release dexmethylphenidate (capsules may be opened and sprinkled on applesauce if unable to swallow tablets or capsules) AND
	  ○ Lisdexamfetamine (Vyvanse) (capsules may be opened and sprinkled on applesauce if unable to swallow tablets or capsules) AND
	  ○ Armodafinil for patients diagnosed with narcolepsy
	
	<u>Initial Approval:</u> 3 months
	
	<u>Continued Approval:</u> 12 months. Confirm patient meets all the above coverage criteria without reasons for non-coverage. In addition, continued approval will be based on clinical documentation of the following:
	• Patient is responding positively to therapy. Response is defined as TWO of the following
	  ○ Achieved and maintains at least a 50% reduction from baseline in core symptoms of
	  hyperactivity, impulsivity, and attention
	  ○ Documented improvement in target goal created by patient and physician (e.g., turning in assignments on time, improved classroom behavior)
	  ○ Documented improved attention and social skills
	  ○ No aggressive behaviors documented

Strensiq (Asfotase alfa)	**Candidates for treatment with Strensiq must meet ALL the following criteria:** • Documented diagnosis of perinatal/infantile or juvenile onset hypophosphatasia (HPP) • Prescribed by Endocrinologist or Geneticist • Onset of clinical signs and symptoms of HPP prior to age 18 years (e.g., respiratory insufficiency, vitamin B6 responsive seizures, hypotonia, failure to thrive, waddling gait, low trauma fractures) OR radiographic evidence supporting diagnosis of HPP at the age of onset prior to 18 years

Drug	Prior Authorization Criteria
	○ NOTE: premature dental abnormalities cannot be sole qualifier for treatment initiation in adults) • Positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing **OR** meets at least **TWO** of the following criteria: ○ Serum alkaline phosphatase (ALP) level below that of normal range for Age ○ Serum pyridoxal-5'-phosphate (PLP) levels elevated **AND** patient has not received vitamin B_6 supplementation in the previous week ○ Urine phosphoethanolamine (PEA) level above that of normal range for Age ○ Radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, osteomalacia, widened growth plates, areas of radiolucency or sclerosis) • Presence of **two or more** of the following: ○ Rachitic deformities (rachitic chest, bowed legs, knock-knees) ○ Craniosynostosis (premature closure of skull bones) ○ Premature loss of primary teeth prior to 5 years of age ○ Delay in skeletal growth resulting in delay of motor development ○ History or presence of non-traumatic fractures or delayed fracture healing ○ History of vitamin B6 dependent seizures ○ Nephrocalcinosis (high calcium levels in kidney) or history of elevated serum calcium • Patient weight documented and dose is consistent with FDA labeled dosing <u>Initial Approval:</u> 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Approve for member to fill via the outpatient pharmacy benefit only** <u>Continued Approval:</u> 12 months. Confirm patient meets all above criteria and during the last 6 months of treatment, has the patient experienced improvement in the skeletal characteristics of hypophosphatasia (HPP) (e.g., improvement of the irregularity of the provisional zone of calcification, physeal widening, metaphyseal flaring, radiolucencies, patchy osteosclerosis, ratio of mid-diaphyseal cortex to bone thickness, gracile bones, bone formation and fractures) **AND** change in labs (decrease from baseline in TNSALP substrate, increase in serum ALP levels). • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Approve for member to fill via the outpatient pharmacy benefit only** <u>Reasons for Non-coverage:</u> • Currently prescribed bisphosphonate (e.g., alendronate, ibandronate)
Stivarga (Regorafenib)	**Candidates for Stivarga (regorafenib) should meet ALL the following criteria:**

Drug	Prior Authorization Criteria

	Diagnosis of colorectal cancer:
	• Prescribed by a hematologist or oncologist.
	• Age ≥18 years
	• Diagnosis of advanced (stage III) or metastatic (stage IV) colorectal cancer
	• Documented treatment failure, intolerance, or contraindication to ALL of the following:
	  ○ A fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
	  ▪ Examples include: FOLFOX, FOLFIRI, FOLFOXIRI, CAPOX
	  ○ Anti-VEGF therapy (e.g., bevacizumab (Avastin), ziv-afilbercept (Zaltrap)
	• Tumor has ONE of the following:
	  ○ Tumor is RAS mutant-type OR
	  ○ Tumor is RAS wild-type AND patient has a documented treatment failure, intolerance, or contraindication to anti-EFFR therapy (e.g., cetuixumb (Erbitux), panitumumab (Vectibix), etc)
	
	Diagnosis of gastrointestinal stromal tumor (GIST):
	• Prescribed by a hematologist or oncologist.
	• Age ≥18 years
	• Diagnosis of locally advanced (stage III), unresectable, or metastatic (stage IV) GIST
	• Documented treatment failure, intolerance or contraindication to imatinib (Gleevec) AND sunitinib (Sutent)
	
	Diagnosis of hepatocellular carcinoma:
	• Prescribed by a hematologist or oncologist
	• Age ≥ 18 years
	• Diagnosis of advanced (stage IIIb or IIIc) or metastatic (stage IV) hepatocellular carcinoma
	• Child-Pugh Class A Liver Function
	• Documentation patient is not a candidate for immunotherapy
	• Documented treatment failure or intolerance to ONE of the following: levantinib Lenvima) or sorafenib (Nexavar)
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. For continued approval for treatment with Regorafenib, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria.
	• Patient is responding positively to therapy based on stabilization of disease or no disease progression

Sucraid
(Sacrosidase)
	Candidates for treatment with Sucraid should meet all the following criteria:
	• Prescribed by a gastroenterologist, pediatric gastroenterologist, or medical geneticist
	• Diagnosis of congenital sucrase-isomaltase deficiency (CSID) confirmed by one the following
	  ○ Small bowel biopsy
	  ○ Molecular genetic testing
	  ○ Sucrose hydrogen breath test
	• Will be used with a sucrose free, low starch diet

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	Reasons for Non-coverage:
	• Hypersensitivity to yeast, yeast products, glycerin (glycerol) or papain
	
	Initial approval**:** 12 months
	
	Continued approval**:** 12 months
	• Member must continue to meet criteria listed above.
	• Member has adequate response and tolerance documented by a specialist, demonstrated by reduction in the following in:
	  ○ Abdominal pain, cramps, bloating, gas or vomiting
	  ○ Number of stools per day
	  ○ Watery, loose stools and improved consistency
	  ○ Number of symptomatic days

Sunosi (Solriamfetol)	**Candidates for treatment with Sunosi should meet ALL the following criteria:** Criteria for approval for excessive somnolence with narcolepsy: • Prescribing restricted to sleep specialists AND • Patient has diagnosis of excessive daytime sleepiness associated with narcolepsy AND • Patient has tried and failed at least three CNS stimulants (e.g., armodafinil, modafinil, methylphenidate, dextroamphetamine/amphetamine, dextroamphetamine) AND • The patient's BP is adequately controlled AND • Patient's self-reported sleep log demonstrates adequate sleep opportunity per Sleep Specialist (7 to 9 hours for most patients) Initial Approval: 12 months Continued Approval: 12 Months. Confirm patient meets all above criteria. In addition, continue approval if documented beneficial effect from therapy during sleep specialist follow up in the last 6 months. Criteria for approval for somnolence associated with Obstructive Sleep Apnea (OSA): • Prescribing is restricted to sleep specialists AND • Patient has diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea (OSA) AND • Patient has received standard treatment for underlying airway obstruction (e.g., continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BIPAP]) for at least one month prior to initiating Sunosi AND • Patient will continue using above treatment modality (CPAP or BIPAP) for duration of therapy with Sunosi OR patient has a documented intolerance to CPAP or BIPAP AND a. If using CPAP: Patient's CPAP recording demonstrates adequate sleep opportunity per Sleep Specialist (7-9 hours is required for most patients) AND • Patient has tried and failed modafinil and armodafinil AND

Drug	Prior Authorization Criteria
	• Patient's BP is adequately controlled Initial approval: 12 months Continued approval: 12 months. Confirm patient meets all above criteria. In addition, continue approval if documented beneficial effect from therapy during sleep specialist follow up in the last 6 months.

Supprelin LA (Histrelin) implant	**Candidates for Supprelin LA (histrelin) should meet ALL the following criteria**:
	
	• Prescribed by or in consultation with Pediatric Endocrinologist. Pediatric Endocrinology referral approved by KPGA.
	• Age ≥ 2 years
	• Diagnosis of ONE of the following:
	  ○ Central precocious puberty confirmed by ALL of the following:
	  ▪ Measurement of blood concentrations of total sex steroids (estrogens/testosterone)
	  ▪ Measurement of LH and FSH after stimulation with a GnRH analog
	  ▪ Assessment of bone vs. chronological age **OR**
	  ○ Gender dysphoria diagnosed by pediatric endocrinology who has confirmed:
	  ▪ The adolescent has demonstrated long-lasting or intense pattern of gender nonconformity or gender dysphoria
	  ▪ Gender dysphoria worsened with the onset of puberty
	  ▪ That puberty has started in the adolescent
	  ▪ No medical or psychological/social contraindications to GnRH agonist treatment
	• Failed (failure defined as the inability to suppress physical signs of puberty), intolerant, or allergic to Lupron Depot AND Eligard
	
	Approval Duration: 1 year
	
	Dosing:
	Children ≥2 years: 50 mg implant surgically inserted every 12 months. Discontinue at the appropriate time for the onset of puberty (if used for central precocious puberty).

Symdeko (Tezacaftor/ Ivacaftor)	**Candidates for treatment with Symdeko should meet ALL the following criteria**: • Confirmed diagnosis of cystic fibrosis (CF) • Prescribed by a pulmonologist • Age ≥ 6 years • Homozygous for *F508del* mutation OR • At least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to Symdeko:

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>
<table>
<tr><th colspan="6">List of CFTR Gene Mutations that Produce CFTR Protein and are Responsive to Symdeko</th></tr>
<tr><td>E56K</td><td>R117C</td><td>A455E</td><td>S945L</td><td>R1070W</td><td>3272-26A→G</td></tr>
<tr><td>P67L</td><td>E193K</td><td>F508del*</td><td>S977F</td><td>F1074L</td><td>3849+10kbC→T</td></tr>
<tr><td>R74W</td><td>L206W</td><td>D579G</td><td>F1052V</td><td>D1152H</td><td></td></tr>
<tr><td>D110E</td><td>R347H</td><td>711+3A→G</td><td>K1060T</td><td>D1270N</td><td></td></tr>
<tr><td>D110H</td><td>R352Q</td><td>E831X</td><td>A1067T</td><td>2789+5G→A</td><td></td></tr>
<tr><td colspan="6">*A patient must have two copies of the F508del mutation or at least one copy of a responsive mutation presented in the table above to be indicated.</td></tr>
</table>

○
Patient is not currently taking a strong CYP3A4 Inducer (e.g., rifampin, St. John’s wort, rifabutin, phenobarbital, carbamazepine, and phenytoin)

<u>Initial Approval</u>: 12 months

<u>Continued Approval</u>: 12 months. Confirm patient meets all above criteria. In addition, continue approval if:

Patient has documented evidence of response to therapy (e.g., improvement or stable ppFEV1, improvement in BMI, decrease in pulmonary exacerbations) AND
ALT/AST levels have been checked within the last 3 months (ALT/AST should be monitored at baseline, every three months for one year, then once yearly thereafter).
In the event of significant elevations of transaminases, e.g., patients with ALT or AST > 5 X upper limit of normal or ALT or AST > 3x upper limit of normal with concomitant bilirubin > 2x upper limit of normal, therapy should be temporarily discontinued. Following the resolution of transaminase elevations consider the benefits and risks of resuming treatment.

<u>Ordering Information:</u>
Symdeko is available through the KP Specialty Pharmacy. Prescribers must complete the KP Specialty Pharmacy Symdeko Drug Order Form at http://pharmacyprod.appl.kp.org/kp-cms/California/DrugInformation/ViewMedSafetyDNMgmtCA.aspx?I32Object=1787&nodeValue=113# and fax it to KP-Specialty Pharmacy (1-650-301-5790).
</td></tr>
<tr><td>Synarel
(Nafarelin)</td><td>Candidates for nafarelin should meet ALL the following criteria:

Criteria for central precocious puberty:

Prescribed by Pediatric Endocrinologist. Pediatric Endocrinology referral approved by KPGA.

</td></tr>
</table>

	• Age ≥ 2 years and < 13 years
	• Diagnosis of central precocious puberty confirmed by ALL of the following:
	  ○ Measurement of blood concentrations of total sex steroids (estrogens/testosterone)
	  ○ Measurement of LH and FSH after stimulation with a GnRH analog
	  ○ Assessment of bone age vs. chronological age
	• Failed (failure defined as the inability to suppress physical signs of puberty), intolerant, or allergic to Lupron Depot AND Eligard.
	• Age ≥ 2 years and < 13 years
	
	Initial Approval Duration: 12 months
	
	Continued Approval: 12 months if patient meets the following requirements:
	• Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in growth velocity and bone age advancement, and improvement in final height prediction.
	• Absence of unacceptable toxicity from the drug. (i.e., convulsions, development or worsening of psychiatric symptoms, etc.).
	• Will not be used in combination with growth hormone.
	• Patient is less than 13 years of age.
	
	Criteria for endometriosis:
	
	• Female AND age ≥ 18 years
	• Documented diagnosis of endometriosis
	• Prescribed by Ob-Gyn
	• Documented minimum three-month trial, intolerance, OR contraindication to each of the following (use of drugs can occur simultaneously):
	  ○ One combined oral contraceptive AND
	  ○ One progestin-only therapy (Depo-Provera, Levonorgestrel-releasing IUD, progestin only pill) AND
	  ○ Lupron Depot or similar GnRH agonist AND
	  ○ Myfembree (relugolix, estradiol, and norethindrone) or Orilissa (elagolix)
	
	Reasons for Non-coverage:
	
	• Pregnancy
	• Known osteoporosis
	
	Initial Approval: 6 months
	
	Continued Approval: No continued approval based on prescribing guidance; therapy should not exceed 6 months due to decreases in bone mineral density (BMD).

Drug	Prior Authorization Criteria
	For new members who were initiated on Synarel outside of KPGA: • Patients should meet all above coverage criteria without reasons for non-coverage and total therapy should NOT exceed 6 months.

Syprine
(Trientine hydrochloride)
 	
Preferred: Trientine hydrochloride
(generic Syprine)
	Candidates for treatment with trientine hydrochloride (Syprine) should meet ALL the following criteria:
	
	• Diagnosis of Wilson's Disease (Hepatolenticular degeneration)
	• History of intolerance, failure or contraindication to penicillamine (i.e., generic Cuprimine or Depen)
	• Prescribed by a Gastroenterologist or Hepatologist
	• For brand name Syprine, must meet one of the following:
	  ○ Documented adequate trial of at least 3 months demonstrating an intolerance to generic trientine hydrochloride OR
	  ○ Documented allergy to components of generic trientine
	  ▪ Note: Intolerance is defined as increased sensitivity to the potential adverse effects of a medication.
	
	Initial approval: 12 months
	
	Continued approval: 24 months if documented positive clinical response to trientine hydrochloride (i.e., generic Syprine) therapy
	
	For new members who were initiated on trientine hcl (Syprine) outside of KPGA**:** continue approval for treatment with trientine hydrocholoride if ALL the above criteria are met.

Tabrecta
(Capmatinib)
	Candidates for Tabrecta should meet ALL of the following criteria:
	
	• Diagnosis of Non-Small Cell Lung Cancer (NSCLC)
	• Prescribed by a hematologist/oncologist
	• Documentation that disease is metastatic OR surgical resection is likely to result in severe morbidity
	• Age ≥18 years
	• Patient has ONE of the following:
	  a. Mesenchymal epithelial transition (C-MET) exon 14 skipping mutations
	  b. High-level MET amplification
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months if the patient has experienced any of the following:
	• Patient continues to meet the above criteria
	• Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread
	• Absence of unacceptable toxicity from the drug.
	  a. Examples of unacceptable toxicity include the following: interstitial lung disease (ILD), pneumonitis, severe hepatotoxicity, etc.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
Tafinlar (Dabrafenib) **PLUS** **Mekinist** (Trametinib)	**Candidates for treatment Tafinlar PLUS Mekinist should meet ALL the following criteria:** <u>Diagnosis of Glioma</u> • Prescribed by a hematologist or oncologist. • Patient is ≥1 year of age. • Cancer is positive for BRAFV600 mutation. <u>Diagnosis of Melanoma</u> • Prescribed by a hematologist or oncologist. • Patient is ≥6 years of age. • Cancer is positive for BRAF V600K or V600E mutation. • Patient has ONE of the following: o Adjuvant treatment (Combination of BRAF and MEK): Patient has stage IIB, IIC or III melanoma AND lymph node involvement following completely resection. o Patient has advanced or metastatic or unresectable melanoma (combination of BRAF and MEK) AND a documented treatment failure, intolerance, or contraindication to KP preferred regimen with vemurafenib (Zelboraf) PLUS cobimetinib (Cotellic). o Single agent Dabrafenib: Treatment of unresectable or metastatic melanoma in patients with a BRAF V600E mutation AND a documented treatment failure, intolerance, or contraindication to KP preferred regimen with vemurafenib (Zelboraf). <u>Diagnosis of non-small cell lung cancer</u> • Prescribed by a hematologist or oncologist. • Patient is ≥6 years of age. • Patient has advanced or metastatic disease. • Cancer is positive for BRAFV600E mutation. <u>Diagnosis of Thyroid Cancer</u> • Prescribed by a hematologist or oncologist. • Patient is ≥6 years of age. • Cancer is positive for BRAFV600E mutation. • Patient has ONE of the following: o Patient has locally advanced, metastatic, or unresectable anaplastic thyroid carcinoma OR o Patient has unresectable, persistent, or metastatic follicular, oncocytic or papillary thyroid carcinoma AND disease is refractory to iodine treatment. <u>Diagnosis of other solid tumors</u> • Prescribed by a hematologist or oncologist. • Patient is ≥1 years of age. • Patient has an unresectable OR metastatic solid tumor and no satisfactory alternative treatment options. • Cancer is positive BRAFV600E mutation. • Patient has a documented failure to at least one prior systemic treatment. <u>Diagnosis of Ovarian Carcinoma</u>

Drug	Prior Authorization Criteria

	• Prescribed by a gynecologist or oncologist.
	• Trametinib (Mekinist) will be used as a single agent.
	• Patient has a diagnosis of low grade, recurrent ovarian carcinoma.
	
	Reasons for non-coverage:
	• Patient with colorectal cancer because of known intrinsic resistance to BRAF inhibition, or wild-type BRAF solid tumors.
	
	Initial Approval: 12 months
	• The following quantity limits will apply:
	  ○ Tafinlar - 120 capsules per 30 days
	  ○ Mekinist 0.5 mg tablets – 90 tablets per 30 days
	  ○ Mekinist 2 mg tablets – 30 tablets per 30 days
	
	Continued Approval: 12 months. For continued approval for treatment with Tafinlar plus Mekinist, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria.
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	• Quantity limits:
	  ○ Tafinlar - 120 capsules per 30 days
	  ○ Mekinist 0.5 mg tablets – 90 tablets per 30 days
	  ○ Mekinist 2 mg tablets – 30 tablets per 30 days
	
	For new members who were initiated on Tafinlar outside of KPGA: Patient should meet ALL the following criteria:
	• Prescribed by a hematologist or oncologist.
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.

Takhzyro
(Lanadelumab-flyo)
	Candidates for treatment with Takhzyro should meet ALL the following criteria:
	• Prescribed by allergist or immunologist
	• Age ≥ 2 years
	• A diagnosis of one of the following:
	  ○ Type I hereditary angioedema (HAE) with documented C4 level below the lower limit of normal as defined by the laboratory performing the test AND C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test; OR
	  ○ Type II HAE with documented C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test with documentation provided
	• Documented use for long term HAE prophylaxis to minimize the frequency and/or severity of recurrent attacks
	• Patient has experienced HAE attacks of high severity and/or frequency (e.g., airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, or painful facial distortion) with baseline HAE attack rate of ≥ 2 attacks per 4 weeks

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• Takhzyro is NOT being used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze or Haegarda) Reasons for Non-coverage: • Treatment of angioedema acute attacks in adult and adolescent patients with HAE (Treatment for prophylaxis only) Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Approve for member to fill via the outpatient pharmacy benefit only** Continued Approval: 12 Months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, continue approval based on clinical documentation of functional improvement, a decrease in frequency of HAE attack, and an improvement in severity and duration of attacks. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **Approve for member to fill via the outpatient pharmacy benefit only** Dosing and Administration: • Children 2 to < 6 years: 150 mg every 4 weeks • Children 6 to < 12 years: 150 mg every 2 weeks • Children 12 years and older and Adults: Administer 300 mg every 2 weeks. • Dosing every 4 weeks may be considered in patients who are well controlled . • Patients may self-administer
Taltz (Ixekizumab)	**Candidates for treatment with Taltz should meet ALL the following criteria PLUS the individual disease state criteria below:** • Prescriber is a dermatologist or rheumatologist. • Medication is not being used in combination with another biologic or advanced small molecule (e.g., tofacitinib, upadacitinib, apremilast) for the same indication • Then follow the disease state specific criteria below, based on diagnosis: Criteria for diagnosis of plaque psoriasis: • Documented moderate-to-severe plaque psoriasis • Inadequate response (of at least a 3-month trial), intolerance and/or contraindication to each of the following: ○ 1 TNF inhibitor i. Preferred options: adalimumab (Amjevita [preferred], Humira), infliximab (Infliximab-dyyb/Inflectra [preferred]) ii. Others: etanercept (Enbrel), certolizumab (Cimzia) ○ 1 ustekinumab product (e.g., Yesintek [preferred], Stelara)

Drug	Prior Authorization Criteria
	○ Cosentyx ○ Tremfya ○ Skyrizi • Prescribed the maintenance dose when transitioning from another biologic agent: Taltz 80 mg every 4 weeks. If loading dose is ordered, documented clinical rationale must be provided (ie. actively flaring, BSA >50%, prior ER visits for psoriasis). • Pediatric patients (<18 years) should meet the following criteria: ○ Inadequate response, intolerance or contraindication to each of the following: i. Phototherapy + 2 topical therapies (unless contraindicated or clinical reason to avoid treatment) ii. Biologics order of preference for pediatrics: preferred ustekinumab product (Yesintek [ustekinumab-kfce]) → Cosentyx → Enbrel → Taltz <u>Criteria for psoriatic arthritis:</u> • Documented active psoriatic arthritis • Inadequate response (of at least a 3-month trial), intolerance and/or contraindication to each of the following: ○ 1 TNF inhibitor i. Infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade) ii. Adalimumab product (Amjevita [preferred], Humira) iii. Others: Golimumab (Simponi), Certolizumab (Cimzia), Etanercept (Enbrel) ○ 1 ustekinumab product unless patient has documented axial disease (Yestinek [preferred], Stelara) ○ 1 IL-17 Inhibitor (e.g., Cosentyx (secukinumab), Bimzelx (bimekizumab)) ○ 1 IL-23 Inhibitor (e.g., Tremfya (guselkumab), Skyrizi (risankizumab)) ○ 1 Janus Kinase (JAK) Inhibitor i. Tofacitinib ii. Others: Upadacitinib (Rinvoq) ○ Abatacept (Orencia) <u>Criteria for axial spondyloarthritis:</u> • Documented diagnosis of ankylosing spondylitis or nonradiographic axial spondyloarthritis (nr-axSpA) • Inadequate response (of at least a 3-month trial), intolerance and/or contraindication to each of the following: ○ 2 TNF Inhibitors: i. Infliximab product (Infliximab-dyyb/Inflectra [preferred], Remicade) ii. Adalimumab product (Amjevita [preferred], Humira) iii. Others: Golimumab (Simponi), Certolizumab (Cimzia), Etanercept (Enbrel) ○ 1 IL-17 Inhibitor: i. Secukinumab product (Cosentyx) ○ 1 Janus Kinase (JAK) inhibitor: i. Tofacitinib ii. Others: Upadacitinib (Rinvoq)

Drug	Prior Authorization Criteria
	Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for member to fill via the outpatient pharmacy benefit only** Continued Approval: 12 months. Continue approval if the following criteria are met: • For new members who were initiated outside of KPGA: Confirm patient meets all above coverage criteria without reasons for non-coverage and is confirmed to be clinically stable by a specialist during follow-up in the last 6 months. • For existing members who have previously met the criteria: Documented clinically significant benefit from the medication during specialist follow up in the last 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for member to fill via the outpatient pharmacy benefit only**
Talzenna (Talazoparib)	**Candidate for treatment with Talzenna for oncologic indications should meet ALL the following:** • Prescribed by a hematologist/oncologist • Age ≥ 18 years • Patient has diagnosis of o locally advanced or metastatic breast cancer (ALL of the following must be met): ▪ BRCA-mutation positive ▪ HER2-negative ▪ Talazoparib (Talzenna) will only be considered for use after trial and failure (e.g., intolerance, allergic reaction, disease progression) to KP's preferred PARP inhibitor, olaparib (Lynparza®), AND the same intolerance, contraindication, or adverse event would not be expected to occur with Talzenna. ▪ Talazoparib (Talzenna) will only be considered for use after trial and failure (e.g., intolerance, allergic reaction, disease progression) to KP's preferred PARP inhibitor, olaparib (Lynparza®), AND the same intolerance, contraindication, or adverse event would not be expected to occur with Talzenna. OR o Treatment of adult patients with homologous recombination repair (HRR) gene–mutated metastatic castration-resistant prostate cancer (mCRPC) in combination with Xtandi (enzalutamide) ▪ HRR gene mutations were defined as a mutation in at least 1 of 12 genes of interest (BRCA1, BRCA2, PALB2, ATM, ATR, CHEK2, FANCA, MLH1, MRE11A, NBN, RAD51C, CDK12) ▪ Patients should also receive a GnRH analog or had prior bilateral orchiectomy ▪ In the first line setting if no prior docetaxel/no prior novel hormone therapy used **OR** have progressed on prior androgen deprivation therapy (Abiraterone/prednisone) or docetaxel.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Reasons for Non-Coverage: • Patient has a history of myelodysplastic syndrome (MDS) • Patient has a history of acute myeloid leukemia (AML) Approval Period: 12 months Continued Approval: 12 months. Patients should meet ALL the following: • Patient continues to meet the above criteria; • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread; • Absence of unacceptable toxicity from therapy (any ≥ grade 3 toxicity that does not improve with dose reduction and/or holding therapy); • Females of reproductive potential only: patient will be advised to use effective contraception during therapy and for 6 months after the last dose; • Males with female partners of reproductive potential only: patient will be advised to use effective contraception during treatment and for 3 months after the last dose

Targretin gel
(Bexarotene)
	Candidates for bexarotene gel should meet ALL the following criteria:
	
	Diagnosis of cutaneous T-cell lymphoma:
	• Diagnosis of stage IA or IB cutaneous T-cell lymphoma
	• Prescribed by dermatology or oncology
	• Age ≥18 years
	• Maximum prescribed frequency is four times per day
	• Documented treatment failure, contraindication or intolerance to topical tazarotene AND at least 1 additional skin-directed therapy:
	  ○ Topical corticosteroid
	  ○ Topical imiquimod
	  ○ Topical mechlorethamine (nitrogen mustard, Valchlor)
	  ○ Topical carmustine (BiCNU)
	  ○ Electron beam radiation therapy
	  ○ Phototherapy (NB-UVB or PUVA)
	
	Initial Approval: 12 months (with quantity limit of 60 grams per 30 days).
	• **Approve for generic bexarotene gel only.**
	
	Continued Approval: 12 months (with quantity limit of 60 grams per 30 days)
	
	For new members who were initiated on bexarotene gel prior to joining KPGA: Approve generic bexarotene gel if patient is confirmed to be clinically stable on it by a specialist in the last 6 months and meets full criteria above.
	
	For existing members who have previously met the full criteria above: Approve generic bexarotene gel after confirming:
	• Patient continues to meet the full criteria above

Drug	Prior Authorization Criteria
	• There is documentation of disease stabilization or no disease progression during specialist follow-up in the past 6 months.

Tarpeyo (Budesonide)	**Candidates for treatment with Tarpeyo must meet ALL the following criteria:**
	
	• Age ≥ 18 years
	• Prescribed by nephrologist
	• Documented diagnosis of IgA nephropathy (IgAN) verified by renal biopsy
	• Blood pressure ≤ 150/100
	• Currently prescribed maximum tolerated dose of one of the following for at least 3 months or documented intolerance, contraindication
	  ○ ACE I OR
	  ○ ARB
	• Currently prescribed SGLT2i (e.g., Jardiance, dapagliflozin) for at least 3 months or documented intolerance, contraindication
	
	• High risk of disease progression as defined urine protein-to-creatine ratio (UPCR) > 1.5 and eGFR ≥ 35 mL/min
	• eGFR ≥ 35 mL/min
	
	Initial Approval: 6 months. Quantity limit of 4 capsules per day or 120 capsules per 30-day supply will apply.
	
	Continued Approval: 3 months. The recommended duration of therapy is 9 months. Patient must meet all criteria above without reasons for Non-coverage and Documented clinically significant reduction in proteinuria (~30-50% from baseline)
	
	Reasons for Non-coverage:
	• Dialysis or has undergone kidney transplant
	• Active TB infection
	• Severe hepatic impairment (Child-Pugh Class C)
	• Previously treated with Tarpeyo for 9 months

Tascenso ODT (Fingolimod Lauryl Sulfate)	**Candidates for Tascenso ODT should meet ALL of the following criteria:** • Prescribed by a neurologist • Documented diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease • Age 10-17 years AND weight ≤ 40 kg and needs 0.25 mg daily dose • Patient is unable to swallow fingolimod capsules OR • Patient/provider is unable to obtain fingolimod 0.25 mg capsules (this strength is available only through the manufacturer's limited distribution program) Reasons for Non-coverage: • A recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure

Drug	Prior Authorization Criteria
	• A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a functioning pacemaker • A baseline QTC interval of 500 msec or above • Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol) Initial Approval: 12 months Continued Approval: 12 months
Tasigna (Nilotinib)	**Nilotinib (generic Tasigna) will only be considered for use after a trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction) to KP's preferred TKIs, imatinib or dasatinib (OR when there is a medical contraindication to the preferred product, imatinib or dasatinib).** **Candidates for treatment with Nilotinib for hematologic/oncologic indications should meet all the following:** • Prescribed by a hematologist/oncologist • Requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines • Patient has a diagnosis of one of the following: ○ Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) ▪ Age ≥ 1 year ▪ Confirmed by molecular testing by the detection of the Ph chromosome or BCR-ABL gene prior to initiation of therapy ▪ If the patient has had prior therapy with a TKI (e.g., imatinib, dasatinib) then ONE of the following requirements must be met: • Resistance to prior therapy with TKI ○ T315I mutation negative • Toxicity or intolerance to prior therapy with a TKI ○ Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) ▪ Age ≥ 18 years ▪ Confirmed by molecular testing by the detection of the Ph chromosome or BCR-ABL gene prior to initiation of therapy ▪ If the patient has had prior therapy with a TKI (e.g., imatinib, dasatinib) then ONE of the following requirements must be met: • Resistance to prior therapy with TKI ○ T315I mutation negative • Toxicity or intolerance to prior therapy with a TKI ○ Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) post hematopoietic stem cell transplant (HSCT) ▪ Age ≥ 18 years ▪ After achieving complete response to induction therapy

Drug	Prior Authorization Criteria
	▪ Confirmed by molecular testing by the detection of the Ph chromosome or BCR-ABL gene prior to initiation of therapy ▪ If the patient has had prior therapy with a TKI (e.g., imatinib, dasatinib) then ONE of the following requirements must be met: • Resistance to prior therapy with TKI ○ T315I mutation negative • Toxicity or intolerance to prior therapy with a TKI ○ Gastrointestinal Stromal Tumor (GIST) ▪ Age ≥ 18 years ▪ Disease progression after imatinib, sunitinib, AND regorafenib OR intolerance/contraindication to imatinib, sunitinib, AND regorafenib • For requests for brand name Tasigna, patient has tried generic nilotinib and had an intolerance or allergic reaction that is likely due to the **inactive** components of the generic medication and cannot be explained by other clinical or lifestyle factors. ○ If the request for coverage of brand Tasigna is based upon disease progression or side effects due to the active ingredient nilotinib (e.g., GI issues, hair loss, rash, fatigue, headache, muscle pain / spasms, etc) the request will be denied unless member meets the full criteria. ○ If the physician's request for coverage of brand Tasigna is based upon the physician's and/or member's unwillingness to change to a preferred alternative, the request will be denied unless the member meets the full criteria. <u>Reasons for Non-coverage:</u> • T315I mutation positive <u>Approval period</u>: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval for prescriptions for BRAND Tasigna (excluding Pharmacy Consult Service).** a. Approval from the Physician Program Director of QRM or AAMD is not required for approvals for nilotinib (generic Tasigna). <u>Continued Approval:</u> 12 months. Patient should meet all the following requirements: • Member continues to meet the above criteria AND • Continues to be seen by a hematologist/oncologist AND • Member is responding positively to therapy as defined by stabilization of disease/lack of disease progression or decrease in size of tumor or tumor spread AND • Absence of unacceptable toxicity from the drug AND • NO dual therapy with another tyrosine kinase inhibitor • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval for prescriptions for BRAND Tasigna (excluding Pharmacy Consult Service).** • Approval from the Physician Program Director of QRM or AAMD is not required for approvals for nilotinib (generic Tasigna).

Drug	Prior Authorization Criteria

Tavalisse
(Fostamatinib)
	Candidates for treatment with Tavalisse should meet ALL the following criteria:
	
	• Diagnosis of chronic immune thrombocytopenia (ITP)
	• Prescribed by a hematologist/oncologist
	• At least 18 years of age
	• History of failure, contraindication, or intolerance to Corticosteroids AND at least TWO of the following:
	  ○ Immunoglobulins
	  ○ Splenectomy
	  ○ Thrombopoietin receptor antagonists (e.g.,Promacta)
	  ○ Rituxan (rituximab) or rituximab biosimilar
	
	Initial approval period: 6 months
	
	Continued approval: 12 months. Confirm patient meets all above criteria. In addition, continue approval with documentation of a positive clinical response to Tavalisse therapy.

Tavneos
(Avacopan)
	Candidates for Tavneos should meet ALL of the following criteria:
	
	• Age ≥ 18 years
	• Prescribed by a Rheumatologist, Nephrologist, or Pulmonologist
	• Clinical diagnosis of anti-neutrophil cytoplasmic autoantibody (ANCA) vasculitis (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]), ANCA-positive vasculitis.
	• Positive test for anti-PR3 or anti-MPO (proteinase 3 or myeloperoxidase antibodies) or positive tissue biopsy
	• History of significant intolerance to steroid or relative contraindication to steroid per prescriber judgement (factoring in comorbidities and other clinical considerations) OR
	• Patient requires a decrease in cumulative steroid dose due to steroid-induced complications.
	• Documented baseline labs:
	  ○ Liver function test (ALT, AST, alkaline phosphatase, and total bilirubin)
	  ○ Hepatitis B (HBV) Serology
	  ○ eGFR (estimated glomerular filtration rate)
	  ○ CRP (C-Reactive Protein)
	• Pregnancy test, if of childbearing potential
	
	Reasons for Non-coverage:
	• Diagnosis of eosinophilic granulomatosis with polyangiitis (EPGA)
	• Active, serious infection, including localized infections
	• Active, untreated and/or uncontrolled chronic liver disease (i.e severe hepatic impairment (Child-Pugh C) and includes Hepatitis B or Hepatitis C)
	• Pregnant or breast-feeding
	
	Initial Approval: 6 months

Drug	Prior Authorization Criteria
	Continued Approval: Additional 6 months for a total of 52 weeks of treatment if all criteria above is met and patient does not meet any of the criteria for discontinuation listed below: Criteria for Discontinuation: • Patient has reached 52 weeks of avacopan treatment • Inadequate response or serious intolerance to medication as determined by treating physician • ALT or AST >5x ULN, or if patient develops transaminases >3x ULN with elevation of bilirubin >2x ULN ○ Avacopan should be stopped until avacopan-induced liver injury is ruled out. • Uncontrolled serious infection • Angioedema occurs • HBV reactivation occurs • Non-adherence to medication, recommended diet and lifestyle measures, or follow-up labs and assessments.

Tecfidera
(Dimethyl Fumarate)
 	
Preferred:
 	
Dimethyl fumarate (generic Tecfidera)
Available on the COM formulary
	Candidates for treatment with Tecfidera should meet ALL the following criteria:
	
	• Prescribed by a neurologist
	• Age ≥ 18 years
	• Documented diagnosis of relapsing multiple sclerosis (MS)
	• Patient has tried generic dimethyl fumarate, monomethyl fumarate (Bafiertam) AND diroximel fumarate (Vumerity) and experienced a clinical reaction that cannot be explained by other clinical or lifestyle factors and may be due to the **inactive** components of the generic dimethyl fumarate product
	  ○ Note: if the request for coverage of brand Tecfidera is based upon disease progression or side effects that are due to the active ingredient dimethyl fumarate (e.g., GI intolerance, flushing, liver function test abnormalities, lymphopenia) the request will be denied unless the member meets this full criteria
	  ○ Note: if the physician's request for coverage of brand Tecfidera is based upon the physician's and/or member's unwillingness to change to a preferred alternative, the request will be denied unless the member meets the full criteria
	• Documented persistent or severe intolerance or relative contraindication to ALL therapeutic alternatives: interferon beta 1b (Betaseron), glatiramer acetate (Glatopa) and teriflunomide
	• CBC within the past 6 months shows normal WBC and lymphocyte counts
	• For females of child-bearing age (12-50 years), a baseline negative pregnancy test within the past month AND either a prescription for birth control (IUD or other contraceptive) or documentation of the patient declining contraception and being counseled of the potential risk of pregnancy
	
	Reasons for Non-coverage:

Drug	Prior Authorization Criteria
	Tecfidera should NOT be used in patients with any of the following: • Lymphocyte count < 0.5 x 10^9/L for over 6 months • Signs and symptoms of serious infection • JCV antibody positive, previously treated with Tysabri and sustained lymphocyte count < 0.8 x 10^9/L on two or more lab tests over ≥ 3 months. • ALT or AST elevation 3X normal or higher or severe liver disease • Pregnancy Initial Approval: 1 year Continued Approval: 1 year **For new members who were initiated on Tecfidera outside of KPGA:** patient must meet the full criteria above for approval of Tecfidera. **For existing members who have previously met the full criteria above:** continue approval for treatment with Tecfidera if ALL the following criteria are met: • Documented beneficial effect from therapy during neurology follow up • Confirmed trial and failure of generic dimethyl fumarate and all preferred alternatives as described above • CBC with differential including lymphocyte count obtained 6 months after initiation of treatment then at least once every 12 months • Lymphocyte count > 0.5 x 10^9/L • No signs and symptoms of serious infection • Confirmed trial of preferred agents generic dimethyl fumarate, Bafiertam (monomethyl fumarate) and Vumerity (diroximel fumarate)

Tecvayli
(Teclistamab-cqyv)
	Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.
	
	Candidates for treatment with Tecvayli should meet all the following criteria:
	• Patient is 18 years of age or older
	• Prescribed by a Hematologist/Oncologist certified in the Tecvayli REMS program (registration available at TECVAYLI REMS)
	• Documented diagnosis of relapsed or refractory multiple myeloma
	• Patient has received at least four prior lines of therapy, including at least ONE drug from each of the following categories:
	  ○ A proteasome inhibitor (e.g. bortezomib, ixazomib, carfilzomib, etc.) AND
	  ○ An immunomodulatory agent (e.g., lenalidomide, thalidomide, etc.) AND
	  ○ An anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc.).
	
	• Patient has received at least four prior lines of therapy, including at least ONE drug from each of the following categories:

Drug	Prior Authorization Criteria
	○ A proteasome inhibitor (e.g., bortezomib, ixazomib, carfilzomib, etc.) AND ○ An immunomodulatory agent (e.g., lenalidomide, thalidomide, etc.) AND ○ An anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc.). • Patient has not received prior treatment with any B-cell maturation antigen (BCMA) targeted therapy (e.g., idecabtagene vicleucel (Abcema), ciltacabtagene autoleucel (Carvykti), elranatamab-bcmm (Elrexfio), etc). Initial approval**:** 12 months • Cycle 1 may be approved for administration at a KP-affiliated inpatient facility. • Subsequent cycles should be approved for back-office administration in a KP-infusion center ONLY. • **NOTE:** If patient experiences a treatment delay >14 days, an additional cycle may be approved for administration at a KP-affiliated inpatient facility for therapy re-initiation. • **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Continued approval**:** 12 months. Confirm patient meets above criteria. In addition, patient should meet the following: • Criteria above met • No evidence of disease progression or unacceptable toxicity. • **Approve for back-office administration in a KP-infusion center ONLY.** ○ **NOTE:** If patient experiences a treatment delay >14 days, an additional cycle may be approved for administration at a KP-affiliated inpatient facility for therapy re-initiation. • **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Dosing and Administration: • For SUBQ administration only. • The recommended dosage of Tecvayli includes step-up doses of 0.06 mg/kg on Day 1 and 0.3 mg/kg on Day 4, followed by the first treatment dose of 1.5 mg/kg on Day 7. Tecvayli is administered once weekly by a healthcare provider thereafter, until disease progression or unacceptable toxicity. • Patients should be hospitalized for 48 hours after administration of the step-up doses and the first treatment dose. Pretreatment medication is given prior to each step-up dose and the first treatment dose.
Tempo Personalized Diabetes Management Platform	Candidates for Tempo products must meet **ALL** the following criteria: • Prescribed by endocrinologist ○ Endocrinology team provides education/training on proper use • Documented diagnosis of diabetes

Drug	Prior Authorization Criteria

Tempo Smart Button
 	
Tempo Welcome Kit
 	
Tempo Refill Kit
 	
Tempo Pens include Lyumjev Tempo Pen, Basaglar Tempo Pen, Humalog Tempo Pen
	• Age ≥ 18 years
	• Documentation patient has access to a device with the ability to install and use TempoSmart App (e.g., smartphone, tablet)
	• Treatment program including at least three insulin injections per day requiring self-adjustments of insulin dose for at least 6 months
	• Inadequate BG control despite multiple daily insulin injections as documented by at least one of the following:
	  ○ A1C ≥ 7%
	  ○ Recurrent hypoglycemic events (BG <70) in the past month
	  ○ History of severe glycemic excursions
	  ○ Dawn phenomenon with fasting sugars >200 mg/dL routinely
	• Medical rationale of need for smart device with electronic dose documentation to achieve and maintain A1C control, rather than standard insulin vial or pen
	  ○ MUST document trial of preferred insulin (e.g., glargine-yfgn, Kirsty) with inadequate BG control
	• **Coverage is NOT authorized for patients with existing coverage for an insulin pump device.**
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. Confirm patient continues to meet all criteria above without reasons for non-coverage **AND**
	
	• Documented improved glycemic control as evidenced by A1C improvement or decrease in glycemic variability.
	Note:
	• For new members who were initiated outside for KPGA: Confirm patient meets all above criteria for continued approval.
	
	Reasons for non-coverage:
	• Existing coverage/use of insulin pump
	• Ineligible for Lyumjev (insulin lispro-aabc), Basaglar (insulin glargine) or Kirsty
	• Tempo Smart Button is only compatible with the 3 insulins listed.

Tepezza
(Teprotumumab-trbw)
	Candidates for treatment with Tepezza should meet ALL the following criteria:
	
	**Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).*
	
	• Prescribed by an Oculoplastic Surgeon
	• Age ≥18 years
	• Confirmed diagnosis of active thyroid eye disease (TED) by an Oculoplastic Surgeon
	• Clinical Activity Score (CAS) ≥4 (on the 7-item scale) (refer to the EUGOGO Atlas for CAS criteria)
	• Moderate-to-severe active TED (not sight-threatening but has an appreciable impact on daily life), associated with at least one of the following documented:
	  ○ lid retraction ≥2 mm
	  ○ moderate or severe soft tissue involvement

Drug	Prior Authorization Criteria
	○ exophthalmos ≥3 mm above normal for race and gender ○ intermittent or constant diplopia • Inadequate response, intolerance, or contraindication to either of the following, with or without radiation therapy: ○ IV methylprednisolone plus oral mycophenolate mofetil* OR ○ High dose IV methylprednisolone* ▪ NOTE: Refer to the EUGOGO 2021 clinical practice guidelines for specific dose and regimen • Patient is euthyroid • Patient agrees to use adequate contraception if female of reproductive potential, initiated prior to treatment and continued for 6 months post-treatment • If patient is steroid refractory, documented inadequate response, intolerance, or contraindication to at least 1 of the following: ○ orbital decompression ○ tocilizumab ○ rituximab • Baseline Hb1AC, thyroid function test, thyroid stimulating immunoglobulins • Baseline screening for HIV, Hepatitis B, and Hepatitis C • Baseline pregnancy test if of childbearing potential Reasons for Non-coverage: • Patient is an active smoker • HbA1C >9% • Clinically inactive disease or mild disease (e.g., decrease in CAS of ≥2 points or decrease in proptosis of ≥2 mm from baseline to treatment initiation) • Presence of sight threatening complications (i.e., corneal ulceration, dysthyroid optic neuropathy, and or globe subluxation) • Pre-existing inflammatory bowel disease (IBD) • Pregnancy or breastfeeding • Current drug or alcohol abuse (within 6 months prior to treatment) • Malignant condition in the past 12 months (except for successfully treated basal/squamous cell carcinoma of the skin) • Untreated or uncontrolled human immunodeficiency virus (HIV), hepatitis C or hepatitis B infection. Initial Approval Period: 4 infusions • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Continued Approval: Additional 4 infusions for a total treatment duration of 8 infusions if patient continues to meet full criteria above AND does not meet any of the criteria for discontinuation listed below. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Criteria for discontinuation: • Patient develops symptoms consistent with inflammatory bowel disease • Documented worsening of TED after at least 8 weeks of treatment • No improvement in TED after 4 doses of teprotumumab • Development of hearing impairment after initiation of teprotumumab • Intolerance to medication • Non-adherence to medication administration, follow-up labs, or assessments • Pregnancy is diagnosed or woman is breastfeeding Dosing and Administration: • 10 mg/kg for the first infusion followed by 20 mg/kg every 3 weeks for 7 additional infusions (total of 8 infusions). • Administer each intravenous (IV) infusion over 60 to 90 minutes. • Requires infusion clinic administration
Tepmetko (Tepotinib)	**Candidates for Tepmetko should meet ALL of the following criteria:** • Diagnosis of Non-Small Cell Lung Cancer (NSCLC) • Prescribed by a hematologist/oncologist • Documentation that disease is metastatic OR surgical resection is likely to result in severe morbidity • Age ≥ 18 years • Patient's disease has a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping. • Documented failure, intolerance, or contraindication to Tabrecta (capmatinib). Initial Approval: 6 months Continued Approval: 12 months if the patient has experienced any of the following: • Patient continues to meet the above criteria • Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread • Absence of unacceptable toxicity from the drug. ○ Examples of unacceptable toxicity include the following: interstitial lung disease (ILD), pneumonitis, severe hepatotoxicity, etc.
Testosterone Products **Aveed** (Testosterone undecanoate)	**Candidates for testosterone undecanoate (Aveed, Jatenzo, Kyzatrex, Tlando) should meet ALL the following criteria:** • Documented diagnosis of primary hypogonadism or hypogonadotrophic hypogonadism confirmed by labs ○ Serum testosterone concentrations measured in the morning on 2 separate days and these serum concentrations are below normal range (<300 ng/dL)

Drug	Prior Authorization Criteria

Jatenzo (Testosterone undecanoate)
 	
Kyzatrex (Testosterone undecanoate)
 	
Tlando (Testosterone undecanoate)
	• Age ≥ 18 years to < 65 years
	• Prescribed by endocrinologist
	• Inadequate treatment response after documented adequate therapeutic trial (defined as minimum of 6 weeks and total testosterone <400 ng/dL) of **all** of the following unless contraindication/intolerance:
	  ○ Testosterone 1.62% gel pump or packets
	  ○ Testosterone cypionate or depo-testosterone intramuscular injection
	  ○ Testosterone transdermal solution
	  ○ Androderm 4 mg patches
	
	Initial Approval: 6 months
	
	Continued Approval: 12 months. Confirm patients meets coverage criteria and does not have any reasons for Non-coverage AND
	
	• Adequate response to therapy as demonstrated by testosterone levels of >400-600 ng/dL total testosterone from lab within past 6 months
	
	Reasons for Non-coverage:
	
	• Breast cancer or suspected prostate cancer
	• Pregnancy. Testosterone may cause fetal harm.
	• Hypogonadal conditions not associated with structural or genetic etiologies.
	• Blood pressure is not adequately controlled (>140/90, BP should be repeated within 3 weeks of initiating therapy or changing dose)
	• Age ≥ 65 years. There is no data in this population.
	• Indication is age related low testosterone
	
	Ordering information (Aveed only):
	• Aveed is available only through a restricted program called the Aveed REMS Program

Tezspire (Tezepelumab-ekko)	**Candidates for treatment with Tezspire (tezepelumab-ekko) should meet ALL the following criteria:**
	
	Criteria for asthma:
	• Prescribed by a Pulmonologist or an Allergist
	• Age ≥ 12 years
	• Patient has a diagnosis of severe persistent asthma
	• Patient has had uncontrolled severe asthma in the past 12 months, demonstrated by one of the following:
	  ○ Two or more asthma exacerbations requiring treatment with oral corticosteroids (OCS) for > 3 days
	  ○ One or more asthma exacerbations requiring hospitalization, or an emergency room visit
	• Patient has one of the following:

Drug	Prior Authorization Criteria
	○ Severe eosinophilic asthma with an inadequate response (after a 4-month trial), allergy, or intolerance to Fasenra (benrazlizumab [preferred]) ○ Severe allergic asthma with an inadequate response (after a 4-month trial), allergy, or intolerance to Xolair (omalizumab) ○ Severe asthma with non-eosinophilic and non-allergic phenotype and OCS dependent* with an inadequate response (after a 4-month trial), allergy, or intolerance to Dupixent (dupilumab) ○ Severe asthma with non-eosinophilic and non-allergic phenotype and not OCS dependent* *NOTE: OCS dependent is two or more asthma exacerbations requiring oral (e.g., prednisone) or systemic corticosteroids (e.g., IM triamcinolone and/or IV methylprednisolone) in the past 12 months • Patient has uncontrolled severe asthma despite ALL of the following: ○ Documented trigger avoidance measures ○ Comorbidities that can cause asthma exacerbations (e.g., gastroesophageal reflux disease [GERD], allergic rhinitis, or sinusitis) ○ Documented adherence therapy under bullet 6d [MRAR ≥ 80%. If MRAR < 80%, reviewer can confirm adherence in the last ≥ 6 months based on medication sold dates found in KPHC medication tab (e.g., 6 one month fills or two 90-day fills)]) ○ Aggressive drug therapy regimen including one of the following: ▪ If diagnosis of non-eosinophilic and non-allergic phenotype and OCS dependent: high-dose inhaled corticosteroid (ICS) plus a long-acting beta-agonist (LABA) combination [e.g., fluticasone 500 mcg/salmeterol 50 mcg (Wixela Inhub) 1 puff twice daily or Advair HFA (fluticasone 230mcg/salmeterol 21mcg) 2 puffs twice daily] AND ➢ OCS dependent (i.e., two or more asthma exacerbations requiring oral or systemic steroids in the past 12 months) ▪ If diagnosis of non-eosinophilic and non-allergic phenotype and not OCS dependent: high-dose inhaled corticosteroid (ICS) plus a long-acting beta-agonist (LABA) combination [e.g., fluticasone 500 mcg/salmeterol 50 mcg (Wixela Inhub) 1 puff twice daily or Advair HFA (fluticasone 230mcg/salmeterol 21mcg) 2 puffs twice daily] **AND** ➢ Daily use of a long-acting muscarinic antagonist (LAMA) [e.g., Spiriva (tiotropium)] **OR** ➢ Leukotriene receptor antagonist (LTRA) (e.g., montelukast) • Tezspire (tezepelumab-ekko) is used with a high-dose (or maximally tolerated) ICS and at least one additional asthma controller medication, such as a LABA, LRTA, LAMA • NOT currently receiving another biologic used for the treatment of asthma [e.g., Fasenra (benralizumab), Dupixent (dupilumab), Nucala (mepolizumab), Xolair (omalizumab), or Cinqair (resilizumab)] Reasons for Non-coverage:

Drug	Prior Authorization Criteria

	• Concurrent use of live vaccines
	• Treatment of other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease
	• Pre-existing or untreated helminth parasitic infection
	• Relief of acute bronchospasm or status asthmaticus
	
	Initial Approval: 4 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	• **APPROVE FOR PREFILLED PEN ONLY for member to fill via the outpatient pharmacy benefit only. PREFILLED SYRINGE AND VIAL NOT FOR OUTPATIENT USE.**
	
	Continued Approval: 12 months if the member continues to meet **ALL** criteria above and meets any of the following below:
	• Reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath
	• Decrease in administration of rescue medication, short acting beta agonist – e.g., albuterol inhaler or albuterol nebulizing solution
	• Decrease in exacerbation frequency (no increase in ICS dose or OCS dose)
	• Increase in predicted FEV1 from the pretreatment baseline
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	• **APPROVE FOR PREFILLED PEN ONLY for member to fill via the outpatient pharmacy benefit only. PREFILLED SYRINGE AND VIAL NOT FOR OUTPATIENT USE.**
	
	Criteria for chronic rhinosinusitis with Nasal Polyps (CRSwNP):
	• Prescribed by Otolaryngologist or Allergist
	• Age ≥ 12 years
	• Otolaryngologist or Allergist documentation of bilateral nasal polyposis after full endoscopic sinus surgery
	• History of failure, intolerance, or contraindication to all of the following after full endoscopic sinus surgery:
	  ○ Two or more short courses of systemic corticosteroids in the last 12 months
	  ○ Intranasal steroid spray or rinse (i.e., fluticasone, triamcinolone, mometasone spray and/or budesonide rinse) for 3 months
	  ○ Montelukast for 3 months
	  ○ Dupixent AND THEN Nucala AND THEN Xolair for 6 months
	• Not currently receiving any of the following:
	  ○ Dupixent, Xolair, Fasenra, Nucala, Cinqair, or Adbry
	• Patient will continue a nasal corticosteroid with Tezspire unless contraindicated or intolerance to nasal corticosteroids.

Drug	Prior Authorization Criteria
	Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **APPROVE FOR PREFILLED PEN ONLY for member to fill via the outpatient pharmacy benefit only. There is not an elevated risk for anaphylaxis with patient self-administration that warrants observed injection. PREFILLED SYRINGE AND VIAL NOT FOR OUTPATIENT USE.** Continued Approval: 12 months. For continued approval for treatment with Tezspire, patient should meet ALL the following criteria: • **For new members who were initiated on Tezspire outside of KPGA:** confirm patient meets all the above criteria without reasons for non-coverage. • **For existing members who previously met the full criteria above:** patient must have completed an appointment with an Otolaryngologist or Allergist with documented clinically significant benefit within the last 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **APPROVE FOR PREFILLED PEN ONLY for member to fill via the outpatient pharmacy benefit only. PREFILLED SYRINGE AND VIAL NOT FOR OUTPATIENT USE.** Dosage and Administration: • Pre-filled syringe and vial: For administration by healthcare provider only • Pre-filled pen: For administration by patient and/or patient caregiver

Tibsovo
(Ivosidenib)
	Candidates for treatment with Tibsovo should meet ALL the following criteria:
	
	Criteria for Acute Myeloid Leukemia
	• Diagnosis of acute myeloid leukemia (AML) with an IDH1 mutation
	• Prescribed by hematology/oncology.
	• Age ≥ 18 years
	• Patient has ONE of the following:
	  ○ Disease is relapsed or refractory OR
	  ○ New diagnosis of AML in patients with ONE of the following:
	  ▪ Age >75 years
	  ▪ Comorbidities that preclude the use of intensive induction chemotherapy
	  ▪ Age >60 years and not a candidate or declines intensive induction chemotherapy.
	  ▪ Age >60 years and receiving post-induction therapy following response to previous lower intensity therapy.

Drug	Prior Authorization Criteria

	Criteria for Biliary Tract Cancer
	• Diagnosis of cholangiocarcinoma with IDH1 mutation
	• Prescribed by hematology/oncology.
	• Age ≥ 18 years
	• Disease is ONE of the following:
	  ○ Locally advanced
	  ○ Unresectable
	  ○ Metastatic
	• Disease has progressed on or after at least one prior systemic chemotherapy regimen
	
	Criteria for Bone Cancer
	• Diagnosis of chondrosarcoma with IDH1 mutation
	• Prescribed by hematology/oncology.
	• Age ≥ 18 years
	• Disease is ONE of the following:
	  ○ Conventional (grades 1-3)
	  ○ Dedifferentiated
	
	Reasons for Non-coverage:
	• Unable to swallow whole tablets
	• Several renal impairment (eGFR <30 mL/min/1.73m^2)
	• Renal impairment requiring dialysis
	• Moderate to severe hepatic impairment (total bilirubin ≥1.5X ULN and any value for AST)
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. Continued approval for treatment with Tibsovo should meet ALL of the criteria above in addition to the criteria below:
	• Patient does not show evidence of progressive disease while on Tibsovo therapy.
	• Absence of significant toxicity (e.g., development of Guillain-Barre syndrome, QTc prolongation with sign and symptoms of life-threatening arrhythmia, etc)
	• Continued monitoring by Hematology/Oncology

Zepbound (Tirzepatide) - Weight Loss Treatment **Preferred:** **Zepbound KwikPen** **Non-preferred:**	**Candidates for treatment with the preferred Tirzepatide product (Zepbound KwikPen) for weight loss should meet ALL the following criteria:** Mounjaro is NOT interchangeable with Zepbound for weight loss. Zepbound is the only tirzepatide product approved for weight loss. • Must verify the Member's Benefits to confirm in a Plan with Class III (formerly morbid obesity) Rider AND documented **in office** baseline body weight taken within the past 1 month. A patient reported weight documented/added to vitals in a video/telephone/secure

Drug	Prior Authorization Criteria

Zepbound Prefilled Single-Dose Pen	message is **NOT** acceptable.
	• Age ≥ 18 years
	• Prescribed by a Kaiser Permanente affiliated Endocrinologist, Weight Management Specialist, Adult Medicine or Family Medicine Clinician
	• For adults, whose current baseline body weight recorded in the office meets or exceeds calculated body mass index (BMI)
	  ○ BMI ≥ 40 kg/m^2 with or without comorbid conditions OR
	  ○ BMI ≥ 35 kg/m^2 with at least one weight-related comorbid condition, such as Type 2 diabetes, hypertension, ASCVD defined as acute coronary syndromes, MI, stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, TIA, carotid stenosis ≥50%, or symptomatic peripheral arterial disease presumed to be of atherosclerotic origin, congestive heart failure, chronic kidney disease stage 3 or higher and/or severe obstructive sleep apnea (using standard hypopnea scoring rules, with apnea-hypopnea index [AHI-4%] ≥ 30) on valid sleep study within the past 5 years AND current weight within 5% of weight at time of study.
	• Documented contraindication,* intolerance or failure to lose and maintain ≥ 5% body weight after a 3-month trial **to at least 2 of the following**:
	  ○ Phentermine* or diethylpropion
	  ○ Qsymia* (phentermine/topiramate ER) or separate prescriptions
	  ○ Contrave (naltrexone/bupropion) or separate prescriptions
	  ○ Orlistat (common formulations include Alli, Xenical)
	• Documented contraindication, intolerance, or failure to lose and maintain ≥ 5% body weight after a minimum 4-month trial of ONE of the following:
	  ○ Wegovy HD 7.2 mg weekly
	  ○ Semaglutide (Wegovy or Ozempic) at maximally tolerated dose if unable to titrate further
	• Not currently using another GLP-1 RA agents (i.e., Victoza, Ozempic, Rybelsus), GLP-1 RA/GIP agents (i.e. Mounjaro), or DPP-4 inhibitors (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin)
	
	Initial Approval: 6 months
	First Continued Approval: 6 months
	Continued Approval: 12 months (after first 6-month continued approval)
	
	Continued Approvals: Ensure patient has achieved ≥ 8% weight loss from baseline weight by 6 months or ≥ 15% weight loss from baseline weight by 12 months as documented **in office** visit encounter. A patient reported weight documented in a video/telephone/secure message is **NOT** acceptable. Do not consider baseline BMI.
	• For patients who are currently on Mounjaro subcutaneous formulation, approve for preferred Zepbound KwikPen.
	
	For new members who were initiated on tirzepatide outside of KPGA: Patients should continue to meet all above coverage criteria except for baseline BMI and switched to preferred GLP-1 RA.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	*Maintained on a stimulant medication for **ADHD** is a contraindication to phentermine use. Phentermine contraindicated with uncontrolled HTN (blood pressure >140/90 mmHg on 2 or more appropriately dose adjusted HTN meds), hx of ASCVD, hyperthyroidism, glaucoma, agitated states, hx of drug abuse. If phentermine/Qsymia is contraindicated, patients aged 18 or older must trial Contrave (or separate prescriptions) and Orlistat unless contraindication or intolerance.

Tirzepatide Products - Diabetes Indication
 	
Zepbound KwikPen or Mounjaro
	Candidates for treatment with tirzepatide for type 2 diabetes should meet ALL the following criteria:
	
	• Prescribed by a Kaiser Permanente affiliated Endocrinologist, Adult Medicine or Family Medicine clinician
	• Age requirements:
	  ○ Patient age ≥ 18 years for Zepbound
	  ○ Patient age ≥ 10 years for Mounjaro
	• Documented diagnosis of Type 2 diabetes
	• A1C within 2% of designated goal after completion of required 3-month medication trials and within the past 3 months. If on one of the insulin regimens noted below, A1C above goal is acceptable.
	  ○ A1C goal <7% OR
	  ○ A1C goal < 8% if:
	  ▪ Age ≥ 65 years OR
	  ▪ Age 18-64 years with dementia, blindness, lower extremity amputation, CKD 4/5, ESRD, cardiomyopathy/CHF, or cardiovascular disease (acute coronary syndromes, history of MI, stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, TIA, carotid stenosis ≥ 50%, or symptomatic peripheral arterial disease presumed to be of atherosclerotic origin)
	
	• Patient is currently taking **ALL of the following agents for ≥ 3 months** with MRAR ≥ 80%* unless documented intolerance or contraindication:
	  ○ Metformin at maximally tolerated dose (optimal dose 1500 to 2000 mg daily)
	  ▪ If GI intolerance with metformin IR, must document trial of metformin SR titrated to maximally tolerated dose
	  ○ SGLT-2 inhibitor (e.g., dapagliflozin, Jardiance)
	  ○ **ONE of the following** insulin regimens:
	  ▪ Basal insulin (e.g., glargine, NPH) at a dose of ≥ 0.5 units/kg/day
	  ▪ Basal/bolus insulin regimen (e.g., glargine/NPH PLUS Kirsty/Humulin R) at a dose of ≥ 1.5 units/kg/day
	  ▪ Any regimen with a total daily dose of ≥ 200 units daily
	  ▪ U-500 insulin use
	  ▪ Insulin pump use
	• Documented contraindication, intolerance or failure to achieve ≥ 0.8% A1C lowering or A1C goal after at least a 3-month trial to at least **TWO of the following** preferred GLP-1 agonists (only liraglutide required if patient age 10-17):
	  ○ Liraglutide (Victoza) 1.8 mg subq daily or maximally tolerated dose (NF review required)
	  ○ Semaglutide (Ozempic) 2 mg subq weekly or 9 mg orally daily or maximally tolerated dose (QRM review required)

Drug	Prior Authorization Criteria
	○ Semaglutide (Rybelsus R1 formulation) 14 mg orally daily or (Rybelsus R2 formulation) 9 mg orally daily or maximally tolerated dose (QRM review required) ○ Note: If failure to achieve ≥ 0.8% A1C lowering or A1C goal after at least a 3-month trial to Ozempic 2 mg weekly, trial of liraglutide (Victoza) or Rybelsus not required. • Not currently using another GLP-1 RA agent (i.e., Victoza, Ozempic, Wegovy), GLP-1 RA/GIP agent (i.e., Zepbound), or DPP-4 inhibitor (medications containing alogliptin, linagliptin, saxagliptin, or sitagliptin) Initial approval period: 6 months. Patient must obtain A1C after initiating therapy. Continued approval: 1 year. Ensure current A1C shows documented lowering of 1% from initial A1C or A1C now at designated goal. For new members who were initiated outside of KPGA: Confirm patient meets all coverage criteria and A1C within 2% of or at designated goal *If MRAR < 80%, reviewer can confirm adherence in the last 90 days based on medication sold dates found in Health Connect medication tab (e.g., 3 one-month fills or one 90-day fill).
Tivdak (Tisotumab vedotin-tftv)	**Candidates for treatment with Tivdak should meet ALL of the following criteria:** • Prescribed by Hematologist/ Oncologist • Patient is ≥18 years of age • Diagnosis of recurrent or metastatic cervical cancer • Failure of single-agent or combination chemotherapy regimen, with or without bevacizumab (e.g., cisplatin/paclitaxel/bevacizumb, cisplatin/paclitaxel, cisplatin alone), unless contraindicated or clinically significant adverse effects are experienced • Prescribed as single agent therapy • Patient has a baseline ophthalmology exam (e.g., visual acuity and slit lamp), prior to each dose and as clinically indicated Reasons for Non-coverage: • Concurrent use with other anticancer therapy • Dosing exceeds single dose limit of Tivdak 2 mg/kg (up to maximum of 200 mg for weight ≥100 kg) • Patient has known coagulation defect leading to an increased risk of bleeding • Patient has a history of Stephens-Johnsons Syndrome Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, must meet criteria below: • Patient does not show evidence of progressive disease while on Tivdak therapy

Drug	Prior Authorization Criteria
	• Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: grade 3 or peripheral neuropathy, hemorrhage, recurrent or persistent grade 2 or greater pneumonitis, keratitis, conjunctival ulceration, etc. • Patient has been adherent to premedication and required eye care before, during, and after infusion. • Continued monitoring by Hematology/Oncology • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** <u>For new members who were initiated outside of KPGA:</u> • Hematologist or oncologist visit • The patient is confirmed stable on therapy, and safety screenings have been ordered or completed • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • <u>For existing members who have previously met the full criteria above:</u> • Documented beneficial effect during Hematologist/Oncologist visit • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**

Trastuzumab Products*
 	
Preferred:
*Hercessi (Trastuzumab-strf)
 	
*QRM review not required)
 	
Non-Preferred Trastuzumab Products (listed by order of preference):
 	
Ogivri (Trastuzumab-dkst)
 	
Trazimera (Trastuzumab-qyyp)
 	
Ontruzant (Trastuzumab-dttb)
	Candidates for treatment with a non-preferred trastuzumab product should meet ALL the following criteria:
	
	Non-preferred trastuzumab products will only be considered for use after trial and failure (e.g., intolerance, allergic reaction, disease progression, infusion reaction) to KP's preferred therapy, Hercessi (trastuzumab-strf) AND the same intolerance, contraindication, or adverse event would not be expected to occur with the non-preferred trastuzumab product.
	
	<u>CRITERIA FOR NON-PREFERRED TRASTUZUMAB PRODUCTS USE FOLLOWING BIOSIMILAR (Hercessi) USE:</u>
	• Patient was previously stable on the reference product for a duration of at least 3 infusion
	• Patient has received at least 2 infusion of the formulary preferred biosimilar with one of the following:
	  ○ Increased side effects or development of a new side effect not previously experienced with the reference product
	  ○ Side effect(s) must be grade 2 or 3 persists despite interventions to mitigate occurrence of side effect(s)
	  ○ Loss of efficacy with formulary biosimilar after objective findings on physical exam or lab abnormalities
	• Patient meets disease state specific criteria below.
	
	<u>SIDE EFFECT GRADING, PER COMMON TERMINOLOGY CRITERIA FOR ADVERSE EVENTS (CTCAE):</u>
	• Grade 1: mild, asymptomatic or mild symptoms; clinical or diagnostic observations only;

Drug	Prior Authorization Criteria

Kanjinti (Trastuzumab-anns)
 	
Herzuma (Trastuzumab-pkrb)
 	
Herceptin (Trastuzumab)
	intervention not indicated
	• Grade 2: moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living
	• Grade 3: severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living
	• Grade 4: life-threatening consequences; urgent intervention indicated
	• Grade 5: death related to adverse event
	
	<u>Disease specific criteria for use in Breast Cancer (all of the following criteria must be met):</u>
	• Diagnosis of HER2-positive breast cancer; AND
	• Prescribed by an oncologist; AND
	• Age ≥ 18 years; AND
	• Baseline left ventricular ejection fraction (LVEF) within normal limits; AND
	• Patient must have one of the following (a or b) AND
	  ○ Dose does NOT exceed* 8 mg/kg IV for adjuvant therapy OR 4 mg/kg IV for treatment of metastatic disease
	  ○ Dose/product is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must provide supporting evidence).
	  ○ **Prescribed regimen must be FDA-approved or recommended by NCCN*
	• Used as adjuvant therapy in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.) OR as a single agent following anthracycline-based therapy; OR
	• Used as neoadjuvant therapy for breast preservation in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.); OR
	• Used for treatment of leptomeningeal metastases via intrathecal route; OR
	• Used for recurrent or metastatic disease; AND
	  ○ Used as a single agent in patients who have received one or more prior treatments for metastatic disease; OR
	  ○ Used in first-line therapy in combination with paclitaxel; OR
	  ○ Used in combination with endocrine therapy in patients with hormone-receptor positive disease; AND
	  i. Patient is post-menopausal; OR
	  ii. Patient is pre-menopausal and is treated with ovarian ablation/suppression; OR
	  iii. Patient is a male receiving concomitant suppression of testicular steroidogenesis; OR
	  ○ Used in combination with cytotoxic chemotherapy OR lapatinib OR pertuzumab and a taxane as first-line therapy OR pertuzumab as subsequent therapy in patients who were previously treated with trastuzumab without pertuzumab; AND
	  i. Disease is hormone receptor-negative; OR
	  ii. Disease is hormone receptor-positive and used with or without endocrine therapy
	
	<u>Approval period:</u>

Drug	Prior Authorization Criteria

	Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).
	• 12 months may be granted for the following:
	  ○ Neoadjuvant treatment of HER2-positive breast cancer a non-referred trastuzumab product is used as a component of or in combination with a chemotherapy regimen that includes docetaxel or paclitaxel
	• 12 months may be granted for the following:
	  ○ Adjuvant treatment of HER2-postiive breast cancer when all of the following are met:
	  ▪ A non-preferred trastuzumab product is used as a component of, in combination with, or following a chemotherapy regimen, with or without pertuzumab
	  ▪ If a non-preferred trastuzumab product is used with pertuzumab, a pertuzumab-containing regimen was not used as neoadjuvant therapy
	  ○ Leptomeningeal metastases from HER2-positive breast cancer
	  ○ Treatment of HER2-postive metastatic or recurrent breast cancer when any of the following criteria sets are met:
	  ▪ A non-preferred trastuzumab product is used as a single agent in a member who has been previously treated with one or more chemotherapy regimens for metastatic disease
	  ▪ Member has an ER-positive disease and a non-preferred trastuzumab product is used with an aromatase inhibitor (e.g., letrozole, anastrozole, exemestane) in a postmenopausal woman
	  ▪ Member has HR-negative or endocrine-therapy refractory disease and meets either of the following:
	  • A non-preferred trastuzumab product is used in combination with chemotherapy with or without pertuzumab
	  • A non-preferred trastuzumab product is used in combination with lapatinib or pertuzumab, without chemotherapy, and the member has been previously treated with trastuzumab
	
	<u>Disease specific criteria for use in Gastric, Esophageal and Esophagogastric Junction Cancer:</u>
	• Diagnosis of HER2-positive metastatic gastric, esophageal, or EGJ adenocarcinoma
	• Prescribed by an oncologist
	• Age ≥ 18 years
	• A non-preferred trastuzumab product is used in combination with any of the following chemotherapy regimens:
	  ○ Cisplatin and fluorouracil
	  ○ Cisplatin and capecitabine
	• Dose does not exceed* 8 mg/kg IV OR
	• Dose/product is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must provide supporting evidence).
	**Prescribed regimen must be FDA-approved or recommended by NCCN*
	
	<u>Approval period</u>: 12 months
	Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Disease specific criteria for use in Endometrial Carcinoma or Uterine Cancer (off label): • Diagnosis of HER2-positive endometrial cancer with serous histology • Prescribed by an oncologist • Age ≥ 18 years • Disease is advanced (e.g., stage III/IV) or recurrent • Prescribed in combination with carboplatin and paclitaxel • Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for relevant off-label use (prescriber must provide supporting evidence) Approval period: 12 months **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued approval: • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** ALL indications: • Member continues to meet the above criteria without reasons for Non-coverage AND • Member is responding positively to therapy as defined by stabilization or disease or decrease in size of tumor or tumor spread AND • Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: cardiotoxicity (e.g., left ventricular dysfunction; cardiomyopathy, etc.), pulmonary toxicity (e.g., pneumonitis), neutropenia, infusion related reactions, etc.; AND o LVEF has not had an absolute decrease of >16% from pre-treatment baseline and is within the institutional normal limits; OR o LVEF has not had an absolute decrease of >10% from pre-treatment baseline and is below the institutional normal limits AND • Use in the neo-adjuvant and adjuvant setting is limited to a total of 52 weeks of treatment
Tremfya (Guselkumab)	**Candidates for treatment with Tremfya should meet ALL the following criteria PLUS the individual disease state criteria that follow:** • Prescribed by a dermatologist, rheumatologist, or gastroenterologist • Then follow the disease state specific criteria below, based on diagnosis: Diagnosis of Plaque Psoriasis: • Age ≥ 6 years and weight ≥ 40 kg • Documented moderate-to-severe plaque psoriasis • Inadequate response (of at least a 3-month trial), intolerance and/or contraindication to ALL of the following:

Drug	Prior Authorization Criteria
	○ Adalimumab product (Amjevita [preferred]) ○ Ustekinumab product (Yesintek [preferred] ○ Cosentyx (secukinumab) • Prescribed Tremfya 100mg every 8 weeks (without loading dose) for patients transitioning from another biologic therapy. If loading dose is ordered, documented clinical rationale must be provided (e.g., actively flaring, BSA >50%, prior ER visits for psoriasis). Diagnosis of Psoriatic Arthritis: • Age ≥ 6 years and weight ≥ 40 kg • Inadequate response (of at least a 3-month trial), intolerance, and/or contraindication to ALL of the following: ○ 1 TNF inhibitor (e.g., Infliximab (Inflectra [preferred), Remicade), adalimumab (Amjevita [preferred], Humira), etanercept (Enbrel)) ○ Cosentyx (secukinumab) • Inadequate response (of at least 3-month trial), intolerance, and/or contraindication to the following (unless there is documented axial disease): ○ Ustekinumab product (Yesintek [preferred], Stelara) Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for member to fill via the outpatient pharmacy benefit only** Continued Approval: 12 months. Continue approval if the following criteria are met: For new members who were initiated on Tremfya outside of KPGA: Confirm patient meets all medication trials in the initial coverage criteria AND has a documented clinically significant benefit during Specialist follow-up in the last 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for member to fill via the outpatient pharmacy benefit only** For existing members who have previously met the full criteria above: Documented clinically significant benefit from the medication during Specialist follow up in the last 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for member to fill via the outpatient pharmacy benefit only** Diagnosis of ulcerative colitis (UC) • Age ≥ 18 years • Documented moderately to severely active ulcerative colitis • Not prescribed in combination with another biologic agent

Drug	Prior Authorization Criteria

	• Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to the following:
	  ○ Infliximab product (e.g. Inflectra [preferred])
	  ○ Ustekinumab product (e.g. Yesintek [preferred])
	  ○ Xeljanz (tofacitinib) (preferred JAK-inhibitor) OR Rinvoq (upadacitinib). If patient is pregnant, Xeljanz or Rinvoq trial is NOT required.
	
	<u>Diagnosis of Crohn's Disease (CD)</u>
	• Age ≥ 18 years
	• Documented moderately to severely active Crohn's disease
	• Not prescribed in combination with another biologic agent
	• Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to the following:
	  ○ Infliximab product (e.g. Inflectra [preferred])*
	  ○ Adalimumab product (e.g. Amjevita [preferred])*
	  ○ Ustekinumab product (e.g. Yesintek [preferred])
	  ○ Entyvio (vedolizumab) trial not required in CD, if documentation of small bowel, perianal or fistulizing / penetrating disease
	  ○ Rinvoq (upadacitinib). If patient is pregnant, Rinvoq trial is NOT required.
	  ○ *Patient must try/fail all of the agents listed above unless provider documents rationale why additional anti-TNF agent is inappropriate (i.e. primary or secondary non-response despite therapeutic drug level +/- presence of anti-drug antibodies or adverse effect requiring a different mechanism of action, member temporarily located outside of our KP network and cannot receive infusions)
	
	<u>Pediatric criteria for Crohn's disease and ulcerative colitis:</u>
	**Note: not FDA-approved for pediatric IBD conditions*
	• Age < 18 years
	• Patient has had a negative interferon-gamma release assay test for TB infection within the past 24 months or is positive for latent TB and has completed treatment in the past or is currently on treatment
	• Documented inadequate response with or loss of response, intolerance or contraindication to infliximab product (Inflectra preferred)
	  ○ Provider should optimize dose, 5-10 mg/kg and consider dose interval change (q4 weeks)n Adequate therapeutic trial of at least 2 infusions
	• Documented inadequate response (after at least a 3-month trial to each following agent), intolerance or contraindication to ALL of the following:
	  ○ an adalimumab product (Amjevita preferred) and
	  ○ an ustekinumab product (Yesintek preferred)
	• Documented inadequate response with or loss of response, intolerance or contraindication to vedolizumab
	
	<u>Initial Approval for CD or UC:</u> 12 months

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • **<u>Induction (adults):</u> Approve for member to fill via the outpatient pharmacy benefit only** • **<u>Induction (pediatric):</u> Tremyfa 200mg intravenous infusion. Approve intravenous dose given in KP facility only at Week 0, Week 4, and Week 8** • **<u>Maintenance (adults and pediatric):</u> Approve for member to fill via the outpatient pharmacy benefit only** <u>Continued approval for UC or CD (adults and pediatrics)</u>: 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** • <u>For new members (who were initiated outside of KPGA) and existing members :</u> Documented clinical benefit (asymptomatic or in remission) from therapy, by a gastroenterology specialist within the past 12 months.

Treprostinil products (listed in order of preference)
 	
Tyvaso (Treprostinil) Inhalation Solution
 	
Tyvaso (Treprostinil) DPI Institutional or Maintenance Kit
 	
Tyvaso (Treprostinil) DPI Titration Kit
 	
Yutrepia (Treprostinil)
	Candidates for treprostinil should meet ALL the following criteria:
	
	<u>Pulmonary arterial hypertension WHO Group 1:</u>
	• Prescribed by a pulmonologist or pulmonary arterial hypertension (PAH) specialist
	• Age ≥ 18 years
	• Diagnosis of pulmonary arterial hypertension World Health Organization (WHO) Group 1 confirmed by right heart catheterization with physician documentation of WHO/New York Heart Association (NYHA) Functional Class III or IV symptoms
	• Documented failure of, contraindication, or intolerance to at least 2 of the following regimens including ambrisentan+PDE5 and Adempas (riociguat) (in order of preference):
	  ○ Ambrisentan (Letairis) [preferred endothelin receptor antagonist (ERA)] + PDE5 inhibitor (e.g., Sildenalfil [Revatio] or Tadalafil [Adcirca])
	  ○ Other oral ERA (e.g., Bosentan [Tracleer], Macitentan [Opsumit]) + PDE5 inhibitor (e.g., Sildenafil [Revatio], Tadalafil [Adcirca])
	  ○ Oral cGMP stimulator (e.g., riociguat [Adempas])
	• NOT using in combination with another prostacyclin analogue/prostanoid (e.g., Treprostinil or Selexipag)
	
	<u>Pulmonary hypertension associated with interstitial lung disease (PH-ILD) WHO Group 3:</u>
	• Prescribed by a pulmonologist or pulmonary arterial hypertension (PAH) specialist
	• Age ≥ 18 years
	• Diagnosis of pulmonary hypertension associated with interstitial lung disease (ILD) (WHO) Group 3) secondary to idiopathic interstitial pneumonia (IIP), idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema, and WHO Group 3 connective tissue disease
	• A documented trial of Yutrepia required

Drug	Prior Authorization Criteria
	<table><tr><th></th><th>PREFERRED Yutrepia (Treprostinil)</th><th>TYVASO (Treprostinil) DPI[4]</th></tr><tr><td>Availability</td><td>26.5, 53, 79.5, 106 mcg caps for inhalation</td><td>16, 32, 48, 64 cartridges for inhalation</td></tr><tr><td>Target Dose</td><td>79.5-106 mcg 4 times per day in two breaths per dose</td><td>48-64 mcg 4 times per day in a single breath per dose</td></tr><tr><td>Breaths per Dose</td><td>Two breaths per dose</td><td>Single breath per dose</td></tr><tr><td rowspan="4">Equivalent* Dose (mcg)</td><td>26.5</td><td>16</td></tr><tr><td>53</td><td>32</td></tr><tr><td>79.5</td><td>48</td></tr><tr><td>106</td><td>64</td></tr></table> Initial Approval: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued approval: For new members who were initiated outside of KPGA: 12 months. Confirm patient meets all above coverage criteria without reasons for non-coverage and documented clinical benefit from therapy as evidenced by disease stability or improvement noted during specialist follow up in the last 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** For existing members who have previously met the full criteria above: 12 months. Documented clinical benefit from therapy as evidenced by disease stability or improvement noted during specialist follow up in the last 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
Trikafta (Elexacaftor/Teza-caftor/Ivacaftor and Ivacaftor)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** **Candidates for treatment with Trikafta should meet ALL of the following criteria:** • Prescribed by adult or pediatric pulmonology (or other designated specialist) with expertise in providing cystic fibrosis (CF) care • Confirmed diagnosis of CF • Age 2 years or older • Documentation of at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on in vitro data (see table 1)

Drug	Prior Authorization Criteria

- Not being used in combination with another CFTR potentiator [i.e. Kalydeco (ivacaftor), Orkambi (ivacaftor/lumacaftor), Symdeko (ivacaftor/tezacaftor)]

Table 1: List of CFTR Gene Variants Responsive to Trikafta

**Note: Refer to the Trikafta Prescribing Information for additional FDA-approved CFTR gene variants that may not be listed below.*

Variants responsive to TRIKAFTA based on clinical data*				
2789+5G→A	*D1152H*†	*L206W*†	*R1066H*†	*S945L*†
3272-26A→G	*F508del*†	*L997F*†	*R117C*†	*T338I*†
3849+10kbC→T	*G85E*†	*M1101K*†	*R347H*†	*V232D*†
A455E†	*L1077P*†	*P5L*†	*R347P*†	

Variants responsive to TRIKAFTA based on in vitro data‡				
1140-1151dup	*E264V*	*H620P*	*N396Y*	*S1251N*
1461insGAT	*E282D*	*H620Q*	*N418S*	*S1255P*
1507_1515del9	*E292K*	*H939R*	*N900K*	*S13F*
2055del9	*E384K*	*H939R;H949L*	*P1013H*	*S13P*
2183A→G	*E403D*	*H954P*	*P1013L*	*S158N*
2851A/G	*E474K*	*I1023R*	*P1021L*	*S182R*
293A→G	*E527G*	*I1027T*	*P1021T*	*S18I*
3007del6	*E56K*	*I105N*	*P111L*	*S18N*
3132T→G	*E588V*	*I1139V*	*P1372T*	*S308P*
3141del9	*E60K*	*I1203V*	*P140S*	*S341P*
3143del9	*E822K*	*I1234L*	*P205S*	*S364P*
314del9	*E92K*	*I1234V del6aa*	*P439S*	*S434P*
3331del6	*F1016S*	*I125T*	*P499A*	*S492F*
3410T→C	*F1052V*	*I1269N*	*P574H*	*S50P*
3523A→G	*F1074L*	*I1366N*	*P67L*	*S519G*
3601A→C	*F1078S*	*I1366T*	*P750L*	*S531P*
3761T→G	*F1099L*	*I148L*	*P798S*	*S549I*
3791C/T	*F1107L*	*I148N*	*P988R*	*S549N*
3850G→A	*F191V*	*I148T*	*Q1012P*	*S549R*
3978G→C	*F200I*	*I175V*	*Q1209P*	*S557F*
546insCTA	*F311del*	*I331N*	*Q1291H*	*S589I*
548insTAC	*F311L*	*I336K*	*Q1291R*	*S589N*
A1006E	*F312del*	*I336L*	*Q1313K*	*S624R*
A1025D	*F433L*	*I444S*	*Q1352H*	*S686Y*
A1067P	*F508C*	*I497S*	*Q151K*	*S737F*
A1067T	*F508C;S1251N*	*I502T*	*Q179K*	*S821G*
A1067V	*F508del;R1438W*	*I506L*	*Q237E*	*S898R*
A107G	*F575Y*	*I506V*	*Q237H*	*S912L*
A1081V	*F587I*	*I506V;D1168G*	*Q237P*	*S912L;G1244V*
A1087P	*F587L*	*I521S*	*Q30P*	*S912T*
A120T	*F693L(TTG)*	*I530N*	*Q359K/T360K*	*S955P*
A1319E	*F87L*	*I556V*	*Q359R*	*S977F*
A1374D	*F932S*	*I586V*	*Q372H*	*S977F;R1438W*
A141D	*G1047D*	*I601F*	*Q493L*	*T1036N*
A1466S	*G1047R*	*I618N*	*Q493R*	*T1053I*
A155P	*G1061R*	*I618T*	*Q552P*	*T1057R*
A234D	*G1069R*	*I807M*	*Q98P*	*T1086A*
A234V	*G1123R*	*I86M*	*Q98R*	*T1086I*
A238V	*G1173S*	*I980K*	*R1048G*	*T1246I*
A309D	*G1237V*	*K1060T*	*R1066G*	*T1299I*
A349V	*G1244E*	*K162E*	*R1070P*	*T1299K*
A357T	*G1244R*	*K464E*	*R1070Q*	*T351I*
A455V	*G1247R*	*K464N*	*R1070W*	*T351S*
A457T	*G1249E*	*K522E*	*R1162L*	*T351S;R851L*
A462P	*G1249R*	*K522Q*	*R1162Q*	*T388M*
A46D	*G1265V*	*K951E*	*R117C;G576A;R668C*	*T465I*
A534E	*G126D*	*L1011S*	*R117G*	*T501A*
A554E	*G1298V*	*L102R;F1016S*	*R117H*	*T582S*

Drug	Prior Authorization Criteria

A566D	*G1349D*	*L1065R*	*R117L*	*T908N*
A62P	*G149R;G576A;R668C*	*L1227S*	*R117L;L997F*	*T990I*
A872E	*G178E*	*L1324P*	*R117P*	*V1008D*
c.1367_1369dupTTG	*G178R*	*L1335P*	*R1239S*	*V1010D*
C225R	*G194R*	*L137P*	*R1283G*	*V1153E*
C491R	*G194V*	*L1388P*	*R1283M*	*V11I*
C590Y	*G213E*	*L1480P*	*R1283S*	*V1240G*
C866Y	*G213E;R668C*	*L159S*	*R1438W*	*V1293G*
D110E	*G213V*	*L15P*	*R170H*	*V1293I*
D110H	*G226R*	*L15P;L1253F*	*R248K*	*V1415F*
D110N	*G239R*	*L165S*	*R258G*	*V201M*
D1152A	*G253R*	*L167R*	*R297Q*	*V232A*
D1270N	*G27E*	*L210P*	*R31C*	*V317A*
D1270Y	*G27R*	*L293P*	*R31L*	*V322M*
D1312G	*G314E*	*L320V*	*R334L*	*V392G*
D1377H	*G314R*	*L327P*	*R334Q*	*V456A*
D1445N	*G424S*	*L32P*	*R347L*	*V456F*
D192G	*G437D*	*L333F*	*R352Q*	*V520I*
D192N	*G461R*	*L333H*	*R352W*	*V562I*
D373N	*G461V*	*L346P*	*R516S*	*V562I;A1006E*
D426N	*G463V*	*L441P*	*R553Q*	*V562L*
D443Y	*G480C*	*L453S*	*R555G*	*V591A*
D443Y;G576A;R668C	*G480D*	*L467F*	*R600S*	*V603F*
D529G	*G480S*	*L558F*	*R668C*	*V754M*
D565G	*G500D*	*L619S*	*R709Q*	*V920L*
D567N	*G545R*	*L633P*	*R74Q*	*V920M*
D579G	*G551A*	*L636P*	*R74Q;R297Q*	*V93D*
D58H	*G551D*	*L88S*	*R74Q;V201M;D1270N*	*W1098C*
D58V	*G551R*	*L927P*	*R74W*	*W1282G*
D614G	*G551S*	*L967F;L1096R*	*R74W;D1270N*	*W1282R*
D651H	*G576A*	*L967S*	*R74W;R1070W;D1270N*	*W202C*
D651N	*G576A;R668C*	*L973F*	*R74W;S945L*	*W361R*
D806G	*G576A;S1359Y*	*M1137R*	*R74W;V201M*	*W496R*
D836Y	*G622D*	*M1137V*	*R74W;V201M;D1270N*	*Y1014C*
D924N	*G622V*	*M1210K*	*R74W;V201M;L997F*	*Y1032C*
D979A	*G628A*	*M150K*	*R751L*	*Y1032N*
D979V	*G628R*	*M150R*	*R75L*	*Y1073C*
D985H	*G930E*	*M152L*	*R75Q*	*Y1092H*
D985Y	*G970D*	*M152V*	*R75Q;L1065P*	*Y109H*
D993A	*G970S*	*M265R*	*R75Q;N1088D*	*Y109N*
D993G	*G970V*	*M348K*	*R75Q;S549N*	*Y122C*
D993Y	*H1054D*	*M394L*	*R792G*	*Y1381H*
E1104K	*H1079P*	*M469V*	*R792Q*	*Y161C*
E1104V	*H1085P*	*M498I*	*R810G*	*Y161D*
E1126K	*H1085R*	*M952I*	*R851L*	*Y161S*
E116K	*H1375N*	*M952T*	*R933G*	*Y301C*
E116Q	*H1375P*	*M961L*	*S1045Y*	*Y563N*
E1221V	*H139L*	*N1088D*	*S108F*	*Y89C*
E1228K	*H139R*	*N1195T*	*S1118F*	*Y913S*
E1409K	*H146R*	*N1303I*	*S1159F*	*Y919C*
E1433K	*H199Q*	*N1303K*	*S1159P*	
E193K	*H199Y*	*N186K*	*S1188L*	
E217G	*H609L*	*N187K*	*S1235R*	

Initial Approval: 12 months

- **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.**

Continued Approval: 12 months. Confirm patient meets all above coverage criteria. Do not continue if ALT or AST > 5 X ULN or ALT or AST > 3 x ULN with bilirubin > 2 X ULN. In addition, must have documentation of at least one of the following:

- Patient has improved, maintained or shown a less than expected decline in pulmonary health as demonstrated by reduced pulmonary exacerbations
- Patient has improved or maintained nutritional health as demonstrated by an increase or less than expected declined in BMI

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• Prescriber attests to patient having a clinically meaningful response to therapy • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.**

Trodelvy (Sacituzumab govitecan-hziy)	**Candidates for Trodelvy should meet ALL of the following criteria:**
	
	<u>Diagnosis of triple negative breast cancer:</u>
	• Prescribed by an oncologist or hematologist
	• Age ≥ 18 years
	• Diagnosis of recurrent, unresectable, or metastatic triple negative breast cancer (mTNBC)
	• Patient meets **ONE** of the following:
	  ○ Tumor is positive for PD-L1 **AND** Trodelvy will be used in combination with pembrolizumab OR pembrolizumab and berahyaluronidase alpha-pmph **OR**
	  ○ Documentation patient is NOT a candidate for PD-1 or PD-L1 inhibitor therapy **AND** Trodelvy will be used a monotherapy
	  ▪ <u>NOTE:</u> examples of PD-1 and PD-L1 therapy include: pembrolizumab, nivolumab, cemiplimab, dostarlimab, tislelizumab, toripalimab, retifanlimab, atezolizumab, durvalumab, avelumab, cosibelimab
	
	<u>Diagnosis of hormone receptor (HR)-positive and human epidermal growth factor 2 (HER2)-negative breast cancer:</u>
	• Prescribed by an oncologist or hematologist
	• Prescribed by an oncologist or hematologist
	• Age ≥ 18 years
	• Diagnosis of locally advanced or metastatic HR-positive/HER2-negative breast cancer
	• Patient has a documented treatment failure, intolerance, or contraindication to ALL of the following:
	  ○ Endocrine based therapy (e.g., anastrozole, letrozole, fulvestrant, etc) **AND**
	  ○ A CDK4/6 inhibitor (e.g., abemaciclib, palbociclib, ribociclib, etc) **AND**
	  ○ At least two additional systemic therapies
	  ▪ <u>NOTE:</u> Examples of systemic therapies include, but are not limited to: cisplatin, carboplatin, doxorubicin, cyclophosphamide, paclitaxel, docetaxel, capecitabine, gemcitabine, ixabepilone, vinorelbine, eribulin, epirubicin, liposomal doxorubicin, atezolizumab + albumin-bound paclitaxel, etc
	
	<u>Initial Approval:</u> 12 months
	• **Approve for administration ONLY in KPGA infusion center, absent director level approval**
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	<u>Continued Approval:</u> 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage. In addition, confirm patient meets ALL the following:
	• **Approve for administration ONLY in KPGA infusion center, absent director level approval**
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**

Drug	Prior Authorization Criteria
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread • Absence of unacceptable toxicity from therapy (any ≥ grade 3 toxicity that does not improve with dose reduction and/or holding therapy)

Truqap
(Capivasertib)
	Candidates for treatment with capivasertib should meet ALL the following criteria:
	
	For locally advanced or metastatic breast cancer
	• Prescribed by an oncologist
	• Age ≥ 18 years
	• Diagnosed with locally advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, with one of the following mutations: PIK3CA, AKT1, or PTEN
	• Truqap will be used in combination with Faslodex (fulvestrant)
	• Patient has ONE of the following:
	  ○ Documented disease progression on an endocrine-based regimen (e.g., letrozole, anastrozole, tamoxifen) with or without a CDK4/6 inhibitor (e.g., ribociclib, palbociclib, or abemaciclib) in the metastatic setting
	  ○ Documented disease recurrence on or within 12 months of completing adjuvant therapy with an endocrine-based regimen (e.g., letrozole, anastrozole, tamoxifen) with or without a CDK4/6 inhibitor (e.g., ribociclib, palbociclib, or abemaciclib).
	For metastatic castrate sensitive prostate cancer
	• Prescribed by an oncologist
	• Age <u>> 18 years</u>
	• Diagnosed with metastatic castrate sensitive or known as androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer that is **PTEN-deficient** as detected by an FDA-authorized test
	• In combination with abiraterone and prednisone
	
	<u>Reasons for Non-Coverage:</u>
	• Pregnancy or lactation
	
	<u>Initial Approval Period</u>: 12 months with a quantity limit of 64 tablets per 28 days.
	
	<u>Continued Approval Period</u>: 12 months if patient meets ALL the initial criteria above and patient does not show evidence of progressive disease on Truqap therapy.
	• Quantity Limit: 64 tablets per 28 days

Trutakna (atacicept-vymj)	**Candidates for treatment with Trutakna should meet ALL the following criteria:** • Prescribed by nephrologist • Age <u>></u> 18 years • Documented diagnosis of IgA nephropathy (IgAN) verified by renal biopsy • High risk of disease progression defined by urine protein-to-creatinine (UPCR) >1.5

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	• eGFR >/= 30 mL/min
	• Proteinuria ≥1 g/day
	• Blood pressure ≤ 150/100 mmHg
	• Currently prescribed maximum tolerated dose of one of the following for at least 3 months or documented intolerance/contraindication to:
	  ○ ACEI (e.g., lisinopril, benazepril) OR
	  ○ ARB (e.g., losartan, valsartan)
	• Currently prescribed SGLT2i (e.g., Jardiance, dapagliflozin) for at least 3 months or documented intolerance, contraindication
	• Inadequate response (trial of at least 3 months), intolerance, or contraindication to ALL of the following:
	  ○ Fabhalta (iptacopan)
	  ○ Filspari (sparsentan) OR Vanrafia (atrasentan)
	  ○ Tarpeyo
	  ○ Voyxact (sibeprenlimab-szsi)
	• Not used in combination with Fabhalta (iptacopan), Filspari (sparsentan), Vanrafia (atrasentan), Tarpeyo, or Voyxact (sibeprenlimab-szsi)
	
	Initial Approval: 6 months
	
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	• **Quantity Limit: 4 pens/28 days**
	
	Continued Approval: 12 months. Continue approval if the following criteria are met:
	
	• Documented clinically significant reduction in proteinuria (~30-40% from baseline)
	
	For new members who were initiated Trutakna outside of KPGA: Confirm patient meets all above coverage criteria and has a documented clinically significant benefit from the medication during nephrologist follow-up in the last 12 months.
	
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	• **Quantity Limit: 4 pens/28 days**
	
	For existing members who have previously met the full criteria above: Documented clinically significant benefit from the medication during nephrologist follow up in the last 12 months
	
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	• **Quantity Limit: 4 pens/28 days**

Tryngolza (Olezarsen)	**Candidates for treatment with Tryngolza (olezarsen) should meet ALL of the following criteria PLUS the individual disease state criteria that follow:** • Age ≥ 18 years • Then follow the disease state specific criteria below, based on diagnosis: Diagnosis of Familial Chylomicronemia Syndrome (FCS): • Prescribed by an endocrinologist, geneticist, or cardiologist

Drug	Prior Authorization Criteria

	• Diagnosis with FCS confirmed by genetic testing
	• Fasting triglyceride (TG) level ≥ 880 mg/dL in the past 1 month prior to starting therapy
	• Documented history of pancreatitis in past 10 years
	• Documentation that Tryngolza (olezarsen) will be used as an adjunct therapy to diet
	
	Diagnosis of Severe Hypertriglyceridemia (sHTG):
	
	• Prescribed by an endocrinologist or cardiologist
	• Pre-treatment fasting triglyceride ≥ 880 mg/dL drawn within the past 1 month while on stable triglyceride lowering therapy
	• Currently prescribed ALL the following OR documented intolerance or contraindication:
	  ○ Maximally tolerated statin therapy (if intolerant, patient must have tried at least TWO statins)
	  ○ Omega 3 fatty acid
	  ○ Fenofibrate (not required if patient is on high intensity statin therapy [e.g., atorvastatin 40-80 mg daily or rosuvastatin 20-40 mg daily])
	• Baseline A1C < 9.5% drawn within past 3 months
	
	Initial Approval: 6 months
	
	Continued Approval: 12 months. Continue approval if the following criteria are met:
	
	For new members who were initiated on Tryngolza outside of KPGA: Confirm patient has documented clinically significant benefit from Tryngolza during Specialist follow-up in the last 12 months.
	
	For existing members who have previously met the full criteria above: Documented clinically significant benefit from Tryngolza during Specialist follow-up in the last 12 months AND documentation of at least 30% reduction in TG levels since starting therapy.
	
	Ordering Information:
	• Tryngolza is available through PANTHERx Rare Pharmacy. Providers should enroll their patients using this form: Start-Form.pdf

Tryvio
(Aprocitentan)
	Candidates for treatment with Tryvio should meet all the following criteria:
	
	• Age ≥ 18 years
	• Prescribed by cardiology, nephrology
	• Documented diagnosis of resistant HTN and BP remains above goal >140/90 mmHg on 2 consecutive measurements in the past 4 weeks
	  ○ Document starting BP
	• Currently prescribed **ALL the following** or documented adequate therapeutic trial at maximally tolerated dose for at least 4 weeks, or intolerance, contraindication
	  ○ Angiotensin converting enzyme (ACE) inhibitor (e.g., lisinopril) OR angiotensin II receptor blocker (ARB) (e.g., losartan)
	  ○ Calcium channel blocker (e.g., amlodipine)
	  ○ Thiazide-type diuretic (e.g., HCTZ, chlorthalidone)
	  ○ Mineralocorticoid Receptor Antagonists (e.g., spironolactone)

Drug	Prior Authorization Criteria

	• Trial of **one of the following** or documented adequate therapeutic trial at maximally tolerated dose for at least 4 weeks or intolerance, contraindication
	  ○ Beta-blocker (e.g., carvedilol)
	  ○ Direct vasodilator (e.g., hydralazine)
	  ○ Central alpha-adrenergic agonists (e.g., clonidine)
	  ○ Alpha-blocker (e.g., doxazosin)
	Reasons for non-coverage:
	
	• Pregnancy or lactation
	• eGFR < 15 mL/min
	• Moderate to severe hepatic impairment (Child-Pugh class B and C)
	
	Initial Approval: 3 months
	
	Continued Approval: 12 months. Patient must meet all criteria above without reasons for non-coverage and provider documents improvement in BP since therapy initiation.
	
	For new members who were initiated on Tryvio outside of KPGA:
	
	Confirm patient meets all above coverage criteria without reasons for non-coverage AND upcoming appt scheduled with specialty prescriber (e.g., cardiology, nephrology)
	
	Ordering Information:
	
	Tryvio is exclusively available through the Walgreens Specialty Pharmacy. 130 Enterprise Dr. Pittsburgh PA. 888-347-3416.

Tukysa
(Tucatinib)
	Candidates for treatment with Tukysa (tucatinib) should meet ALL the following criteria:
	
	• Prescribed by an Oncologist
	• Age ≥ 18 years
	• Tucatinib will be used for one of the following diagnoses:
	  ○ Advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer in combination with trastuzumab and capecitabine, in adults with or without brain metastases who have received one or more anti-HER2-based regimens in the metastatic setting (i.e., trastuzumab (Herceptin, Kanjinti), pertuzumab (Perjeta), ado-trastuzumab emtansine (Kadcyla)) OR
	  ○ RAS wild-type HER2-positive unresectable or metastatic colorectal cancer in combination with trastuzumab that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
	
	Reasons for Non-coverage:
	• CrCl <30ml/minute if given with capecitabine
	
	Initial Approval: 12 months

Drug	Prior Authorization Criteria
	Continued Approval: 12 months if patient meets ALL the initial criteria above and the following: • No documented disease progression • Patient has not developed unacceptable toxicity (i.e., severe diarrhea despite use of antidiarrheal agents and/or severe hepatotoxicity)
Turalio (Pexidartinib)	**Candidates for treatment with Turalio should meet ALL the following criteria:** • Prescribed by a hematologist, oncologist, rheumatologist OR orthopedic specialist • The patient is ≥18 years of age • Patient diagnosed of symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity (e.g., disability or degeneration of affected joint) or functional limitations (e.g., limitation of joint movement) • Measurable disease with a minimum tumor size of 2 cm, AND • Surgical removal of the tumor would be associated with worsening functional limitation or severe morbidity. Initial Approval: 6 months Continued Approval: 12 months. Confirm patient meets all above coverage criteria. In addition, patient must meet the following criteria: • Documented positive clinical response to Turalio • Absence of unacceptable toxicity from the drug Ordering Information: • Pexidartinib is only available through a restricted Risk Evaluation and Mitigation Strategy (REMS) program that requires the participation of prescribers, patients, and pharmacies (www.TURALIOREMS.com).

TWIIST Insulin Pump	**Candidates for TWIIST Insulin Pump must meet ALL the following criteria**
	• Prescribed by an endocrinologist
	  ○ Endocrinologist team educates patient on proper use
	• Documented diagnosis of type 1 DM
	• Age ≥ 6 years
	• Documented frequency of glucose self-testing of at least three times per day or regular use of calibrated CGM.
	• Treatment program including at least three insulin injections per day requiring frequent self-adjustments of insulin dose for at least 6 months
	• Total rapid acting insulin requirement < 300 units per 72 hours
	  ○ **Use only rapid-acting U-100 insulin** formulations. Rapid acting insulin examples: insulin aspart-xjhz (Kirsty), insulin lispro (Humalog), insulin aspart (Novolog)
	• **Medical necessity/documentation explaining rationale for advanced time to occlusion detection technology that cannot be achieved using traditional DME insulin pump.**
	• Inadequate BG control despite multiple daily insulin injections as documented **by at least one:**
	  ○ A1C ≥ 7%

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ Recurrent hypoglycemic events (BG <70) in the past month ○ History of severe glycemic excursions ○ Dawn phenomenon with fasting sugars > 200mg/dL routinely • **Coverage is not authorized for patients with existing coverage for an alternate insulin pump device (verify last insulin pump approval, if applicable)** Reason for Non-coverage • T2DM • **Must have access to a compatible Apple device** (e.g., iPhone running iOS 18 or later, and Apple Watch Series 10 or newer) to ensure full functionality and integration with the insulin pump. Initial Approval: 12 months. Approve for 10 cassettes per 30 days Continued Approval: Confirm patient continues to meet all criteria above without reasons for non-coverage. • In addition, endocrinologist documents improved glycemic control as evidenced by A1C improvement or decrease in glycemic variability. • Documentation of visit in past 12 months. Notes: • For new members who were initiated outside of KPGA, confirm, patient meets all the above criteria for continued approval. • The pump is not currently approved or available for patients with Type 2 DM • Use rapid-acting U-100 insulins only.
Tysabri (Natalizumab)	**Candidates for treatment with Tysabri should meet ALL of the following criteria:** • Testing for anti-JC virus (JCV) antibodies is recommended in patients considering or receiving Tysabri • Not prescribed in patients with: ○ Current diagnosis or history of progressive multifocal leukoencephalopathy (PML) ○ JCV antibody positive and immunosuppression (due to HIV, AIDS, leukemia, lymphoma or organ transplantation) ○ JCV antibody positive and history of antineoplastics or immunosuppressants (e.g.: adalimumab, alefacept alemtuzumab, anakinra, azathioprine, cladribine, cyclophosphamide, cyclosporine, daclizumab, efalizumab, etanercept, fludarabine phosphate, infliximab, intravenous immunoglobulin, leflunomide, mercaptopurine, methotrexate, mitoxantrone, mycophenolate mofetil, mycophenolic acid, pemetrexed, rituximab, trastuzumab) • For females of childbearing age (12-50 years), a baseline negative pregnancy test within the past month AND either a prescription for birth control (IUD or other contraceptive) or documentation of the patient declining contraception and being counseled of the potential risk of pregnancy. • Then follow the disease state specific criteria below, based on diagnosis: For Multiple Sclerosis:

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>
Tysabri should be reserved for treatment of patients with relapsing forms of multiple sclerosis exhibiting high-disease activity or prognostic factors for early progression to secondary progressive multiple sclerosis.

• Diagnosis of relapsing-remitting multiple sclerosis (RRMS) or progressive-relapsing MS (PRMS)
• Prescriber is a Neurologist
• Tysabri is prescribed for use as monotherapy for treatment of multiple sclerosis
• Documented JC virus antibody test within 6 months
• Documented inadequate response to ONE or more moderately effective DMT (interferon beta, glatiramer acetate, dimethyl fumarate or teriflunomide) OR
• Documented evidence of high-risk features for early progression to secondary-progressive MS (see Table 1)
*<u>NOTE:</u> Injection fatigue or fear of needles is not a reason for intolerance or inadequate response.

<u>Table 1:</u> High-risk features for early progression
<table>
<tr><td colspan="2">History of MS relapse with</td><td rowspan="2">Lesion load</td></tr>
<tr><td>Duration/Symptom</td><td>Frequency/Treatment</td></tr>
<tr><td>- ≥ 30 days and significant functional limitations besides ongoing sensory symptoms
- Sphincter OR
- Ambulatory OR
- Cerebellar (ataxia or tremor) impairment
- Visual acuity of 20/200 or worse
- Brain stem (dysarthria, dysphagia)</td><td>- ≥ 1 relapse/year average over 2 to 3 years OR
- Requiring plasma exchange</td><td>- High T2 load (> 20 lesions on brain MRI) OR
- ≥ 2 Gad+ lesions OR
- ≥ 1 cord lesion OR
- Posterior fossa lesions OR
≥ 4 lesions over 2 years on DMT OR
- Tumefactive lesions OR</td></tr>
</table>
<u>Initial Approval:</u> 12 months
• Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)

<u>Continued approval</u>: 12 months

<u>For new members who were initiated on Tysabri outside of KPGA:</u>
• Approve Tysabri if patient has had a visit with a neurologist and beneficial response to therapy has been documented by Specialist within the last 6 months.
</td></tr>
</table>

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** For existing members who have previously met the full criteria above: • If last assay for anti-JCV antibodies was negative, patient must have repeat JCV antibody test within the past 12 months AND documented beneficial response to therapy by neurologist within the last 12 months. • If last assay for anti-JCV antibodies was positive, patient must have documented beneficial response to therapy by the neurologist within the past 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** For Crohn's Disease: • Diagnosis of moderately to severely active Crohn's disease that is asymptomatic or in clinical remission • Prescribed by a gastroenterologist • Documented JC virus antibody test within 3 months • NOT prescribed in combination with another biologic agents (infliximab, etanercept, adalimumab, etc.), or other immunosuppressants (6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) Initial approval period: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for administration ONLY in KPGA infusion center, absent director level approval** Continued approval: 12 months. Confirm patient meets all coverage criteria and has demonstrated clinical benefit (asymptomatic or in clinical remission) documented during specialist follow-up within the past 12 month • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for administration ONLY in KPGA infusion center, absent director level approval** Ordering Information: • Prescribers must be enrolled TOUCH Prescribing Program. For information on how to enroll in the program, please visit https://www.touchprogram.com/TTP/tolTOUCHEnroll.jsp#Prescribers. If approved for coverage, Tysabri is available through the KP Specialty Pharmacy. Prescribers must complete the KP Specialty Pharmacy Tysabri Order Form at http://pharmacy.kp.org/Kp-CMS/California/DrugInformation/ViewMedSafetyDNMgmt CA.aspx?I32Object=1119&nodeValue=113 and fax it to KP-SP (1-650-301-5790).
Tzield (Teplizumab)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.**

Drug	Prior Authorization Criteria

	Candidates for Tzield should meet ALL of the following criteria:
	
	**Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).*
	
	• Prescribed by a Pediatric or Adult Endocrinologist
	• Meets one of the following
	  ○ Prescribed to delay the onset of Stage 3 T1D age 1 to 45 and with Stage 2 T1D
	  ○ Delay the decline in endogenous insulin production in age 8 to 17 diagnosed with Stage 3 T1D
	• The patient has received Interregional Consultative Panel alignment with TSPMG Endocrinology Chief endorsement to use Tzield
	• Documented abnormal glucose tolerance by oral glucose tolerance test (OGTT) defined as:
	  ○ fasting blood glucose >00mg/dL and <126 mg/dL OR
	  ○ 2-hour glucose ≥140 mg/dL and <200 mg/dL OR
	  ○ 30-, 60-, or 90-minute value on OGTT ≥200 mg/dL
	• Presence of at **least two** diabetes autoantibodies:
	  ○ glutamic acid decarboxylase 65 (GAD) autoantibody
	  ○ zinc transporter 8 (ZnT8) autoantibody
	  ○ islet cell autoantibody (ICA)
	  ○ insulin autoantibody (IAA)
	  ○ insulinoma-associated antigen-2 (IA-2) autoantibody
	
	**Caution in patients who have been treated with radiation for lymph diseases
	
	Approval Period: One time approval for one 14-day treatment cycle
	• Approve for administration at a KP facility only
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**

Ubrelvy (Ubrogepant)	**Candidates for treatment with Ubrelvy (ubrogepant) should meet the following criteria:** • Age ≥ 18 years AND • Prescribed by a Neurologist, or providers in the Department of Neurology who specialize in headache management AND • New member already taking ubrogepant (Ubrelvy) or rimegepant (Nurtec ODT) and has documented failure of two or more abortive migraine therapies OR • A documented contraindication to treatment with triptans, such as coronary artery disease, history of stroke, peripheral vascular disease, ischemic bowel disease, basilar or hemiplegic migraine, unstable angina, and uncontrolled hypertension OR • Documented inadequate response and/or intolerance to three different triptans or triptan dosage forms e.g., sumatriptan tablet, naratriptan tablet, rizatriptan ODT, sumatriptan intranasal. Initial Approval Period: 6 months. Quantity limit of 10 tablets per 30 days will apply. • Approve ½ tablets for lower strength (Ubrelvy 100 mg, ½ tablet ONCE PRN) unless patient is unable or unwilling to split tablets

Drug	Prior Authorization Criteria
	Continued Approval: 12 months. Quantity limit of 10 tablets per 30 days will apply. Continue approval if the following criteria are met: • **For new members who were initiated on an oral CGRP therapy (Ubrelvy or Nurtec ODT) outside of KPGA**, approve ubrogepant if patient has previously tried and failed 2 or more abortive migraine therapies. Otherwise, patient must meet the above coverage criteria without reasons for Non-coverage. • Documented beneficial effect and tolerance of the medication.
Uceris (Budesonide Extended Release 24 Hour Tablet)	**Candidates for treatment with budesonide 9 mg tablets (generic Uceris) should meet ALL the following criteria:** • Prescribed by gastroenterologist • Diagnosis of ulcerative colitis • Documented trial of prednisone or documented failure, intolerance or contraindication. • Documented trial of mesalamine product or documented failure, intolerance or contraindication. Initial Approval: 8 weeks Continued Approval: One additional 8 week course if prescriber deems medically necessary Reasons for Non-coverage: • Crohn's Disease

Uplizna
(Inebilizumab-cdon)
	Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)
	
	Candidates for treatment with Uplizna should meet ALL of the following criteria:
	
	Criteria for the diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD)
	• Prescribed by a Multiple Sclerosis Specialist or Neurologist if no regional subspecialist.
	• Age ≥ 18 years with confirmed diagnosis of NMOSD
	• Patient is AQP4 antibody seropositive
	• Documentation of ONE of the following:
	  ○ Severe breakthrough relapse while on rituximab for at least 6 months not attributed to rapid steroid discontinuation (rituximab induction dose of 1,500 to 2,000 mg split in two IV infusions given 2 weeks apart followed by 500 mg IV infused every 6 months or adjusted as needed per prescriber). Examples of severe breakthrough relapse include, but are not limited to:
	  ▪ hospitalization for neurological deficits from NMOSD relapse (e.g., quadriparesis or paraparesis) AND/OR
	  ▪ optic neuritis severity (hand motion only or worse) confirmed by an ophthalmologist
	  ○ Recurrent moderate breakthrough relapses after 6-month trial of rituximab in combination with maximum tolerated doses of either mycophenolate mofetil or azathioprine. Maximum doses shown below:
	  ▪ Mycophenolate mofetil dose: 1,000 to 2,000 mg/day to target an absolute lymphocyte count of 1,000 to 1,500 cells/µL
	  ▪ Azathioprine dose: 3 mg/kg/day

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• Documented baseline CBC with differential, TB test, pregnancy test if childbearing potential, quantitative serum immunoglobulins, Liver function (AST, ALT, bilirubin), HBV screening. Reasons for Non-coverage: • No prior trial of mycophenolate mofetil or azathioprine for mild or moderate breakthrough relapse while on rituximab. • Pregnant or woman of childbearing potential and not on a reliable birth control. • Contraindication to medication • Prior life-threatening reaction to inebilizumab • Active hepatitis B infection • Active or untreated latent TB Initial Approval Period: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Criteria for Discontinuation: • Life-threatening or disabling infusion reaction occurs • Serious opportunistic infection or recurrent infections if immunoglobulin levels indicate immune compromised. • Recurrent relapses or MRI changes 3-6 months after initiation of therapy • Patient has other serious untreated infection (e.g., viral) • Intolerance to medication • Non-adherence to medication administration and/or follow-up assessments • Pregnancy Continued Approval: 6 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage or meets criteria for discontinuation. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Dosing and Administration: • IV Administration: 300 mg on day 1, followed by 300 mg 2 weeks later; subsequent doses of 300 mg are administered once every 6 months (beginning 6 months after the first 300 mg dose). • Premedicate with antihistamine, antipyretic, and corticosteroid 30 to 60 minutes prior to infusion. Administer diluted infusion over ~90 minutes at an increasing rate: 42 mL/hour for first 30 minutes, followed by 125 mL/hour for the next 30 minutes, then 333 mL/hour until completion. • **Available via Cardinal Health Specialty Distribution** Criteria for the diagnosis of Immunoglobulin G4-related disease (IgG4-RD): • Prescribed by or in consultation with an endocrinologist, gastroenterologist, immunologist, nephrologist, neurologist, pulmonologist, rheumatologist, or a physician who specializes in treating immune-mediated disorders • Age ≥ 18 years • Documentation of a diagnosis of IgG4-RD confirmed by **BOTH** of the following:

Drug	Prior Authorization Criteria
	○ Biopsy of at least one involved organ AND immunostaining confirms presence of IgG-positive cells ○ Radiologic evidence (i.e., CT, MRI, PET) of tumor-like swelling of an involved organ • Inadequate response, intolerance and/or contraindication to **BOTH** of the following: ○ Glucocorticoids (e.g., prednisone, methylprednisolone) ○ Rituximab • Uplizna is not being used in combination with a disease modifying therapy for the treatment of IgG4-related disease (rituximab) Initial Approval Period: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: 6 months. Approve for 300 mg IV infusion every 6 months for maintenance if the following criteria are met: • Age ≥ 18 years **AND** prescriber documentation of clinical benefit (e.g., reduction in corticosteroid dose, reduction in number of disease flares, increase in duration of flare-free period, and absence of disease activity) • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Dosing and Administration: ○ IV Administration: 300 mg on day 1, followed by 300 mg 2 weeks later; subsequent doses of 300 mg are administered once every 6 months (beginning 6 months after the first 300 mg dose). ○ **Available via Cardinal Health Specialty Distribution** Criteria for the diagnosis of myasthenia gravis: • Prescribed by or in consultation with a Neurologist with specialty in neuromuscular disorders • Diagnosis of generalized myasthenia gravis (gMG) • Patient is 18 years or older • Confirmed anti-acetylcholine receptor (AChR) antibody positive OR anti-muscle-specific tyrosine kinase (MuSK) antibody positive • No history of thymoma or thymic neoplasm OR patient has history of thymoma and has had a thymectomy that was completed over 3 months ago • Patient has a Myasthenia Gravis Activities of Daily Living (MG-ADL) scale score of 5 or higher • Patient is currently taking pyridostigmine for symptomatic management as prescribed unless there is a severe intolerance or contraindication • Trial of corticosteroid for at least 3 months and patient experienced inadequate disease control or patient has an intolerance or contraindication to corticosteroid therapy • Trial of at least one non-steroidal immunosuppressive therapy for the duration indicated: ○ Azathioprine or mycophenolate for at least 12 months ○ Rituximab or rituximab biosimilar for at least 12 months ○ Other disease modifying therapy (e.g., cyclophosphamide, cyclosporine, tacrolimus, methotrexate) for at least 6 months • Patient has tried and failed or has a contraindication to chronic IV immune globulin (IVIG)

Drug	Prior Authorization Criteria
	Reasons for Non-coverage: • Patient is prescribed concomitant monoclonal antibody therapy for myasthenia gravis such as Vyvgart / Vyvgart Hytrulo, Epysqli / Soliris (eculizumab-aagh), Ultomiris, Rystiggo, or Zilbrysq. • Active hepatitis B infection • Active or untreated latent TB Initial Approval: 6 months • **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued approval: 12 months • For first renewal: patient must show documented improvement of at least 2 points on the Myasthenia Gravis-Activities of Daily Living scale (MG-ADL) • For subsequent renewals: patient must show documented maintenance of stable MG-ADL score or documented beneficial effect from therapy during Neurology follow-up in the last 12 months • **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** For new members who were initiated on Uplizna for myasthenia gravis outside of KPGA, approve if ALL the following criteria are met: • Patient has had a visit with a Neurologist with specialty in neuromuscular disorder to discuss consideration of chronic IVIG as an alternative treatment option • Patient has tried and failed a corticosteroid AND at least one non- steroidal immunosuppressive therapy as listed above • Patient confirmed to be stable on therapy by Neurologist • **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**

Uptravi
(Selexipag)
	Candidates for Uptravi (selexipag) should meet ALL the following criteria:
	
	• Prescribed by pulmonologist or pulmonary arterial hypertension (PAH) specialist
	• Age ≥ 2 years
	• Diagnosis of pulmonary arterial hypertension (WHO Group 1) confirmed by right heart catheterization physician documentation of WHO/New York Heart Association (NYHA) Functional Class II, III or IV symptoms
	• Documented failure of, contraindication, or intolerance to at least 3 of the following regimens including ambrisentan+PDE5, Adempas (riociguat) and Yutrepia (treprostinil) DPI (in order of preference):
	  ○ Ambrisentan (Letairis) [preferred endothelin receptor antagonist (ERA)] + Tadalafil (Adcirca)
	  ○ Other oral ERA (e.g., bosentan (Tracleer), Opsumit (macitentan) + PDE5 inhibitor (e.g., sildenafil [Revatio], tadalafil [Adcirca])
	  ○ Oral cGMP stimulator [e.g., Adempas (riociguat)]
	  ○ Oral prostacyclin analogue [e.g., Orenitram (treprostinil)]
	  ○ Dry powder inhaled prostacyclin analogue [e.g., Yutrepia (treprostinil)]
	• NOT using in combination with a prostacyclin analogue/prostanoid (e.g., treprostinil or selexipag)

Drug	Prior Authorization Criteria
	Initial Approval: 12 months Continued Approval for new members: 12 months. Confirm patient meets all above coverage criteria and documented clinical benefit from therapy as evidenced by disease stability or improvement noted during specialist follow up in the last 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval for existing members: 12 months. Documented clinical benefit from therapy as evidenced by disease stability or improvement noted during specialist follow up in the last 12 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**

Ultomiris
(Ravulizumab)
	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Candidates for treatment with Ultomiris must meet ALL the following criteria:
	
	Criteria for Generalized Myasthenia Gravis:
	• Prescribed by or in consultation with a Neurologist with specialty in neuromuscular disorders
	• Diagnosis of generalized myasthenia gravis (gMG)
	• Patient is 18 years or older
	• Confirmed anti-acetylcholine receptor (AChR) antibody positive
	• No history of thymoma or thymic neoplasm OR patient has history of thymoma and has had a thymectomy that was completed over 3 months ago
	• Patient has a Myasthenia Gravis Activities of Daily Living (MG-ADL) scale score of 5 or higher
	• Patient is currently taking pyridostigmine for symptomatic management as prescribed unless there is a severe intolerance or contraindication
	• Trial of corticosteroid for at least 3 months and patient experienced inadequate disease control or patient has an intolerance or contraindication to corticosteroid therapy
	• Trial of at least one non-steroidal immunosuppressive therapy for the duration indicated:
	  ○ Azathioprine or mycophenolate for at least 12 months
	  ○ Rituximab for at least 12 months
	  ○ Other disease modifying therapy (e.g., cyclophosphamide, cyclosporine, tacrolimus, methotrexate) for at least 6 months
	• Patient has tried and failed or has a contraindication to chronic IV immune globulin (IVIG)
	
	Reasons for Non-coverage:
	• Patient is prescribed concomitant monoclonal antibody therapy for myasthenia gravis such as Vyvgart, Vyvgart Hytrulo, Epysqli (Soliris), Rystiggo or Zilbrysq
	• Unresolved serious Neisseria meningitidis infection
	• Not vaccinated against Neisseria meningitidis, unless risk of treatment delay outweighs infection risk

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	Initial Approval: 6 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Continued Approval: 12 months.
	• For new members who were initiated on ravulizumab (Ultomiris) outside of KPGA, approve if ALL the following criteria are met
	  ○ Patient has had a visit with a Neurologist with specialty in neuromuscular disorder to discuss consideration of chronic IVIG as an alternative treatment option
	  ○ Patient has tried and failed a corticosteroid AND at least one non-steroidal immunosuppressive therapy as listed above
	  ○ Patient confirmed to be stable on therapy by Neurologist
	• For first renewal of ravulizumab: documented improvement of at least 2-points on the Myasthenia Gravis-Activities of Daily Living scale (MG-ADL)
	• For subsequent renewals after first renewal: documented maintenance of stable MG-ADL score or documented beneficial effect from therapy during Neurology follow up in the last 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Criteria for neuromyelitis optica spectrum disorder (NMOSD
	
	• Prescribed by a Multiple Sclerosis Specialist or Neurologist (if no regional subspecialist) or Neuro-ophthalmologist
	• Age ≥ 18 years with confirmed diagnosis of NMOSD
	• Patient is AQP4 antibody seropositive
	• Patient has documentation of ONE of the following:
	  ○ Severe breakthrough relapse while on rituximab for at least 6 months not attributed to rapid steroid discontinuation (rituximab induction dose of 1,500 to 2,000 mg split in two IV infusions given 2 weeks apart followed by 500 mg IV infused every 6 months or adjusted as needed per prescriber). Examples of severe breakthrough relapse include, but are not limited to:
	  ▪ hospitalization for neurological deficits from NMOSD relapse (e.g., quadriparesis or paraparesis)
	  ▪ optic neuritis severity (hand motion only or worse) confirmed by an ophthalmologist
	  ○ Recurrent moderate breakthrough relapses after 6-month trial of rituximab in combination with maximum tolerated doses of either mycophenolate mofetil or azathioprine. Maximum doses shown below:
	  ▪ mycophenolate mofetil: 1,000 to 2,000 mg/day to target an absolute lymphocyte count of 1,000 to 1,500 cells/µL
	  ▪ azathioprine: 3 mg/kg/day
	• Documented baseline meningococcal vaccination status and complete blood count with differential
	• Ravulizumab is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ULTOMIRIS and SOLIRIS REMS. Confirm REMS.

Drug	Prior Authorization Criteria
	Reasons for Non-coverage: • Patient is pregnant or woman of childbearing potential and not on a reliable birth control • Unresolved serious Neisseria meningitidis infection • Not vaccinated against Neisseria meningitidis, unless risk of treatment delay outweighs infection risk Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage or criteria for discontinuation listed below. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Criteria for Paroxysmal Nocturnal Hemoglobinuria: • Age ≥ 1 month and has a weight of at least 5 kg and diagnosed with paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow cytometry • Prescribed by a specialist in the area of practice related to the patient's diagnosis (e.g., hematologist, oncologist, immunologist, or genetic specialist) • Documented baseline hemoglobin is ≤7 g/dl **OR** the patient has symptoms of anemia and the hemoglobin is ≤9 g/dl • Documented baseline value for serum lactate dehydrogenase (LDH) ≥1.5 times the upper limit of normal • Documented baseline meningococcal vaccine at least 2 weeks prior to start of therapy • Ultomiris will be used as monotherapy and patient is not receiving treatment with another terminal complement inhibitor such as Epysqli (eculizumab-aagh) or Soliris (eculizumab). • Prescribing physician is enrolled in the Ultomiris REMS program Reasons for Non-coverage: • Unresolved serious Neisseria meningitidis infection • Not vaccinated against Neisseria meningitidis, unless risk of treatment delay outweighs infection risk Initial Approval: 6 months. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: 12 months. • Confirm patient has documented improvement in disease control via follow-up appointment with prescribing clinician AND meets all above coverage criteria without reasons for Non-coverage or criteria for discontinuation listed below. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Criteria for Atypical Hemolytic Uremic Syndrome (aHUS): • Age ≥ 2 months and weight ≥ 5 kg and diagnosed with aHUS

Drug	Prior Authorization Criteria
	• Prescribed by a specialist in the area of practice related to the patient's diagnosis (e.g., hematologist, oncologist, immunologist, genetic specialist or nephrologist) • A diagnosis of Shiga toxin-related HUS has been ruled out • Documented baseline levels for platelet count, serum lactate dehydrogenase (LDH), plasma exchange/infusion requirement, and serum creatinine/eGFR • Documented baseline meningococcal vaccine at least 2 weeks prior to start of therapy • Ultomiris will be used as monotherapy and patient is not receiving treatment with another terminal complement inhibitor such as Epysqli (eculizumab-aagh) or Soliris (eculizumab). • Prescribing physician is enrolled in the Ultomiris REMS program Reasons for Non-coverage: • Unresolved serious Neisseria meningitidis infection • Not vaccinated against Neisseria meningitidis, unless risk of treatment delay outweighs infection risk Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: 12 months. • Confirm patient has documented improvement in disease control via follow-up appointment with prescribing clinician AND meets all above coverage criteria without reasons for Non-coverage or criteria for discontinuation listed below. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Criteria for Discontinuation (ALL indications): • Patient is being treated for serious meningococcal infection • Patient has other serious untreated infection (e.g., viral) • Documented major intolerance to medication • Must have follow up visit documented within 6 months. • Clinician documented non-adherence to medication administration and/or follow-up assessments. • For NMOSD indication ONLY: Recurrent relapses or MRI changes 3-6 months after initiation of therapy
Ustekinumab Products **Preferred:** **Yesintek** (Ustekinumab-kfce) – No PA required	**Candidates for treatment with branded Stelara or a QRM Ustekinumab product should meet ALL the following criteria PLUS the individual disease state criteria that follows:** • Patient has a negative interferon-gamma release assay test for TB infection within the past 24 months or is positive for latent TB and has completed treatment in the past or is currently on treatment • Medication is not being used in combination with another biologic or advanced small molecule (e.g., tofacitinib, upadacitinib, apremilast) for the same indication • Documented inadequate response, intolerance and/or contraindication after at least a 3-month trial of Yesintek and then a preferred QRM ustekinumab product from the lefthand column. If the request is for a preferred QRM ustekinumab product in a patient who previously tried Yesintek, proceed to approval. **Reviewers must obtain approval from the**

Drug	Prior Authorization Criteria
QRM Ustekinumab Products: PA required **Preferred QRM:** **Starjemza** (Ustekinumab-hmny) **Imuldosa** (Ustekinumab-srlf) **Otulfi** (Ustekinumab-aauz) **Steqeyma** (Ustekinumab-stba) **Pyzchiva** (Ustekinumab-ttwe) **Selarsdi** (Ustekinumab-aekn) **Non-preferred QRM:** **Unbranded ustekinumab (Stelara)** **Wezlana** (Ustekinumab-auub)	**Physician Program Director of QRM or AAMD prior to providing QRM PA approval for branded Stelara.** ○ Inadequate response defined as documented new or worsening symptoms, lack of clinical improvement, significant disease flare not characteristic of previous disease course confirmed by objective findings and physical assessment. • If the request is for a non-preferred QRM ustekinumab product, then follow the disease state specific criteria below, based on diagnosis: **Criteria for plaque psoriasis:** • Prescribed by a Dermatologist • Age ≥ 6 years • A documented inadequate response intolerance and/or contraindication **ALL** of the following after at least a 3-month trial: ○ Cosentyx (secukinumab) ○ Adalimumab product (e.g., Amjevita [preferred], Humira) • When transitioning to ustekinumab, starting with a maintenance dose is efficacious. If a loading dose is ordered, documented clinical rationale must be provided (i.e., actively flaring, BSA >50%, prior ER visits for psoriasis). • If above criteria are met, approve for **unbranded ustekinumab**, which is equivalent to branded Stelara. • **For Pediatric Patients** (Must try in order of preference): Documented inadequate response, intolerance, or contraindication to both preferred Ustekinumab Product(s): Yesintek and then preferred QRM ustekinumab product → Cosentyx → Enbrel → Unbranded Ustekinumab **Criteria for psoriatic arthritis:** • Prescribed by a Rheumatologist • Age ≥ 6 years • A documented inadequate response after at least a 3-month trial, intolerance and/or contraindication **ALL** of the following: ○ At least ONE tumor necrosis factor (TNF-α) inhibitor. (e.g., Infliximab (Infliximab-dyyb/Inflectra [preferred], Remicade), adalimumab (Amjevita [preferred], Humira), etanercept [Enbrel]) ○ Xeljanz (Tofacitinib) ○ Cosentyx (secukinumab) • If above criteria are met, approve for **unbranded ustekinumab**, which is equivalent to branded Stelara. **Adult Criteria for moderate to severe Crohn's disease or ulcerative colitis:** • Prescribed by a Gastroenterologist • A documented inadequate response after at least a 3-month trial, intolerance and/or contraindication to **ALL** of the following in the order of preference below: ○ Infliximab product (e.g. Infliximab-dyyb/Inflectra [preferred], Remicade) ○ Adalimumab product (e.g. Amjevita [preferred], Humira) ○ Entyvio (vedolizumab) (a trial is not required in CD, if documentation of small bowel, perianal or fistulizing / penetrating disease

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ Xeljanz (tofacitinib) (for UC only, preferred JAK inhibitor) OR Rinvoq (upadacitinib) (for CD and UC) ○ Cimzia (certolizumab) – for CD only AND patient is in remission ○ Simponi (golimumab) – for UC only ○ Patient must try/fail **ALL** of the agents listed above unless provider documents rationale why additional anti-TNF agent is inappropriate (i.e., primary or secondary non-response despite therapeutic drug level +/- presence of anti-drug antibodies or adverse effect requiring a different mechanism of action, member temporarily located outside of our KP network and cannot receive infusions) • If above criteria are met, approve for **unbranded ustekinumab**, which is equivalent to branded Stelara. **Pediatric criteria for Crohn's disease or ulcerative colitis:** **Note: not FDA-approved for pediatric IBD conditions* • Prescribed by a Gastroenterologist • Patient is < 18 years of age • A documented inadequate response with or loss of response after at least a 3 month trial (or as noted for infliximab), intolerance or contraindication to **ALL** of the following: ○ Infliximab: Provider should optimize dose, 5-10 mg/kg and consider dose interval change (Q4 weeks). Adequate therapeutic trial of at least 2 infusions required. ○ Adalimumab unless prescriber documents non-response to anti-TNF agent • If above criteria are met, approve for **unbranded ustekinumab**, which is equivalent to branded Stelara. Initial Approval: 12 months • **Induction for CD or UC (adults and pediatric): approve one-time intravenous dose given in office** • **All other indications: approve for member to fill via the outpatient pharmacy benefit only** ○ Quantity Limit for ustekinumab = 90 mg (1ml) per 8 weeks (NOTE: Providers may request an exception for this maintenance dose requirement when applicable by showing objective evidence of disease progression or inadequate control justifying change in dose interval). • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for member to fill via the outpatient pharmacy benefit only** Continued Approval: 12 months. • **For CD and UC (adults and pediatric):** Documented clinical benefit (asymptomatic or in remission) from therapy, by a gastroenterology specialist within the past 12 months. Approve maintenance dose for CD and UC: 90 mg every 8 weeks subcutaneously • **All other indications:** Confirm patient meets all above coverage criteria AND documented clinically significant benefit from the medication during specialist follow-up in the last 12 months. • Approve maintenance dose for Crohn's disease: 90 mg every 8 weeks subcutaneously

Drug	Prior Authorization Criteria
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for member to fill via the outpatient pharmacy benefit only**

Vafseo
(Vadadustat)
	Candidates for treatment with Vafseo (vadadustat) should meet all the following criteria:
	• Prescribed by a nephrologist
	• Age ≥18 years
	• Diagnosis of anemia due to Chronic Kidney Disease (CKD)
	• Patient has been **receiving dialysis for at least 3 months**
	• Inadequate hemoglobin level or contraindication to erythropoiesis-stimulating agent (ESA) (e.g., Epogen, Procrit), and will discontinue ESA therapy prior to starting Vafseo.
	  ○ Must try both options listed below:
	  ▪ Epoetin
	  ▪ Darbepoetin
	  ○ NOTE: Inadequate response= defined Hemoglobin (Hb) level less than 11 g/dL while treated OR >300 IU/kg per week of epoetin alfa or 1.5 mcg/kg per week of darbepoetin
	• Baseline labs including hemoglobin level, ferritin, b12, TSAT, liver panel within 3 months of initial request
	  ○ Hemoglobin (Hb) level must be within 8-10 g/dL prior to initiation
	  ○ Document baseline Hb in initial approval
	
	<u>Reasons for Non-coverage</u>
	
	• Patient has anemia due to CKD not on dialysis
	• Patient has uncontrolled hypertension
	• Pregnancy and/or lactation
	• Documented cirrhosis or active, acute liver disease
	• Active malignancy
	• Concurrent use of ESA
	• Vafseo will NOT be used concurrently with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (e.g., Jesduvroq [daprodustat])
	
	<u>Initial Approval:</u> 6 months
	
	<u>Continued Approval</u>: 12 months. Confirm patient meets all above coverage criteria and demonstrates clinical benefit compared to baseline without reasons for Non-coverage. In addition, must meet criteria below:
	
	• Patient has an improvement in hemoglobin levels and hemoglobin levels now within 10 to 11.5 g/dL

Vanflyta (Quizartinib)	**Candidates for treatment with Vanflyta should meet all the following criteria:** • Age ≥ 18 years

Drug	Prior Authorization Criteria

	• Prescribed by a hematologist or oncologist certified in the Vanflyta REMS program (registration available at VANFLYTA REMS)
	• Diagnosed acute myeloid leukemia (AML) that is positive for FLT3 internal tandem duplication (FLT3-ITD) as detected by an FDA approved test
	• Vanflyta will be used one of the following ways:
	  ○ In combination with standard cytarabine and anthracycline induction
	  ○ In combination with standard cytarabine based consolidation
	  ○ As maintenance therapy following standard cytarabine and anthracycline induction and cytarabine based consolidation
	
	Reasons for Non-coverage:
	
	• Use for maintenance monotherapy following allogenic hematopoietic stem cell transplantation (HSCT)
	• History of ventricular arrhythmias or torsades de pointes
	• Long QT syndrome; QT interval corrected by Fridericia's formula (QTcF) is greater than 450 ms
	• Uncontrolled or significant cardiac disease such as recent myocardial infarction, NYHA Class III or IV congestion heard failure, unstable angina, uncontrolled bradyarrhythmia's, uncontrolled tachyarrhythmias, uncontrolled hypertension, high-degree AV block, severe aortic stenosis, or controlled hypothyroidism.
	• Pregnant or breastfeeding
	
	Initial approval**:** 12 months
	
	Continued approval**:** 12 months. For continued approval, patient must meet ALL the above criteria without reasons for non-coverage in addition to the following:
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor spread
	• No evidence of disease progression
	• Absence of unacceptable toxicity from the drug including, but not limited to, the following:
	  ○ Recurrent QT interval corrected by Fridericia's formula (QTcF) is greater than> 500 ms despite dose reductions
	  ○ Torsades de pointes
	  ○ Polymorphic ventricular tachycardia
	  ○ Signs and symptoms of life-threatening arrhythmia
	  ○ Grade 3 or 4 non-hematologic adverse reactions persisting for more than 28 days
	
	Ordering Information:
	• Vanflyta is only available through a restricted Risk Evaluation and Mitigation Strategy (REMS) program that requires the participation of prescribers, patients, and pharmacies (www.VanflytaREMS.com).

Preferred: **Icosapent ethyl (generic for Vascepa)**	**Candidates for treatment with Vascepa should meet ALL the following criteria:**

Drug	Prior Authorization Criteria

Non-Preferred Vascepa
(Icosapent ethyl)
	Diagnosis of severe hypertriglyceridemia**.** Patient must meet all the following criteria. If criteria is met, approve for generic icosapent ethyl caps.
	
	• Patient has a fasting triglyceride (TG) level >500 milligrams/deciliter
	• Patient has tried or is currently receiving both of the following products for at least 90 days if clinically appropriate (excluding: Hx elevated LFTs, myalgias with statin therapy, CrCl <30, elevated CPK at baseline):
	  ○ A fibrate (e.g., fenofibrate, fenofibric acid) AND
	  ○ A moderate- to high-intensity statin, if tolerated
	• The patient has initial trial of over-the-counter (OTC) omega-3 fatty acid product (e.g., fish oil supplements) AND subsequent trial of Lovaza at maximum recommended dosage for at least 90 days AND has not achieved adequate efficacy (TGs >500)
	• Controlled thyroid hormones (TSH) or active management from provider
	
	Reasons for Non-coverage: Known hypersensitivity to fish oil
	
	Initial Approval: 12 months and must obtain repeat lipid panel showing TG <500 or > 15-20% reduction in TG from prior on-treatment TG level (presumably with Lovaza) with optimal adherence [MRAR ≥ 80% for ≥ 3 months. If MRAR < 80%, reviewer can confirm adherence in the last 90 days based on medication sold dates found in Health Connect medication tab (e.g., 3 one month fills or one 90 day fill)]
	
	Continued Approval: 12 months. Patient must obtain repeat lipid panel showing sustained TG reduction consistent with TG lowering achieved from initial 3-month period.
	
	Criteria for use in cardiovascular risk reduction with elevated triglyceride level. Patient must meet all the following criteria:
	
	• Diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) (includes acute coronary syndromes, history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, carotid stenosis >50%, or symptomatic peripheral arterial disease presumed to be of atherosclerotic origin)
	• Fasting Triglycerides > 200 milligrams/deciliter
	• Vascepa will be an adjunct to maximally tolerated or optimized statin therapy: Patient on moderate or high-intensity statin therapy > 4 weeks prior to the LDL-C and TG qualifying measurements
	• Age ≥ 45 years
	• Documented LDL <100
	• Documented A1c < 9%
	• Documented Blood Pressure <160/100 OR adherence (MRAR >80%) to at least 3 anti-hypertensive agents
	
	Reasons for Non-coverage:
	
	• Severe heart failure (NYHA Class IV, use of home ionotropic therapy, or LVAD)
	• Active severe liver disease (e.g., cirrhosis, ALT or AST >3 × the upper limit of normal)
	• Known hypersensitivity to fish oil
	• Use of PCSK9 inhibitors

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• Patient is on dialysis • Known current drug or alcohol abuse Initial Approval: 12 months Continued Approval**:** 12 months. Patient must meet all criteria above without reasons for Non-coverage.

Velsipity
(Etrasimod Arginine)
	Candidates for treatment with Velsipity must meet ALL the following criteria PLUS the individual disease state criteria that follows:
	• Documented baseline ophthalmologic exam, EKG, LFTs with bilirubin and CBC with differential in the past 6 months
	• Physician has addressed varicella zoster virus (VZV) immunogenicity (i.e., reported history of VZV, documented VZV antibodies or VZV vaccination) via chart note documentation.
	• Females of childbearing potential (12 to 50 years) should have a baseline negative pregnancy test within the past month AND either a prescription for birth control (IUD or other contraceptive) or documentation of the patient declining contraception and being counseled of the potential risk of pregnancy.
	• Not prescribed if patient has experienced myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or class III or IV heart failure in the last 6 months; history or presence of Mobitz type II second-degree or third-degree atrioventricular block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker
	• Not prescribed in combination with another biologic agent for the same indication or advanced small molecule (e.g., tofacitinib, upadacitinib) for the same indication
	• Then follow the disease state specific criteria below, based on diagnosis:
	
	Criteria for ulcerative colitis:
	• Age ≥ 18 years
	• Prescribed by a gastroenterologist
	• Documented moderately to severely active ulcerative colitis (UC)
	• Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL the following:
	  ○ Infliximab product (e.g., Inflectra [preferred])
	  ○ Ustekinumab product (e.g., Yesintek [preferred])
	  ○ Tofacitinib (preferred JAK-inhibitor) OR Rinvoq (upadacitinib). If patient is pregnant, tofacitinib or Rinvoq trial is NOT required
	  ○ Tremfya (guselkumab)
	
	Initial Approval: 12 months
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	
	Continued approval for UC and CD: 12 months.
	• For new members and existing members Documented clinical benefit (asymptomatic or in remission) from therapy, by a gastroenterology specialist within the past 12 months.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• **Approve for member to fill via the outpatient pharmacy benefit only**

Vemlidy (Tenofovir alafenamide)	**Candidates for treatment with Vemlidy should meet ALL the following criteria:**
	
	• Diagnosis of Hepatitis B and prescribed by Gastroenterologist or Infectious Disease Specialist
	• Documented failure, intolerance, or contraindication to entecavir 1mg.
	• Documented failure, intolerance, or contraindication tenofovir disoproxil fumarate (Viread) based on the following:
	  ○ DEXA Scan showing T-Score of < -2.0 OR Renal impairment defined by CrCl < 10 mL/min
	
	<u>Post Transplant Patients Solid Organ (i.e., heart, liver or kidney):</u>
	• Prescribed by a Transplant Specialist for solid organ transplant
	• Documented failure, intolerance, or contraindication to entecavir 1mg.
	• Documented failure, intolerance, or contraindication tenofovir disoproxil fumarate (Viread) based one of the following:
	  ○ DEXA Scan showing T-Score of < -2.0 OR a history of fragility fracture with DEXAS scan showing a T-Score of <u>< -1.0</u>
	  ○ Renal impairment defined by CrCl < 10 mL/min
	
	<u>Initial approval:</u> 12 months
	
	<u>For new members who were initiated on Vemlidy outside of KPGA approve if:</u>
	• Prescribed by gastroenterologist or Infectious Disease specialist.
	• Patient has had a trial, intolerance, or contraindication to TDF (Viread) AND entecavir.
	• Approve a one-time 30 day supply of Vemlidy if patient is coming in prescribed Vemlidy and are unable to verify history of previous medications. Patient should schedule an appointment with Gastroenterology to determine continued Vemlidy eligibility.
	
	<u>Continued approval</u>: 24 months. Confirm patient meets all the above criteria. In addition, continue approval if documented that the member's condition continues to benefit from treatment based on provider's assessment.

Veopoz (Pozelimab)	**Candidates for treatment with Veopoz (pozelimab) should meet ALL the following criteria:** • Prescribed by a hematologist or other specialists with expertise in the diagnosis of CHAPLE disease • Patient is ≥1 year of age • Patient has a genetic test confirming diagnosis of CD55-deficient protein-losing enteropathy (PLE) OR CD55 deficiency with complement hyperactivation, angiopathic thrombosis, protein-losing enteropathy (i.e., CHAPLE disease) • Patient has a serum albumin level ≤3.2 g/dL • Patient has one or more of the following signs and symptoms of active disease documented within the past 6 months: abdominal pain, diarrhea, peripheral edema, or facial edema

Drug	Prior Authorization Criteria

	• Documentation Veopoz will not be used in combination with other complement protein C5 inhibitors (e.g., Soliris [eculizumab], Ultomiris [ravulizumab], etc)
	
	Reasons for non-coverage:
	• Unresolved *Neisseria meningitidis* infection
	• Patient is not currently vaccinated against meningococcal infection (serogroups A, C, W, and Y [MenACWY] and serogroup B [Men B]) unless documentation that risks of delaying treatment outweigh risk of developing a bacterial infection.
	
	Initial Approval: 12 months
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Continued Approval: 12 months. For continued approval, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria
	• Documentation patient is demonstrating a positive clinical response from baseline such as normalization of serum albumin, reduction of peripheral or facial edema, reduction in abdominal pain or diarrhea, etc.
	• Patient is not receiving treatment with another complement C5 protein inhibitor (e.g., Soliris, Ultomiris, etc)
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Dosage and Administration:
	• Day 1 (loading dose): Administer a single 30 mg/kg dose IV
	• Day 8 and thereafter (maintenance dose): Inject 10 mg/kg as SQ once weekly starting on day 8
	  ○ The maintenance dose may be increased to 12 mg/kg once weekly if there is in adequate clinical response after at least 3 weekly doses
	  ○ The maximum maintenance dose is 800 mg once weekly.
	  ○ Doses greater than 400 mg require 2 injections.
	
	Ordering information: Veopoz is available through the *myRARE* program. If approved for coverage, prescriber must complete the Patient Enrollment Form VEOPOZ_myRARE_for_VEOPOZ_Start_Form.pdf. Once enrolled, medication is available through Orsini Specialty Pharmacy (1-800-410-8575) or FFF Enterprises, Inc (1-800-843-7747).

Veozah (Fezolinetant)	**Candidates for treatment with Veozah should meet ALL the following criteria:** • Prescribed by an Ob-Gyn or Gynecologic Oncology Specialist • Diagnosis of moderate to severe menopausal vasomotor symptoms (VMS) • Patient experiences ≥ 7 hot flashes per day • Patient has a history of failure, intolerance, or contraindication to hormonal therapy (e.g., Prempro [conjugated estrogen/medroxyprogesterone])

Drug	Prior Authorization Criteria

	• Documented inadequate response, intolerances, and/or contraindication after at least 1-month trial to 2 of the following (from different medication classes):
	  ○ Paroxetine* HCL, citalopram, OR escitalopram *Paroxetine should not be administered to women with prior breast cancer taking tamoxifen.
	  ○ Venlafaxine ER
	  ○ Gabapentin
	  ○ Oxybutynin
	• Veozah will NOT be used concurrently with another hormonal (e.g., Prempro [conjugated estrogen/medroxyprogesterone]) or non-hormonal (e.g., Veozah [fezolinetant], Brisdelle [paroxetine mesylate]) agent for VMS.
	
	<u>Reasons for non-coverage:</u>
	• Pregnancy
	• Cirrhosis or baseline serum transaminase concentrations (ALT, AST, serum bilirubin) ≥2 times upper limit of normal (ULN)
	• Severe renal impairment (e.g. eGFR < 30 mL/min
	• <u>≥</u> 2 blood pressure (BP) readings with BP >130/80 in the past 1 month
	
	<u>Initial Approval Period</u>: 4 months
	
	<u>Continued Approval Period</u>: 12 months if patient meets ALL the initial criteria above and the following:
	• Patient has had a reduction in VMS frequency or severity due to Veozah treatment
	
	<u>For new members who were initiated on Veozah outside of KPGA:</u>
	• Confirm patient is clinically stable and still has a need for VMS treatment by a specialist in the past 6 months AND meets all the medication trials in the criteria.

Verquvo
(Vericiguat)
	Candidates for treatment with Verquvo should meet ALL the following criteria:
	• Patient must be at least 18 years old
	• New York Heart Association (NYHA) Heart Failure class II-IV and an ejection fraction < 45% and either:
	  ○ Hospitalized due to heart failure within last 6 months OR
	  ○ Required IV diuretics as an outpatient within the previous 3 months.
	• Verquvo must be prescribed by a Cardiologist
	• Patient is NOT concurrently taking long-acting nitrates or nitric oxide donors (e.g., isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, PDE-5 inhibitors (e.g., vardenafil, tadalafil), or use of intravenous inotropes or presence of implantable left ventricular assist devices
	• Documented trial, intolerance, or contraindication to a preferred SGLT-2 inhibitor (e.g., Jardiance (empagliflozin))
	• Concurrently receiving the maximum tolerated or target dose of guideline-directed medical therapy for heart failure, unless not tolerated or contraindicated:

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ ACE inhibitor (e.g., lisinopril), ARB (e.g., valsartan, losartan), or angiotensin receptor-neprilysin inhibitor [ARNI] (e.g., sacubitril/valsartan) ○ Beta-blocker (e.g., bisoprolol, carvedilol, metoprolol succinate) Reasons for Non-coverage: • Age < 18 years • eGFR <15 mL/min/1.73^2 or on chronic dialysis • Pregnant or breastfeeding • Severe hepatic impairment (Child-Pugh C) Initial Approval: 12 months Continued Approval**:** 12 months if the patient meets ALL the following: • Patient has an ejection fraction of less than 45% • Patient is NOT concurrently taking long-acting nitrates or nitric oxide donors (e.g., isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, PDE-5 inhibitors (e.g., vardenafil, tadalafil), or use of intravenous inotropes or presence of implantable left ventricular assist devices • Documented clinically significant benefit from the medication during specialist follow up in the last 12 months
Verzenio (Abemaciclib)	**Candidates for Verzenio should meet ALL the following criteria:** Diagnosis of early-stage (I-III) breast cancer: • Prescribed by an oncologist. • Age ≥ 18 years • Patient has a diagnosis of hormone-positive, HER2-negative, early stage (I-III) breast cancer • Medication will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor (e.g., anastrazole , letrozole , or exemestane)) • Patient has **ONE** of the following (positive lymph node status is not indicative of metastatic disease): ○ Four or more positive axillary lymph nodes ○ 1 to 3 positive axillary lymph nodes **AND** one of the following: • Tumor size ≥5 cm **OR** • Tumor is histologically grade 3 (G3) Diagnosis of advanced or metastatic breast cancer (stage III unresectable or stage IV): • Prescribed by an oncologist. • Age ≥ 18 years • Patient has a diagnosis of hormone-positive, HER2-negative (stage III unresectable or stage IV) • Patient has documented intolerance to prior treatment with palbociclib (Ibrance) or ribociclib (Kisqali) AND no evidence of diffuse progression **OR**

Drug	Prior Authorization Criteria

	• Patient meets **ONE** of the following:
	  ○ History of Grade 3 or 4 neutropenia and taking palbociclib (Ibrance) 75 mg daily
	  ○ History of Grade 3 or 4 neutropenia and taking ribociclib (Kisqali) 200 mg daily
	  ○ Patient has a relative contraindication to ribociclib defined as ANY of the following:
	  • Long QT syndrome
	  • Baseline QTc ≥450 ms
	  • Use of drugs that are known to prolong QT interval.
	  • Use of tamoxifen
	  • Use of strong CYP3A4 inhibitors
	  • Uncontrolled or significant cardiac disease (such as myocardial infarction or arrhythmias within the past 12 months, congestive heart failure NYHA class III-IV or with LVEF <50%, unstable angina, or bradycardia)
	
	Initial Approval: 12 months with a quantity limit of 60 tablets per 30 days
	
	Continued Approval: 12 months with a quantity limit of 60 tablets per 30 days. For continued approval for treatment with Verzenio, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria.
	• For patients with advanced or metastatic disease (stage III unresectable or stage IV): Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	• For patients with early stage breast cancer (stage I-III): Treatment duration is limited to 24 months for patients treated with abemaciclib for hormone-positive, HER2-negative, early or nonmetastatic breast cancer.
	
	For new members who were initiated on Verzenio outside of KPGA: Patients should meet ALL the following criteria:
	• Prescribed by an oncologist.
	• Age ≥ 18 years
	• Patient is diagnosed with ONE of the following:
	  ○ Hormone-positive, HER2-negative, advanced, or metastatic breast cancer AND patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	  ○ Hormone-positive, HER2-negative, early, or non-metastatic breast cancer
	  • Treatment duration is limited to 24 months for patients treated with abemaciclib for hormone-positive, HER2-negative, early or nonmetastatic breast cancer.
	• Quantity limit of 60 tablets per 30 days.
	
	Dosing and Administration:
	• For advanced or metastatic HR+/HER2 – disease:
	  ○ Initial endocrine-based therapy: 150 mg BID (in combination with endocrine therapy)
	  ○ Progressive disease following endocrine therapy and prior chemotherapy: 200 mg BID as a single agent.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ Progressive disease on prior endocrine therapy: 150 mg twice daily (in combination with fulvestrant) • For early, high risk, HR+/HER2-/node + disease: 150 mg BID (in combination with endocrine therapy) • Administer at approximately the same time each day. May be administered with or without food. Swallow whole; do not crush, chew or split tablets.
Viberzi (Eluxadoline)	**Candidates for treatment with Viberzi should meet ALL following criteria:** • Age ≥ 18 years • Documented diagnosis of moderate to severe irritable bowel syndrome diarrhea predominant (IBS-D) • Prescribed by a gastroenterologist • Documented contraindication or previous trial and/or intolerance to at least two of the following. If >65 years old, trial of one therapy is adequate: ○ Anti-diarrheal (i.e., loperamide, diphenoxylate/atropine*) ○ Tricyclic antidepressant* (i.e., amitriptyline, desipramine, imipramine) ○ Antispasmodic* (i.e., dicyclomine, chlordiazepoxide/clidinium, hyoscyamine) ○ Bile acid sequestrant (i.e., cholestyramine, colestipol, colesevelam) • Documented contraindication or previous trial and/or intolerance to alosetron • Do not approve in any of the following cases: ○ History of cholecystectomy ○ Known or suspected biliary duct obstruction or sphincter of Oddi disease or dysfunction ○ Alcoholism/abuse/addiction, or more than 3 alcoholic beverages/day consumed ○ Severe hepatic impairment (Child-Pugh Class C) ○ Known or suspected mechanical gastrointestinal obstruction ○ History of chronic or severe constipation ○ A history of pancreatitis or structural disease of the pancreas, including pancreatic duct obstruction ○ Chronic use of medications that can cause constipation (i.e., antidiarrheals, alosetron, opioids, tricyclic antidepressants, antispasmodics, bile acid sequestrants). *Loperamide may be used with Viberzi for acute management of severe diarrhea*. ** Beer's Criteria; NOT recommended if >65 years old*. Initial Approval Period: 6 months Continued Approval: 12 months. Confirm patient meets all above coverage criteria and ALL criteria below: • Beneficial effect documented during gastroenterology follow-up as demonstrated by at least one of the following: (1) improvement in abdominal pain, or (2) improvement in stool frequency and consistency • Patient tolerating treatment without serious adverse effects such as new or worsening abdominal pain, with or without pancreatic enzyme elevations or severe constipation

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
Vigabatrin Products **Preferred:** Vigabatrin powder packet (generic for Vigadrone/Sabril) **Non-preferred (in order of preference):** Vigabatrin tablet (generic for Vigadrone/Sabril) Vigafyde (vigabatrin) Vigadrone (Vigabatrin) Sabril (Vigabatrin)	**Candidates for treatment with Vigabatrin Products should meet ALL of the following criteria. If criteria is met, approve for preferred generic vigabatrin powder packet or generic vigabatrin tablet**. Do not approve non-preferred branded products unless there is a significant nonmodifiable barrier to using generic vigabatrin powder or generic vigabatrin tablet Criteria for Diagnosis of Infantile Spasms and tuberous sclerosis • Prescribed by a neurologist • Between the ages of 1 month to 2 years old. • Indication of infantile spasms (IS) including IS due to tuberous sclerosis or prevention of seizures in tuberous sclerosis. • Must have vision tested to the extent possible depending on the age of the child at baseline before beginning treatment and at least every 3 months. Criteria for Diagnosis of Refractory Complex Partial Seizures: • Prescribed by a neurologist. • Tried and failed at least 2 other anticonvulsant agents. • Vigabatrin used as adjunct therapy. • Potential benefit must outweigh the potential risk of vision loss. • Must have vision tested at baseline before beginning treatment and at least every 3 months. Initial Approval period: 6 months Continued approval: 12 months. Documented beneficial effect from therapy during neurology follow up. Caution: • Peripheral visual field defect, the risk increases with higher doses and longer duration. • Should not be used with other drugs associated with serious adverse ophthalmic effects such as retinopathy or glaucoma unless the benefit outweighs the risk. • Renal impairment: CrCl greater than 50 to 80 mL/min, decrease dose by 25%; CrCl greater than 30 to 50 mL/min, decrease dose by 50%; CrCl greater than 10 to 30 mL/min, decrease dose by 75% Monitoring: • Vision must be tested at baseline and every 3 months • Worsening of depression, suicidal ideation, and abnormal changes in behavior Ordering Information: • All vigabatrin products are available through a restricted distribution Risk Evaluation and Mitigation Strategy (REMS) program called Vigabatrin REMS. Further information is available at www.vigabatrinREMS.com or 1-866-244-8175.

Drug	Prior Authorization Criteria

Vijoice
(Alpelisib)
	PLEASE NOTE: Alpelisib is also marketed as Piqray. If prescribed Piqray, please refer to Piqray's criteria
	
	Candidates for Vijoice should meet ALL of the following criteria:
	
	• Age ≥ 2 years
	• Prescribed by or in consultation with a Geneticist and/or a physician who specializes in the treatment of PROS
	• The patient has at least one severe manifestation of PI3CA-Related Overgrowth Spectrum (PROS) that requires systemic therapy
	  ○ Examples of manifestations include: excessive tissue growth, blood vessel malformations, scoliosis, vascular tumors, and cardiac or renal manifestations
	• The patient has a documented PI3CA mutation confirmed by genetic testing
	
	Reasons for Non-coverage:
	• Hypersensitivity to alpelisib or any of its ingredients
	• Pregnancy or lactation
	
	Initial Approval: 6 months
	
	Continued Approval: 12 months. Confirm the patient meets all above coverage criteria and does not show evidence of disease progression or unacceptable toxicity. In addition, confirm that patient meets one of the following:
	• Reduction in sum of measured target lesion volume
	• Improvement in at least one PROS-related symptom or manifestation
	  ○ Examples: pain, fatigue, vascular malformation, limb asymmetry, intravascular coagulation

Vitrakvi (Larotrectinib)	**Candidates for treatment with Vitrakvi should meet ALL the following criteria:** • Prescribed by a Hematology-Oncology Specialist • Age ≥ 28 days • Documentation of the presence of solid tumors, positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND is without a known acquired resistance mutation • Patient has metastatic disease or disease such that surgical resection is likely to result in severe morbidity OR disease has no satisfactory alternative treatments Initial Approval: 6 months Continued Approval: 12 months. Confirm patient meets all above coverage criteria. In addition, must meet criteria below: • Patient does not show evidence of progressive disease while on Vitrakvi • Absence of significant toxicity • Patient receives continued monitoring as clinically indicated by Hematology/Oncology
Vivjoa (Oteseconazole)	**Candidates for Vivjoa should meet ALL of the following criteria**: • Prescribed by or in consultation with an Infectious Disease or Obstetrics and Gynecology (OB/GYN) Specialist

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	• Patient is documented as one of the following:
	  ○ Female who is postmenopausal OR
	  ○ Female without reproductive potential (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy)
	• Documentation of 3 or more vulvovaginal candidiasis episodes in the past 12 months
	• Documented therapeutic failure to fluconazole 150 mg once weekly for 6 months, in the previous 6 months, OR documented intolerance or contraindication to fluconazole.
	
	Reasons for Non-coverage:
	• Females of reproductive potential
	• Pregnancy or lactation
	• Known hypersensitivity to oteseconazole
	• Severe renal impairment (e.g., eGFR < 30 mL/min) or end stage renal disease (ESRD)
	• Moderate or severe hepatic impairment (e.g., Child-Pugh class B or C)
	
	Approval Period: One time approval of one package per 12 months

Vizimpro
(Dacomitinib)
	Candidates for Vizimpro should meet ALL the following criteria:
	
	• Prescribed by an oncologist.
	• Age ≥ 18 years
	• Patient has a diagnosis of metastatic non-small cell lung cancer.
	• Patient has ONE of the following:
	  ○ Cancer is positive for one of the following EGFR mutations:
	  • Exon 19 deletion
	  • Exon 21 L858R substitution
	  • S768I
	  • L861Q
	  • G719X
	  ○ EGFR mutation status is unknown due to inability to collect sufficient tissue sample for testing.
	• Patient has not experienced disease progression on another EGFR tyrosine kinase inhibitor (e.g., erlotinib, gefitinib, afatinib, osimertinib)
	• Patient has a documented intolerance to osimertinib (Tagrisso)
	
	Initial Approval:
	• For patients with known EGFR status, initial approval for 12 months with a quantity limit of 30 tablets per 30 days.
	• For patients with unknown EGFR status, initial approval for 6 weeks and a quantity limit of 30 tablets per 30 days.
	
	Continued Approval: 12 months. For continued approval for treatment with Vizimpro, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria.
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• Quantity limit of 30 tablets per 30 days. For new members who were initiated on Vizimpro outside of KPGA: • Prescribed by an oncologist. • Age ≥ 18 years • Patient has a diagnosis of EGFR mutation positive non-small cell lung cancer. • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. • Quantity limit of 30 tablets per 30 days.

VMAT2 Inhibitors:
Preferred: Tetrabenazine (generic Xenazine) Available on the COM formulary
 	
Non-Preferred: Xenazine (Tetrabenazine)
 	
Austedo/ Austedo XR (Deutetrabenazine)
	Candidates for treatment with Austedo MUST meet ALL the following criteria based on indication:
	
	Criteria for the diagnosis of chorea associated with Huntington's disease:
	• Documented diagnosis of chorea associated with Huntington's disease
	• Prescribed by a neurologist
	• Patient is 18 years or older
	• Documented inadequate response, intolerance or contraindication to tetrabenazine (for Austedo coverage)
	
	Reasons for Non-coverage:
	• Patients who are suicidal, or who have untreated or undertreated depression
	• Patients with impaired hepatic function
	• Coadministration with or within 14 days of discontinuing monoamine oxidase inhibitors (MAOIs) [i.e., isocarboxazid, phenelzine, selegiline]
	• Coadministration with or within 20 days of discontinuing reserpine
	• Patients taking other VMAT2 Inhibitors [tetrabenazine (Xenazine), valbenazine (Ingrezza) or deutetrabenazine (Austedo)
	• Patients with congenital long QT syndrome or with arrhythmias associated with prolonged QT interval.
	
	Criteria for tardive dyskinesia, Must meet ALL the following criteria:
	• Documented diagnosis of tardive dyskinesia
	• Prescribed by a neurologist or psychiatrist
	• Patient is 18 years and older
	• Abnormal Involuntary Movement Scale (AIMS) score of at least 6
	• Documented intolerance or contraindication or failed a 12-week trial of tetrabenazine
	• Documented inadequate response, intolerance or contraindication to at least 2 of the agents or regimens listed below:
	  ○ Switching offending antipsychotic to quetiapine/ quetiapine ER or clozapine
	  ○ Benzodiazepine
	  ○ Amantadine
	
	Reasons for Non-coverage:
	• Patients who are suicidal, or who have untreated or undertreated depression
	• Patients with impaired hepatic function

Drug	Prior Authorization Criteria
	• Coadministration with or within 14 days of discontinuing monoamine oxidase inhibitors (MAOIs) [i.e., isocarboxazid, phenelzine, selegiline] • Coadministration with or within 20 days of discontinuing reserpine • Patients taking other VMAT2 Inhibitors [tetrabenazine (Xenazine), valbenazine (Ingrezza) or deutetrabenazine (Austedo) • Patients with congenital long QT syndrome or with arrhythmias associated with prolonged QT interval. Initial Approval: 3 months Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, patient has shown improvement by retaining or decreasing baseline AIMS score since starting the medication. Discontinue therapy if no improvement over prior therapy after 3 months.

Vonjo
(Pacritinib)
	Candidates for treatment with Vonjo should meet ALL the following criteria:
	
	• Age ≥ 18 years
	• Prescribed by Hematologist/Oncologist
	• Documented diagnosis of intermediate – or – high-risk primary or secondary (post-polycythemia vera or post-essential thrombocytopenia) myelofibrosis
	• Member has recent platelet count **(within the last 30 days)** below 50,000/uL
	• Documented splenomegaly on physical exam
	• Documented history of failure, contraindication or intolerance to hydroxyurea
	
	Reasons for Non-coverage:
	• Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin) or inducers (e.g., phenobarbital, phenytoin)
	• Moderate (Child-Pugh B) and severe hepatic impairment (Child-Pugh C)
	• eGFR ≤ 30 ml/min
	• Recent history of myocardial infarction, severe/unstable angina, symptomatic congestive heart failure, ongoing Grade ≥3 dysrhythmias, prolonged QTc (>500 msec)
	
	Initial Approval: 6 months
	
	Continued Approval: 12 months. For continued approval for treatment with Vonjo, patient should meet ALL the following criteria:
	
	For new members who were initiated on Vonjo outside of KPGA:
	• Member must meet all criteria listed above and ONE of the following:
	  ○ The patient has a spleen volume reduction of 35% or greater from baseline
	  ○ The patient has a 50% or greater reduction in total symptom score (e.g., Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
	  ○ The patient has a 50% or greater reduction in palpable spleen length
	
	For existing members who previously met the full criteria above:
	• Member must meet all criteria listed above and ONE of the following:
	  ○ The patient has a spleen volume reduction of 35% or greater from baseline

Drug	Prior Authorization Criteria
	○ The patient has a 50% or greater reduction in total symptom score (e.g., Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0) ○ The patient has a 50% or greater reduction in palpable spleen length
Voquezna (vonoprazan) **Non-Preferred:** **Voquezna Dual Pak** (vonoprazan tablets 20mg, amoxicillin capsules 500mg) **Voquezna Triple Pak** (vonoprazan tablets 20mg, amoxicillin capsules 500mg, clarithromycin tablets 500mg)	**Candidates for treatment with Voquezna (vonoprazan) should meet ALL the following criteria:** **Criteria for use for diagnosis of non-erosive gastroesophageal reflux disease (NERD) or gastroesophageal reflux disease (GERD):** • Prescribed by Gastroenterology, Adult Medicine or Family Practice • Age ≥ 18 years • Has diagnosis of non-erosive gastroesophageal reflux disease (NERD) or gastroesophageal reflux disease (GERD) • Documented inadequate response, intolerance or contraindication to at least 5 of the following (including rabeprazole, dexlansoprazole and Omeprazole/sodium bicarbonate), titrated to the doses below: ○ Omeprazole 20-40mg once daily ○ Pantoprazole 40mg once to twice daily ○ Lansoprazole 30mg once to twice daily ○ Rabeprazole 20mg once to twice daily ○ Esomeprazole 40mg once to twice daily ○ Dexlansoprazole 60mg once daily ○ Omeprazole/sodium bicarbonate capsules 40/1100mg twice daily OR Omeprazole/sodium bicarbonate oral packet 40/1680mg twice daily **Criteria for use of diagnosis of erosive esophagitis (EE), healing and maintenance therapy:** • Prescribed by Gastroenterology • Age ≥ 18 years • Has diagnosis of erosive esophagitis (EE). Will be prescribed for both healing and maintenance of EE • Documented inadequate response, intolerance or contraindication to at least 5 of the following (including rabeprazole, dexlansoprazole and Omeprazole/sodium bicarbonate) for the dose and durations below: ○ Rabeprazole 20mg once daily for 8 weeks and thereafter ○ Pantoprazole 40mg once daily for 8 weeks and thereafter ○ Omeprazole 20-40mg once daily for 4-8 weeks, then 20mg once daily ○ Lansoprazole 30mg once daily for 8 weeks then 15mg once daily ○ Esomeprazole 20-40mg once daily for 4-8 weeks, then 20mg once daily ○ Dexlansoprazole 60mg once daily for 8 weeks, then 30mg once daily ○ Omeprazole/sodium bicarbonate Initial approval: 6 months. Quantity Limits: 30 tablets / 30 days. Continued approval: none For new member who were initiated outside of KPGA: Patient meets all criteria above **Criteria for use for diagnosis of H.pylori infection:**

Drug	Prior Authorization Criteria

	• **<u>Do not approve QRM request for Voquezna Dual Pak or Voquezna Triple Pak. Approve Voquezna 20mg tablets only.</u>**
	• Prescribed by Gastroenterology
	• Age ≥ 18 years
	• Has a confirmed diagnosis of Helicobacter pylori (H. pylori) infection
	• Documented inadequate response, intolerance or contraindication to ALL of the following 14 day regimens:
	  ○ 1st line Optimized Bismuth Quadruple Therapy (BQT): pantoprazole 40mg twice daily, bismuth subsalicylate 262 four times daily, metronidazole 500mg four times daily and tetracycline 500mg four times daily
	  ○ 2nd line Rifabutin Triple Therapy: pantoprazole 80mg twice daily, rifabutin 150mg twice daily and amoxicillin 1000mg twice daily
	  ○ 3rd line Levofloxacin Triple Therapy: pantoprazole 80mg twice daily, levofloxacin 500mg once daily and amoxicillin 1000mg twice daily OR metronidazole 500mg twice daily (if PCN allergy)
	• If criteria above are met, approve Voquezna 20mg tablets (NOT the dual or triple paks) which will be dispensed in combination with a separate prescription of amoxicillin 500mg capsules and/or clarithromycin 500mg tablets
	
	<u>Initial approval:</u> 2 months
	<u>Do not approve QRM request for Voquezna Dual Pak or Voquezna Triple Pak.</u> Approve Voquezna 20mg tablets only. Amoxicillin and/or clarithromycin will be dispensed as separate prescription(s).
	
	<u>Continued approval:</u> none

Voranigo
(Vorasidenib)
	Candidates for treatment with Voranigo (vorasidenib) must meet ALL the following criteria:
	
	• Prescribed by an oncologist
	• Patient is ≥12 years of age
	• Patient has a diagnosis of Grade 2 astrocytoma or oligodendroglioma
	• Patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrongenase-2 (IDH2) mutation
	• Patient has had prior surgery, including biopsy, sub-total resection, or gross total resection
	
	<u>Reasons for Non-Coverage:</u>
	• Pregnancy
	• Lactation
	
	<u>Initial Approval:</u> 12 months
	• The following quantity limits will apply:
	  ○ 40 mg tablets – 30 tablets per 30 days
	  ○ 10 mg tablets – 90 tablets per 30 days
	
	<u>Continued Approval:</u> 12 months. Patient continues to meet above coverage criteria AND

Drug	Prior Authorization Criteria

	• Documented beneficial effect from therapy without disease progression or unacceptable toxicity (e.g., hepatotoxicity)
	• The following quantity limits will apply:
	  ○ 40 mg tablets – 30 tablets per 30 days
	  ○ 10 mg tablets – 90 tablets per 30 days

Vosevi (Sofosbuvir/ Velpatasvir/ Voxilaprevir)	**Candidates for treatment with sofosbuvir/velpatasvir/voxilaprevir (Vosevi) should meet ALL the following criteria:**
	
	<u>Hepatitis C (HCV):</u>
	
	• Prescribed by Gastroenterologist or Infectious Disease specialist
	• Documented Hepatitis C virus (HCV) infection demonstrated by detectable quantitative HCV RNA level in previous 12 months
	• Documented **one** of the following:
	  ○ Patients with prior peg-interferon/ribavirin treatment experience, compensated cirrhosis (Child-Turcotte-Pugh class A), hepatitis C genotype 3, and a documented Y93H resistance-associated substitution (RAS)
	  ○ Documented intolerance or contraindication to a NS5A-inhibitor (e.g.,daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir) containing regimen
	• Do not approve if documented decompensated cirrhosis [Child-Turcotte-Pugh (CTP): class B or C]
	
	<u>Solid Organ Transplant (i. e. heart, lung, liver, and kidney):</u>
	
	• Prescribed by a Transplant Specialist for solid organ transplant
	• Documented inadequate response, intolerance or contraindication to a NS5A-inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir) containing regimen
	
	<u>Initial Approval:</u>
	• For patients without cirrhosis or compensated cirrhosis (CTP: class A), approve for 12 weeks
	
	<u>Continued approval for new members who were initiated on Vosevi outside of KPGA:</u> confirm diagnosed with hepatitis C and Vosevi initiation date.
	• For patients without cirrhosis or compensated (CTP: class A) cirrhosis, approve for a total of 12 weeks

Vowst (Fecal microbiospore, live-brpk)	**Candidates for treatment with Vowst should meet ALL the following criteria:** • Age ≥ 18 years • Prescribed by an Infectious Disease Specialist or Gastroenterologist • Prescribed for the treatment or the prevention of recurrent *Clostridioides difficile* infection (rCDI) • Documentation of at least 2 recurrent episodes of severe *Clostridiodes difficile* infection (CDI) (≥3 total CDI episodes) within the past 12 months • If patient has not previously received Vowst: Documented completion of antibiotic (i.e vancomycin, fidaxomicin) treatment for recurrent CDI (defined as at least 3 CDI episodes)

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

	• Documentation (i.e., limited access to FMT due to OpenBiome restrictions, noted in chart) that fecal microbiota transplantation (FMT) from a reputable source is unavailable
	  ○ If available, documentation that FMT is contraindicated
	• Documentation of trial and failure or contraindication to Reboyota (fecal microbiota, live-jslm)
	• If patient was previously treated with Vowst:
	  ○ Documented treatment failure (defined as the presence of CDI diarrhea within 8 weeks of the first dose of Vowst) AND a positive stool test for *C. difficile* AND
	  ○ Patient has not previously received more than 1 treatment course of Vowst AND the start of that treatment course was at least 12 days and not more than 8 weeks prior to new request.
	
	Reasons for Non-Coverage:
	• Prescribed to treat CDI
	
	Initial Approval Period: 1 treatment course
	
	Continued Approval Period: 1 additional treatment course if patient meets ALL the initial criteria above.
	
	Notes
	[1]Based on clinical judgement, if unable to use magnesium citrate in patients with impaired renal function, consider 250 mL polyethylene glycol electrolyte solution (GoLYTELY, not approved for this use).

Voxzogo (Vosoritide)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** **Candidates for Voxzogo should meet ALL of the following criteria:** • Prescribed by Geneticist and/or Pediatric Endocrinologist • Patient has open epiphyses • Confirmed diagnosis of achondroplasia through genetic testing confirming FGFR3 gene mutation associated with achondroplasia • Patient is ambulatory or expected to be ambulatory in the near future Reasons for Non-coverage: • Hypochondroplasia or short stature condition other than achondroplasia • eGFR <60 mL/min/1.73 m^2 • Bone age ≥14 years (females) or ≥16 years(males) Initial Approval: 12 months

Drug	Prior Authorization Criteria
	Continued Approval: 12 months. Confirm patient continues to meet the above criteria AND does not meet any of the criteria below for discontinuation. Evaluate each bullet under "Criteria for Discontinuation." For new members initiated on vosoritide outside of KPGA: Patient can continue therapy for up to 1 month until evaluated by pediatric endocrinologist or geneticist AND specialty prescriber documents patient meets coverage criteria AND does not meet any of the criteria for discontinuation. Criteria for Discontinuation: • No response or inadequate response (e.g., no increase in growth velocity) to therapy per prescriber after 12 months of treatment • No further growth potential as indicated by closure of epiphyses • Intolerance to medication • Non-adherence to medication [MRAR ≥ 80%. If MRAR < 80%, reviewer can confirm adherence in the last 90 days based on medication sold dates found in Health Connect medication tab (e.g., 3 one month fills or one 90 day fill)] recommended diet and lifestyle measures, or follow- up labs and assessments
Voydeya (Danicopan)	**Candidates for treatment with Voydeya (danicopan) should meet ALL the following criteria:** • Age ≥ 18 years • Patient is diagnosed with paroxysmal nocturnal hemoglobinuria (PNH) • Voydeya will be used for the treatment of extravascular hemolysis (EVH) AND used as add-on therapy to eculizumab biosimilar (e.g., Epysqli), Soliris (eculizumab) orUltomiris (ravulizumab-cwvz). • Prescribed by a specialist in the area of practice related to the patient's diagnosis (e.g., hematologist, oncologist, immunologist, or genetic specialist) who is certified in the Voydeya REMS program (registration available at Voydeya REMS) Reasons for Non-coverage: • Voydeya will be used as monotherapy • Patient has unresolved serious infection caused by encapsulated bacteria (i.e., Neisseria meningitidis, Streptococcus pneumoniae, and Haemophilus influenzae type B) • Severe hepatic impairment (Child-Pugh C) Initial Approval: 12 months Continued Approval: 12 months. Confirm patient meets all the above coverage criteria and documented clinical benefit from treatment. Ordering Information: Voydeya is available through the KP Specialty Pharmacy. If approved for coverage, prescribers must complete the KP-SP Voydea Order Form and fax it to the KP Specialty Pharmacy at (1-650-301-5790).

Drug	Prior Authorization Criteria

Voyxact
(Sibeprenlimab-szsi)
	Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval.
	
	Candidates for treatment with Voyxact (sibeprenlimab-szsi) should meet ALL of the following criteria:
	
	• Age 18 years of age or older
	• Prescribed by nephrologist
	• Blood pressure </= 150/100
	• Documented diagnosis of IgA nephropathy (IgAN) verified by renal biopsy
	• Documented high risk of disease progression defined by urine protein-to-creatinine (UPCR) >1.5
	• eGFR >/= 30 mL/min
	• Proteinuria ≥1 g/day
	• Currently prescribed maximum tolerated dose of one of the following for at least 3 months or documented intolerance/contraindication to:
	  ○ ACEI (e.g., lisinopril, benazepril) OR
	  ○ ARB (e.g., losartan, valsartan)
	• Currently prescribed an SGLT2I (e.g., Jardiance, dapagliflozin) for at least 3 months or documented intolerance/contraindication.
	• Documented therapeutic trial (defined as at least 3 months), intolerance or contraindication **ALL** the following:
	  ○ Fabhalta (iptacopan)
	  ○ Filspari (sparsentan) OR Vanrafia (atrasentan)
	  ○ Tarpeyo
	
	Note: It has not been established whether Voyxact slows kidney decline over the long-term in patients with IgAN.
	
	<u>Reasons for Non-Coverage:</u>
	
	• Concurrent treatment with Fabhalta (iptacopan), Filspari (sparsentan) OR Vanrafia (atrasentan), Tarpeyo
	
	<u>Initial Approval:</u> 6 months
	
	• **Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval.**
	• **Approve for member to fill via the outpatient pharmacy benefit only**
	
	<u>Continued Approval:</u> 12 months. For continued approval for treatment, patient should meet ALL the following criteria:
	• Documented clinically significant reduction in proteinuria (~ 30-50% from baseline)
	• **Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval.**

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>

- **Approve for member to fill via the outpatient pharmacy benefit only**

Ordering Information: Available via PANTHERx Rare
</td></tr>
<tr><td>Vtama
(Tapinarof)</td><td>

Candidates for Vtama should meet ALL of the following criteria:

Criteria for use for the diagnosis of plaque psoriasis:

- Age ≥18 years
- Diagnosis of moderate to severe plaque psoriasis
- Prescribed by a dermatologist
- Documented history of inadequate response, contraindication, or intolerance to ALL of the following:
  - High or super-high potency topical corticosteroid (e.g., betamethasone dipropionate, augmented 0.05% cream, clobetasol propionate 0.05% ointment, lotion, gel)
  - Topical vitamin D analog (e.g., calcipotriene 0.005% solution, calcitriol 3mcg/g ointment)
  - Topical calcineurin inhibitor (e.g tacrolimus 0.1% ointment)
  - Topical retinoid (e.g. tazarotene 0.1% topical cream)
  - Phototherapy (PUVA, UVB with coal tar or dithranol, UVB standard or narrow-band, or home UVB) of at least a 3-month trial, excluding patients with:
    - Involvement of sensitive areas (e.g. hand, feet, face, body folds or genitals)
    - Concomitant use of medications that cause photosensitivity, history of photosensitivity disorder (e.g. Lupus, Dermatomyositis, Porphyria, Xeroderma pigmentosum), history of melanoma or abnormal moles, history of multiple non-melanoma skin cancers

Criteria for use for the diagnosis of atopic dermatitis:

- Documented mild-to-moderate atopic dermatitis (BSA >5%)
- Prescribed by a dermatologist
- Patient is 2 years of age or older
- Documented inadequate response, intolerance or contraindication to **ALL** of the following:
  - Medium to very high potency topical corticosteroid for a minimum of 2 weeks:

Medium Potency	High and Very High Potency
Triamcinolone acet 0.1%, 0.025% O, C	Betameth diprop aug 0.05% C
Betamethasone val 0.1% C	Fluocinonide 0.05% O, C, G
Mometasone 0.1% O, C	Fluocinonide-emollient 0.05% C
Triamcinolone acet 0.5% C	Desoximetasone 0.25% C
Betamethasone diprop 0.05% C	Betamethasone diprop aug 0.05% O, G
Betamethasone val 0.1% L	Clobetasol 0.05% O, C

</td></tr>
</table>

Drug	Prior Authorization Criteria
	O = oint, C = cream, G = gel, L = lotion ○ Topical calcineurin inhibitors [Pimecrolimus (Elidel) or tacrolimus (Protopic)] for a minimum of 2 weeks ○ Phototherapy of at least a 3-month trial, excluding patients with: ▪ Involvement of sensitive areas (e.g. hand, feet, face, body folds or genitals) ▪ Concomitant use of medications that cause photosensitivity, history of photosensitivity disorder (e.g. Lupus, Dermatomyositis, Porphyria, Xeroderma pigmentosum), history of melanoma or abnormal moles, history of multiple non-melanoma skin cancers ▪ Developmentally unable to stand in light unit alone (pediatric patients) Initial Approval: 12 months (with quantity limited to 60 grams (1 tube) per 30 days) Continued Approval: 12 months. Continue approval if the following criteria are met: • For new members who were initiated outside of KPGA: Confirm patient meets all above coverage criteria without reasons for non-coverage and is confirmed to be clinically stable by a specialist during follow-up in the last 6 months. • For existing members who have previously met the criteria: Documented clinically significant benefit (adequate response) from the medication during specialist follow up in the last 12 months.
Vumerity (Diroximel Fumarate)	**Candidates for treatment with Vumerity should meet ALL the following criteria:** • Age ≥ 18 years • Documented diagnosis of relapsing multiple sclerosis (MS) • Prescribed by a neurologist • Vumerity is prescribed for use as monotherapy disease-modifying treatment for MS • CBC within the past 6 months shows normal WBC and lymphocyte counts • For females of child-bearing age (12-50 years), a baseline negative pregnancy test within the past month AND either a prescription for birth control (IUD or other contraceptive) or documentation of the patient declining contraception and being counseled of the potential risk of pregnancy • Documented persistent or severe intolerance* or contraindication to ALL therapeutic alternatives: Interferon beta 1b (Betaseron), glatiramer acetate (Glatopa) and teriflunomide • Documented adequate trial of dimethyl fumarate with persistent GI intolerance despite attempts to mitigate as evidenced by the following ○ Confirm dimethyl fumarate was initiated by titration: 120 mg twice a day for 7 days followed by maintenance dose of 240 mg twice a day ○ Confirm documented attempts to manage GI side effects including administering with food and counseling that GI side effects may reduce after 1 month on therapy ○ Confirm prescription was filled by patient for at least 90 days and intolerance persisted despite documented attempts to manage and mitigate the GI side effects

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	*NOTE: Injection fatigue or fear of needles is not a reason for intolerance or inadequate response. Reasons for Non-coverage: Diroximel fumarate (Vumerity) should NOT be used in patients with any of the following: • Lymphocyte count < 0.5 x 10^9/L for over 6 months • Signs and symptoms of serious infection • JCV antibody positive, previously treated with Tysabri and sustained lymphocyte count < 0.8 x 10^9/L on two or more lab tests over ≥ 3 months • ALT or AST elevation 3X normal or higher or severe liver disease • Pregnancy Initial Approval Period: 1 year Continued Approval Period: 1 year For new members who were initiated on diroximel fumarate (Vumerity) outside of KPGA**:** continue approval for treatment with Vumerity if ALL the following criteria are met: • Confirm documentation that patient had a persistent GI intolerance to dimethyl fumarate (generic Tecfidera) that was reduced with Vumerity • Confirm documented history of persistent or severe intolerance or contraindication to ALL therapeutic alternatives: Interferon beta 1b (Betaseron), glatiramer acetate (Glatopa) and teriflunomide • Patient has had a visit with MS Specialist and confirmed to be stable on the therapy and discussed consideration of IV rituximab as a DMT alternative with convenient dosing For existing members who have previously met the full criteria above: continue approval for treatment with Vumerity if ALL the following criteria are met: • Documented beneficial effect from therapy during neurology follow up • CBC with differential including lymphocyte count obtained 6 months after initiation of treatment then at least once every 12 months • Lymphocyte count > 0.5 x 10^9/L • No signs and symptoms of serious infection
Vyalev (Foscarbidopa/foslevodopa)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** **Candidates for treatment with Vyalev (foscarbidopa/foslevodopa) should meet ALL the following criteria:** • Patient is at least 18 years of age • Documented diagnosis of Parkinson's disease

Drug	Prior Authorization Criteria

	• Prescribed by, or in consultation with a neurologist or specialist in the treatment of Parkinson's disease
	• Patient continuing to experience ≥ 2.5 hours of "off" time per day despite optimal management of carbidopa-levodopa oral therapy including documentation of the following:
	  ○ Currently taking carbidopa/levodopa immediate release or controlled release 5 or more times per day OR currently taking carbidopa/levodopa extended release (Rytary)
	• Documented inadequate response to, contraindication, or intolerance to at least **TWO** different classes of adjunctive medications for the treatment of Parkinson's disease:
	  ○ Monoamine oxidase (MAO) type B inhibitors (e.g., selegiline, rasagiline)
	  ○ Dopamine agonists, (e.g., pramipexole, ropinirole)
	  ○ Catechol-O-methyl transferase (COMT) inhibitors (e.g., entacapone)
	  ○ Amantadine
	
	Reasons for Non-coverage:
	• Vyalev should NOT be used in patients currently taking or within the last 2 weeks have taken a non-selective monoamine oxidase inhibitor (MAOI) (e.g., phenelzine, isocarboxazid, tranylcypromine)
	
	Initial Approval Period: 6 months
	
	Continued approval: 12 months. Continue approval if the patient has completed a neurology follow up visit in the last 12 months with documented clinical benefit and no reported adverse events to Vyalev.
	
	For new members who were initiated on Vyalev outside of KPGA:
	• Patient has a diagnosis of Parkinson's disease
	• Prior to foscarbidopa/foslevodopa (Vyalev) start, patient was:
	  ○ Experiencing at least 2.5 hours of "off" time per day despite taking carbidopa/levodopa immediate release or controlled release 5 or more times per day OR taking carbidopa/levodopa extended release (Rytary)
	  ○ Previously failed an adequate trial of, or has an allergy or intolerance or contraindication to at least two classes of adjunctive medications as listed above
	
	Ordering Information:
	• Vyalev is only dispensed by Accredo Specialty pharmacy. Approval of this QRM request will indicate approval for both the drug and pump/supplies.
	
	Prescribe should fax enrollment form to Accredo [patient-enrollment-form.pdf]. Accredo will verify coverage. Once approved, Vyalev will be shipped directly to the patient.

Vyjuvek (Beremagene geperpavec)	**Candidates for Vyjuvek should meet ALL of the following criteria:**

Drug	Prior Authorization Criteria
	**Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).* • Prescribed by a dermatologist or pediatric dermatologist • Documented diagnosis of dystrophic epidermolysis bullosa (DEB) • Confirmation of DEB diagnosis by genetic testing including COL7A1 • Presence of wounds that have not healed despite three months of standard wound care, or have recurrent ulceration of wound. If wound pain is causing significant functional impairment, a two-month trial of standard wound care is adequate; and • Wound appears clean with adequate granulation tissue, excellent vascularization, and does not appear infected; and • Ability to maintain and comply with office visits during treatment • For females of childbearing age (12-50 years), a baseline negative pregnancy test at start of treatment • Male or female of childbearing potential should use a reliable birth control method during treatment and for three months after treatment Reasons for Non-coverage: • Current or history of squamous cell carcinoma in the area that will undergo treatment • Actively receiving chemotherapy or immunotherapy • Pregnancy or lactation • Prior allergic reaction to any component of beremagene geperpavec Initial Approval: 3 months. Approve for member to fill via outpatient pharmacy benefit only. Continued Approval: 3 months. Continue approval if wound reopens Criteria for Discontinuation: • Lack of clinically significant signs of improvement after three months of treatment • Lack of resolution of wound after six months of treatment • Discontinue after resolution of wound as beremagene geperpavec does not penetrate intact skin • Intolerance to medication • Non-adherence to medication or follow-up assessments • Pregnancy is diagnosed or women is breastfeeding Dosing and Administration: • For topical application only. • The dose is based on the approximate size of the wound (refer to beremagene geperpavec prescribing information for details)

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>
<table>
<tr><th>Wound Area (cm^2)</th><th>Dose (plaque forming units; PFU)</th><th>Volume (mL)</th></tr>
<tr><td><20</td><td>4×10^8</td><td>0.2</td></tr>
<tr><td>20 to <40</td><td>8×10^8</td><td>0.4</td></tr>
<tr><td>40 to 60</td><td>1.2×10^9</td><td>0.6</td></tr>
</table>

< 3 years old

Maximum weekly dose (plaque forming units (PFU)): 2×10^9
Maximum weekly volume (mL): 1

≥ 3 years old

Maximum weekly dose (plaque forming units (PFU)): 4×10^9
Maximum weekly volume (mL): 2
It may not be possible to apply beremagene geperpavec to all wounds at each treatment visit. Prioritize previously treated wounds if they re-open.

</td></tr>
<tr><td>Vykat XR
(diazoxide choline)</td><td>Candidates for Vykat XR should meet ALL the following criteria:

Prescribed by an Endocrinologist, Geneticist, or Neurologist
Age ≥ 4 years
Patient has genetically confirmed Prader-Will syndrome (PWS) with hyperphagia

Initial Approval: 6 months

Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for non-coverage in addition to criteria below:

Patient is responding positively to therapy and does not show evidence of progressive disease while on therapy

Dosing and Administration:

Administer orally once daily. The maximum recommended dosage is 5.8 mg/kg/day or 525 mg per day.
The recommended oral dosage of VYKAT XR is based on body weight. The recommended starting dosage and titration schedule of VYKAT XR are shown in Table 1.

Table 1: Recommended Starting Dosage and Titration Regimen</td></tr>
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<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>
<table>
<tr><th rowspan="2">Weight</th><th colspan="4">Recommended Once Daily Dosage</th></tr>
<tr><th>Starting Dosage
Weeks 1 and 2</th><th>Titration Dosage
Weeks 3 and 4</th><th>Titration Dosage
Weeks 5 and 6</th><th>Target Maintenance Dosage</th></tr>
<tr><td>20 kg to <30 kg</td><td>25 mg</td><td>50 mg</td><td>75 mg</td><td>100 mg</td></tr>
<tr><td>30 kg to <40 kg</td><td>75 mg</td><td>150 mg</td><td>150 mg</td><td>150 mg</td></tr>
<tr><td>40 kg to <65 kg</td><td>75 mg</td><td>150 mg</td><td>225 mg</td><td>225 mg</td></tr>
<tr><td>65 kg to <100 kg</td><td>150 mg</td><td>225 mg</td><td>300 mg</td><td>375 mg</td></tr>
<tr><td>100 kg to <135 kg</td><td>150 mg</td><td>300 mg</td><td>375 mg</td><td>450 mg</td></tr>
<tr><td>≥135 kg</td><td>150 mg</td><td>300 mg</td><td>450 mg</td><td>525 mg</td></tr>
</table>
Ordering Information:

Vykat XR is only available from PANTHERx Rare Pharmacy VYKAT™ XR - PANTHERx Rare
</td></tr>
<tr><td>TTR Stabilizers/Silencers

<u>Preferred:</u>
Vyndamax
(Tafadamis)

<u>Non-Preferred:</u>
Attruby
(Acoramidis)

Amvuttra
(Vutrisiran)

(In patients with both ATTR-PN and ATTR-CM, Amvuttra (vutisiran) is the only approved option)</td><td>
*Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)

Candidates for treatment with TTR stabilizer/silencer should meet ALL the following criteria:

• Prescribed by Cardiology
• Age ≥ 18 years
• Documented diagnosis of ATTR-CM (Cardiomyopathy of the wild-type or hereditary transthyretin-mediated amyloidosis confirmed by biopsy demonstrating transthyretin (TTR) amyloid deposition OR meeting all three of the following:
  ○ Diagnosis of heart failure (defined as Stage C Heart Failure (HF) plus NYHA Class I, II, or III) and ONE of the following:
    ▪ Echocardiogram with end-diastolic interventricular septal wall thickness > 12 mm
    ▪ Cardiac MRI consistent with or suggestive of amyloidosis
  ○ Pyrophosphate (PYP) scintigraphy cardiac uptake visual score of either:
    ▪ Grade 2 or 3 using the Perugini Grade 1-3 scoring system
    ▪ Calculated heart-to-contralateral lung (H/CL) ratio ≥1.5
  ○ Absence of monoclonal gammopathy after testing for serum immunofixation (IFE) and serum free light chains
• Medical History of HF with at least 1 hospitalization for HF or clinical evidence of HF (without hospitalization) manifested by signs or symptoms of volume overload or elevated intracardiac pressures that required treatment with a diuretic.
• Genetic Testing: Once diagnosed with ATTR-CM, TTR gene sequencing is recommended to determine if mutated or wild-type (patients with a mutation may require family counseling)
  ○ If mutated ATTR-CM and if patients have a polyneuropathy, consider consultation with a neurologist to determine drug of choice.
• Last eGFR ≥ 25 mL/min and patient does not require dialysis
</td></tr>
</table>

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• For Attruby, patient must have documented contraindication, intolerance, or tried and failed Vyndamax. • For Amvuttra: patient must have documented contraindication, intolerance, or tried and failed BOTH Vyndamax AND Attruby. ○ NOTE: in patients with both ATTR-PN and ATTR-CM, Amvuttra (vutisiran) is the only approved option. Trial of Vyndamax and Attruby is NOT required. Reasons for Non-coverage: • Not prescribed in combination with any other TTR silencers or stabilizers including Vyndamax (tafamidis), Attruby (acoramidis), Onpattro (patisiran), Amvuttra (vutrisiran), Wainua (eplonteseren), or Tegsedi (inotersen). • Prior liver or heart transplant • Implanted cardiac mechanical assist device Initial Approval: 12 months Continued approval: 12 months. Confirm patient meets all above coverage criteria without reason for non-coverage. In addition, provider attests to the following: • Positive clinical benefit (e.g. improvement or stabilization in 6-min walking distance, reduction in cardiovascular hospitalization) clinical improvement and tolerating medication. • Routine assessment by cardiology (office visit or video) in past 12 months • Documented adherence to medication and follow-up labs and assessments. For new members who were initiated on Vyndamax, Attruby, or Amvuttra outside of KPGA: confirm patient meets all initial review criteria without reasons for non-coverage.
Preferred: **Vyvgart** (Efgartigimod alfa) **Vyvgart Hytrulo** (Efgartigimod alfa and hyaluronidase) **Vyvgart Hytrulo prefilled syringe (PFS) is preferred over Vyvgart Hytrulo SDV.	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).** **Candidates for treatment with Vyvgart or Vyvgart Hytrulo must meet ALL the following criteria for myasthenia gravis:** • Prescribed by or in consultation with a Neurologist with specialty in neuromuscular disorders • Diagnosis of generalized myasthenia gravis (gMG) • Patient is 18 years or older • No history of thymoma or thymic neoplasm OR patient has history of thymoma and has had a thymectomy that was completed over 3 months ago • Patient has a Myasthenia Gravis Activities of Daily Living (MG-ADL) scale score of 5 or higher • Patient is currently taking pyridostigmine for symptomatic management as prescribed unless there is a severe intolerance or contraindication • Trial of corticosteroid for at least 3 months and patient experienced inadequate disease control or patient has an intolerance or contraindication to corticosteroid

Drug	Prior Authorization Criteria

	therapy
	• Trial of at least one non-steroidal immunosuppressive therapy for the duration indicated:
	  ○ Azathioprine or mycophenolate for at least 12 months
	  ○ Rituximab or rituximab biosimilar for at least 12 months
	  ○ Other disease modifying therapy (e.g., cyclophosphamide, cyclosporine, tacrolimus, methotrexate) for at least 6 months
	• Patient has tried and failed or has a contraindication to chronic IV immune globulin (IVIG)
	
	Reasons for Non-coverage:
	• Patient is prescribed concomitant monoclonal antibody therapy for myasthenia gravis such as Epysqli / Soliris (eculizumab-aagh), Ultomiris, Rystiggo, or Zilbrysq.
	
	Initial Approval: 6 months
	• For Vyvgart IV: approve for administration at KP Infusion center ONLY
	• For Vyvgart Hytrulo: approve PFS for fill via the outpatient benefit ONLY
	• **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Continued approval: 12 months
	• For first renewal: patient must show documented improvement of at least 2 points on the Myasthenia Gravis-Activities of Daily Living scale (MG-ADL)
	• For subsequent renewals: patient must show documented maintenance of stable MG-ADL score or documented beneficial effect from therapy during Neurology follow-up in the last 12 months
	• For Vyvgart IV: approve for administration at KP Infusion center ONLY
	• For Vyvgart Hytrulo: approve PFS for fill via the outpatient pharmacy benefit ONLY
	• **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	For new members who were initiated on Vyvgart or Vyvgart Hytrulo for myasthenia gravis outside of KPGA, approve if ALL the following criteria are met:
	• Patient has had a visit with a Neurologist with specialty in neuromuscular disorder to discuss consideration of chronic IVIG as an alternative treatment option
	• Patient has tried and failed a corticosteroid AND at least one non-steroidal immunosuppressive therapy as listed above
	• Patient confirmed to be stable on therapy by Neurologist
	• For Vyvgart IV: approve for administration at KP Infusion center ONLY
	• For Vyvgart Hytrulo: approve PFS for fill via the outpatient pharmacy benefit ONLY
	• **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)**
	
	Candidates for treatment with Vyvgart Hytrulo must meet ALL the following criteria for chronic inflammatory demyelinating polyneuropathy (CIDP):
	• Prescribed by or in consultation with a Neurologist with specialty in neuromuscular disorders
	• Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP)

Drug	Prior Authorization Criteria
	• Patient is 18 years or older • Patient has had an inadequate response, intolerance or has a contraindication to immune globulin (IVIG or SCIG) Initial Approval: 6 months. • For Vyvgart Hytrulo: approve PFS for fill via the outpatient pharmacy benefit ONLY • **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: 12 months. Confirm patient has completed follow up appointment with Neurologist within the last 12 months. • For Vyvgart Hytrulo: approve PFS for fill via the outpatient pharmacy benefit ONLY • **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** For new members who were initiated on Vyvgart Hytrulo for CIDP outside of KPGA, approve if ALL the following criteria are met: • Patient has had a visit with a Neurologist with specialty in neuromuscular disorder to discuss consideration of IVIG as an alternative treatment option • Patient confirmed to be stable on therapy by Neurologist • **Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Ordering Information: • Vyvgart Hytrulo PFS (efgartigimod alfa and hyaluronidase) is dispensed through local Kaiser outpatient pharmacies. It is not available through KP mail order.

Vyzulta (Latanoprostene Bunod)	**Candidates for treatment with Vyzulta should meet ALL the following criteria:**
	• Documented diagnosis of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension
	• Prescribed by an ophthalmologist
	• Patient is 18 years and older
	• Documented inadequate response, intolerance or contraindication to the following:
	  ○ At least two ophthalmic prostaglandin analogs (e.g., latanoprost etc.) AND
	  ○ At least one ophthalmic beta-blocker (e.g., timolol etc.)
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. Confirm patient meets all above criteria. In addition, continue approval if there is documented positive response to therapy.

Wakix (Pitolisant)	**Candidates for treatment with Wakix should meet ALL the following criteria:** • Prescribed by a Specialist in sleep medicine • Age ≥ 6 years

Drug	Prior Authorization Criteria
	• Patient has Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10 • Patient's self-reported sleep log demonstrates adequate sleep opportunity per Sleep Specialist (7 to 9 hours for most patients) • Patient is unable to take sodium oxybate (generic Xyrem) as demonstrated by ONE of the following: a. Documented cardiovascular disease requiring sodium restriction such as congestive heart failure or refractory hypertension (on 3 or more antihypertensives or failed multiple antihypertensives) b. Adequate trial (≥ 2 months) of sodium oxybate (generic Xyrem) with treatment failure or intolerance documented • Patient has a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy AND has tried and failed or has a contraindication to ALL the following: a. Maximum tolerated dose of modafinil b. One other traditional wake-promoting agent (e.g., amphetamine sulfate, methylphenidate, etc.) c. Solriamfetol (Sunosi) • Patient has a diagnosis of cataplexy and EDS with narcolepsy and has tried and failed venlafaxine AND at least one other agent for the treatment of cataplexy such as an SSRI (e.g., fluoxetine) • Patient must not be on concurrent solriamfetol (Sunosi), or any other oxybate product (i.e., Xyrem, Xywav, Lumryz) Initial Approval: 12 months Continued Approval: 12 months. For new members who were initiated on pitolisant (Wakix) outside of KPGA: • Patient has previously tried and failed sodium oxybate (generic Xyrem) OR documented cardiovascular disease requiring sodium restriction such as congestive heart failure or refractory hypertension (on 3 or more antihypertensive agents or failed multiple antihypertensives). • For EDS with narcolepsy, patient must have tried and failed or have a contraindication to modafinil AND one other traditional wake-promoting agent (e.g., amphetamine sulfate, methylphenidate) AND solriamfetol (Sunosi). • For cataplexy with narcolepsy, patient must have tried and failed venlafaxine and at least one other agent for cataplexy such as an SSRI (e.g., fluoxetine). For existing members who have previously met the full criteria above: • Patient has demonstrated 30% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline OR patient has shown improvement in cataplexy compared to baseline. • Documented positive clinical response in an appointment with a sleep specialist within the past 6 months.

Drug	Prior Authorization Criteria
	Ordering Information • Wakix is dispensed from Accredo Specialty Pharmacy • Providers must complete Wakix prescription referral form at wakix-prescription-referral-form-web-api

Waskyra (Etuvetidigene autotemcel)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval**
	
	**Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel*
	
	Candidates for treatment with Waskyra (etuvetidigene autotemcel) should meet ALL the following criteria:
	• Prescribed by allergy, immunology, or bone marrow transplant specialist
	• Age ≥ 6 months
	• Diagnosis of Wiskott-Aldrich Syndrome (WAS) defined by genetic mutation and at least one of the following criteria:
	  ○ Severe WAS gene mutation, defined by literature data (genotype/phenotype studies)
	  ○ Absent WAS protein (WASP) expression
	  ○ Severe clinical score (Zhu clinical score ≥3)
	• No HLA-identical related donor available for hematopoietic stem cell transplantation (HSCT)
	• Eligible for bone marrow transplant (BMT)
	
	Reasons for Non-Coverage:
	• Hypersensitivity to the active substance or to any of the excipients
	• Ineligible for BMT
	• Ineligible for mobilization protocols in order to obtain CD34+ cells
	• Malignant neoplasia (except local skin cancer) or a documented history of hereditary cancer syndrome
	• Myelodysplasia, cytogenetic alterations characteristic of myelodysplastic syndrome and acute myeloid leukemia, or other serious hematological disorders
	• Documented human immunodeficiency virus (HIV) infection
	• Prior allogeneic HSCT, with evidence of residual cells of donor origin
	• Symptomatic herpes zoster, not responsive to specific treatment
	• Evidence of acute tuberculosis
	• Acute or chronic stable Hepatitis B
	• Presence of positive Hepatitis C RNA test result at screening
	• Previous treatment with gene therapy

Drug	Prior Authorization Criteria
	• End-organ dysfunction, severe active infection not responsive to treatment, or other clinical condition which, in the judgment of the treating physician(s), would make the patient inappropriate for treatment Approval Period: One time approval of one infusion (one full course of therapy) • **Please approve for inpatient administration only** • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** Note: KP members will be referred to external facilities that are certified to administer etu-cel

Wayrilz
(Rilzabrutinib)
	Candidates for treatment with Wayrilz (rilzabrutinib) should meet ALL of the following criteria:
	
	• Prescribed by a hematologist
	• Patient is 18 years of age or older
	• Diagnosed with persistent or chronic immune thrombocytopenia (ITP)
	• Documented platelet count of less than 30 x 10^9/L, OR has a platelet count of less than 50 x 10^9/L and had a prior bleeding event
	• Patient has ONE of the following:
	  ○ History of failure, contraindication or intolerance to a corticosteroid OR IV immunoglobulin OR
	  ○ Patient had an insufficient response to a splenectomy
	• Patient must have documentation of the following:
	  ○ Trial and failure or contraindication to a thrombopoietin receptor agonist (e.g., Alviaz (eltrombopag choline), eltrombopag olamine (generic Promacta), or Doptelet (avatrombopag))
	  ▪ Notes:
	  ○ Treatment failure can be considered after at least 2 months of treatment with an eltrombopag product
	  ○ Alviaz (eltrombopag choline) is KP's preferred eltrombopag product and available on the formulary without prior authorization
	
	Reasons for non-coverage:
	• Concurrent use with a spleen tyrosine kinase (SYK) inhibitor (e.g., Tavalisse [fostamatinib])
	
	Initial Approval: 6 months
	
	Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, must have documented clinical response to therapy, defined as having an improvement in platelet counts from baseline OR a reduction in bleeding events.

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td>Ordering information: At this time, Wayrilz is only available through specialty pharmacies; information on enrollment and ordering is available at: https://www.sanofihemassist.com/us/our-products/wayrilz

Below is the information for contact information for the two specialty pharmacies contracted with Kaiser where Wayrilz can be obtained:

<table>
<tr><th>Pharmacy Name</th><th>Phone Number</th><th>Fax Number</th></tr>
<tr><td>BIOLOGICS BY MCKESSON</td><td>800-850-4306</td><td>800-823-4506</td></tr>
<tr><td>ONCO360</td><td>877-662-6633</td><td>844-474-0880</td></tr>
</table>
</td></tr>
<tr><td>Welireg
(Belzutifan)</td><td>Candidates for Welireg should meet ALL the following criteria:

Diagnosis of von Hippel-Lindau disease:
• Prescribed by an oncologist or hematologist
• Age ≥ 18 years
• Diagnosis of von Hippel-Lindau (VHL) disease
• Patient requires therapy for ONE of the following:
  ○ Associated renal cell carcinoma (RCC)
  ○ Central nervous system (CNS) hemangioblastomas
  ○ Pancreatic neuroendocrine tumors (pNET)
• Individual does not require immediate surgery

Diagnosis of Renal Cell Carcinoma with a Clear Cell Component (ccRCC) :
• Prescribed by a hematologist or oncologist
• Age ≥ 18 years
• Patient as a diagnosis of renal cell carcinoma with a clear cell component (ccRCC)
• Patient meets ONE of the following:
  ○ Medication will be prescribed in combination with pembrolizumab (Keytruda) or pembrolizumab and berahyaluronidase (Keytruda Qlex) AND documentation patient is at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.
  ○ Medication will be used as monotherapy AND disease has progressed after treatment with BOTH of the following:
  i. Programmed death receptor 1 (PD-1) or programmed death-ligand (PD-L1) inhibitor (e.g., pembrolizumab (Keytruda), nivolumab (Opdivo) and avelumab (Bavencio), etc)
  ii. Vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) (e.g., cabozantinib (Cabometyx), lenvatinib (Lenvima), axitinib (Inlyta), tivozanib (Fotivda), pazopanib, sunitinib, sorafenib, etc)

Diagnosis of pheochromocytoma or paraganglioma:
• Prescribed by a hematologist or oncologist
• Patient is ≥ 12 years of age</td></tr>
</table>

Drug	Prior Authorization Criteria

	• Patient has a diagnosis of advanced, unresectable, or metastatic pheochromocytoma or paraganglioma
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. Confirm patient meets all above coverage criteria without reasons for Non-coverage in addition to criteria below:
	• Member is responding positively to therapy and does not show evidence of disease progression while on therapy
	• Absence of unacceptable toxicity to treatment, including but not limited to:
	  ○ Hgb <8 g/dL
	  ○ Recurrent symptomatic hypoxia

Winrevair
(Sotatercept-csrk)
	Candidates for treatment with Winrevair (sotatercept-csrk) should meet ALL the following criteria:
	
	• Prescribed by a cardiologist or pulmonologist
	• Age ≥ 18 years
	• Diagnosed with pulmonary arterial hypertension (PAH) (WHO Group 1) based on right heart catheterization with ALL the following:
	  ○ Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
	  ○ Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
	  ○ Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)
	• Patient is in WHO Functional Class (WHO-FC) II or III
	• Documentation patient is currently receiving at least TWO other (PAH) therapies for at least 3 months from the following drug classes:
	  ○ Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
	  ○ Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
	  ○ Oral cGMP stimulator (e.g., Adempas [riociguat])
	  ○ IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])
	• Documentation patient is currently receiving at least ONE other (PAH) therapy from one of the following drug classes AND has a contraindication or intolerance to ALL of the other drug classes:
	  ○ Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
	  ○ Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
	  ○ Oral cGMP stimulator (e.g., Adempas [riociguat])
	  ○ IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])
	• Check hemoglobin (Hgb) and platelets before initiation of therapy
	
	Initial Approval: 12 months
	
	• Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.

Drug	Prior Authorization Criteria
	• Approve for member to fill via the outpatient pharmacy benefit only Continued Approval: 12 months. Confirm patient meets all the above coverage criteria and documented clinical benefit from treatment. • Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval. • Approve for member to fill via the outpatient pharmacy benefit only

Xalkori
(Crizotinib)
	Candidates for Xalkori should meet ALL the following criteria:
	
	Diagnosis of non-small cell lung cancer:
	• Prescribed by an oncologist.
	• Patient is ≥18 years of age
	• Patient has a diagnosis of advanced, recurrent, or metastatic non-small cell lung cancer.
	• Patient has ONE of the following:
	  ○ Disease is ALK-rearrangement positive AND patient has a documented failure, intolerance, or contraindication to alectinib (Alecensa) AND lorlatinib (Lorbrena)
	  ○ Disease is ROS-1 rearrangement positive AND patient has a documented failure, intolerance, or contraindication to entrectinib (Rozlytrek) OR repotrectinib (Augtyro)
	
	Diagnosis of myofibroblastic tumor:
	• Prescribed by an oncologist.
	• Patient is ≥1 years of age.
	• Patient has a diagnosis of inflammatory myofibroblastic tumor with an ALK- translocation.
	
	Diagnosis of anaplastic large cell lymphoma:
	• Prescribed by an oncologist.
	• Patient is ≥1 years of age.
	• Patient has a diagnosis of relapsed or refractory ALK-positive anaplastic large cell lymphoma.
	
	Initial Approval: 12 months for a 30-day supply for 30 days.
	
	Continued Approval: 12 months. For continued approval for treatment with Xalkori, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria.
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	• The following quantity limits applies – 30-day supply per 30 days.
	
	For new members who were initiated on Xalkori outside of KPGA: Patient should meet ALL the following criteria:
	• Prescribed by an oncologist.

Drug	Prior Authorization Criteria
	• Age ≥ 18 years • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. • The following quantity limits applies – 30-day supply per 30 days.

Xdemvy
(Lotilaner)
	Candidates for Xdemvy should meet ALL of the following criteria:
	
	• Documented diagnosis of Demodex blepharitis in at least one eye supported by:
	  ○ Presence of at least mild erythema of the upper eyelid margin, and
	  ○ Presence of mites upon examination of eyelashes by light microscopy or presence of collarettes on slit lamp examination
	• Patient is 18 years or older
	• Prescribed by Ophthalmologist or Optometrist
	• Documented inadequate response, intolerance or contraindication to:
	• In office procedure- Microblepharoexfoliation (mechanical removal of the eyelash collarettes) AND
	• Tea tree oil eyelid scrubs (ie. (OCuSOFT Oust Lid Scrub) with warm compresses/lid massage (minimum 4-week trial)
	
	Initial Approval: 6 weeks per treatment (with quantity limited to one 10mL bottle per 6 weeks)
	
	Continued Approval: N/A

Xenpozyme
(Olipudase alfa-rpcp)
	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	Candidates for Xenpozyme should meet ALL of the following criteria:
	• Prescribed by a board certified medical geneticist
	• Patient has a clinical diagnosis consistent with acid sphingomyelinase deficiency (ASMD) type B or ASMD type A/B (NPD-A/B)
	• Patient has a definitive diagnosis of ASMD as confirmed by ONE of the following:
	  ○ Detection of biallelic pathogenic mutations in the SMPD1 gene by molecular genetic testing
	  ○ Deficiency of acid sphingomyelinase enzyme activity <10% of controls as measured in peripheral leukocytes, cultured fibroblasts, or lymphocytes
	• Therapy will be used for non-CNS manifestations of disease
	• For patients ≥ 18 years of age, documentation of ALL the following:
	  ○ Diffusion capacity of the lung for carbon monoxide (DLco) ≤ 70%
	  ○ Spleen volume ≥ 6 multiples of normal (MN) as measured by magnetic resonance imaging (MRI)
	  ○ Splenomegaly related score (SRS) ≥ 5
	• For patient < 18 years of age, documentation of ALL the following:
	  ○ Spleen volume ≥ 5 MN as measured by MRI
	  ○ Height Z-score ≤ -1
	• Documented baseline transaminase (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]) levels within 1 month prior to treatment initiation, within 72 hours prior to any infusion during dose escalation

Drug	Prior Authorization Criteria

	• Females of reproductive potential will have pregnancy status verified prior to start of therapy and will use effective contraception during treatment and for 14 days after the last dose if therapy is discontinued
	
	Reasons for Non-Coverage:
	• Patient has a clinical presentation consistent with ASMD type A
	• Patient has a diagnosis of Niemann-Pick disease type C
	• Patient has acute or rapidly progressive neurologic abnormalities
	• Patient requires invasive ventilatory support OR non-invasive ventilatory support while awake and for >12 hours a day
	• Patient has a platelet count less than 60 x 10^3/µL
	• International normalized ratio (INR) >1.5
	• Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) >250 IU/L or total bilirubin >1.5 mg/dL
	
	Initial Approval: 6 months.
	
	Continued Approval: 12 months. Confirm patient meets all above criteria in addition to criteria below:
	• Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include anaphylaxis and severe hypersensitivity reactions, severe infusion-associated reactions, severely elevated liver transaminases, etc.
	• Patient has not experienced progressive/irreversible severe cognitive impairment
	• Disease response with treatment as defined by improvement or stability from pre-treatment baseline by ONE of the following:
	  ○ Improvement in or stability in the percent predicted diffusion capacity of the lungs for carbon monoxide (DLco) or other age-appropriate pulmonary function testing
	  ○ Improvement in or stability of spleen and/or liver volumes
	  ○ Reduction in plasma lyso-sphingomyelin
	  ○ Improvement in or stability of platelet count
	  ○ Improvement in linear growth progression as measured by mean height Z-scores (pediatric patients only)
	
	Dosing and Administration:
	• Pediatrics: IV dosing every 2 weeks starting with 0.03 mg/kg/dose titrated to a final target maintenance dose by Week 16 of 3 mg/kg every 2 weeks.
	• Adults: IV dosing every 2 weeks starting with 0.1 mg/kg/dose titrated to a final target maintenance dose by Week 14 of 3 mg/kg every 2 weeks

Xermelo (Telotristat)	**Candidates for treatment with Xermelo should meet ALL the following criteria:** • Patient has a carcinoid/neuroendocrine tumor and has been diagnosed with carcinoid syndrome diarrhea • Age ≥ 18 years • Prescribed by or given in consultation with an oncologist or gastroenterologist • Patient has been on long-acting somatostatin analog therapy (e.g., Sandostatin® LAR Depot (octreotide subcutaneous injection), Somatuline® Depot (lanreotide subcutaneous

Drug	Prior Authorization Criteria
	injection)) for at least 3 consecutive months AND • Diarrhea is inadequately controlled, defined as at least 4 bowel movements per day, with somatostatin analog therapy AND • The medication will be used in combination with somatostatin analog therapy Initial Approval: 6 months Continued Approval: 12 months. Continued approval for treatment with Xermelo should meet ALL of the criteria above in addition to the criteria below: • Documentation of positive clinical response to Xermelo
Xhance (Fluticasone)	**Candidates for treatment with Xhance should meet ALL the following criteria:** ***Must verify the Member's Benefits to confirm Xhance is NOT Excluded from coverage. Xhance is excluded for ALL Commercial HMO Plans. Xhance is covered for ACA/FEHB, and other non-Commercial HMO plans. If excluded, QRM review is not required.** • Prescribed by Otolaryngology • Documented chronic rhinosinusitis with nasal polyps OR chronic rhinosinusitis • Documented ENT evaluation to consider endoscopic sinus surgery • Document adequate therapeutic trial or intolerance to at least 2 nasal steroids AND montelukast. • Age ≥ 18 years Reasons for Non-coverage: • Documented nasal ulcerations • Nasal surgery or nasal trauma in the past 3 months Initial approval period: 6 months Continued approval period: 12 months if patient meets ALL the initial criteria above and the following: • Documented improvement in symptoms/nasal polyps
Xiaflex (Collagenase Clostridium Histolticum)	**Candidates for treatment with Xiaflex should meet ALL of the following criteria**: Xiaflex is only available through the Xiaflex Experience Program Use of Xiaflex in patient with Dupuytren's contracture: • Documented diagnosis of Dupuytren's contracture with a palpable cord • Must be prescribed and administered by a hand surgeon, orthopedic surgeon or rheumatologist • Documentation of training in Xiaflex injections must be provided by the prescriber • A positive "table top test" – defined as the inability to simultaneously place the affected finger and palm flat against a table top • Documented contracture of at least 20 degrees flexion for a metacarpophalangeal joint

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	contracture or at least 20 degrees flexion for a proximal interphalangeal joint contracture • Documentation that the flexion deformity results in functional limitations • Age ≥ 18 years • Must not have had surgery on the primary joint within the past 90 days <u>Xiaflex will only be used on one cord at a time</u> • Treatment of each cord should be undertaken in sequential order with only one cord receiving Xiaflex at a time <u>Use of Xiaflex in patient with Peyronie's disease:</u> • Documented diagnosis of Peyronie's disease with a palpable plaque • Patient has curvature deformity for at least 30 degrees at the start of therapy • Must be prescribed by a Urologist • Documented Peyronie's symptoms (penile pain, erectile dysfunction, etc.) <u>Reason for Non-coverage:</u> • For the treatment of Peyronie's plaques that involve the penile urethra <u>Initial Approval:</u> • *Dupuytren's contracture:* 3 months • *Peyronie's disease:* one treatment cycle (2 injections) <u>Continued Approval:</u> Confirm patient meets all above coverage criteria without reason for Non-coverage. In addition, continue approval based on information below: • *Dupuytren's contracture:* ○ Injection may be repeated up to a maximum of 3 sessions for cord at 4 week intervals if reduction in primary joint contracture is not 0-5 degrees of full extension ○ Patient must follow-up within 24 hours following an injection for finger extension procedure if a contracture persists in order to qualify for more injections • *Peyronie's disease:* ○ Re-authorization for another treatment cycle may be given if the curvature deformity is more than 15 degrees after previous treatment cycle or if prescribing physician indicates another treatment cycle is clinically indicated (maximum of 4 treatment cycles) ○ Patient must wait six weeks between treatment cycles <u>Dosage and Administration:</u> • *Dupuytren's contracture:* ○ The dose for Xiaflex is 0.58 mg per injection into a palpable cord with a contracture of a metacarpophalangeal (MP) joint or a proximal interphalangeal (PIP) joint,

Drug	Prior Authorization Criteria
	according to the injection procedure ○ Finger extension procedures may be performed approximately 24 hours after the injection in the event the cord has not spontaneously ruptured • *Peyronie's disease:* ○ A treatment cycle consists of two Xiaflex injection procedures and a penile modeling procedure. ○ Induce a penile erection and identify and mark the target area in the Peyronie's plaque to be injected. ○ The penis should be in a flaccid state before injecting Xiaflex. Inject 0.58 mg Xiaflex into the target plaque once on each of two days, 1 to 3 days apart, according to the injection procedure. Perform a penile modeling procedure 1 to 3 days after the second injection of each treatment cycle. <u>Use caution in the following patients:</u> • Caution is advised in those receiving anticoagulation therapy, with the exception of low-dose aspirin (maximum 150 mg/day). <u>Monitoring:</u> • Patient must follow-up with provider within 24 hours following an injection for finger extension procedure
Xolair (Omalizumab)	**Candidates for treatment with Xolair should meet ALL of the following criteria:** <u>Criteria for use of Xolair in patients with asthma:</u> • Prescribed by a pulmonologist or allergy specialist • Pre-filled Syringe: age ≥ 6 years; Autoinjector: age ≥ 12 years • Documented moderate to severe persistent asthma • Documented atopic asthma by the BOTH of the following: ○ Specific IgE to inhalant allergens by skin PRICK test or CAP ("RAST") blood test ○ Determination of atopic status by an Allergist • Baseline total IgE serum level from 30-700 international units/mL for age ≥ 12 years OR between 30 and 1300 international units/ml for age 6 to 11 years, unless current or recent (prior 6 months) Xolair, Dupixent, or Tezspire use • Documented uncontrolled asthma defined as ONE of the following: ○ Two or more asthma exacerbations in the past 12 months requiring systemic corticosteroids for ≥ 3 days OR at least one serious exacerbation requiring hospitalization or ER visit in the past 12 months ○ Asthma Control Test (ACT) consistently < 20 over the past 12 months ○ Dependence on oral corticosteroid (OCS) for asthma control • Receiving high-dose or maximally tolerated inhaled corticosteroid plus long-acting beta-agonist (ICS/LABA)[±] for ≥ 3 consecutive months with or without OCS [±]For age ≥ 12 years: fluticasone/salmeterol 500/50 mcg 1 puff twice daily or budesonide/formoterol 160/4.5 mcg 2 puffs BID For ages 6 to < 12 years: fluticasone /salmeterol 100/50 mcg 1 puff twice daily or budesonide/formoterol 80/4.5 mcg 2 puffs BID <u>Criteria for use of Xolair in patients with chronic idiopathic urticaria:</u> • Documented diagnosis of chronic idiopathic urticaria

Drug	Prior Authorization Criteria

	• Age ≥ 12 years
	• Prescribed by an allergy specialist or dermatologist
	• Tried and failed4-weekONE therapy for a minimum of 4 weeks on ALL of the following unless contraindicated:
	  ○ At least two different high-dose second generation H1-antihistamines (e.g., loratadine, cetirizine) 2 – 4 times normal dose daily doseOR two second-generation H1 antihistamines in combination (e.g., fexofenadine 180 mg daily in the am plus cetirizine 10-20 mg daily at bedtime)
	
	Reasons for Non-coverage:
	• History of anaphylaxis or other adverse reaction to omalizumab or any of its ingredients
	• Acute asthma exacerbation within the previous two weeks of requiring any of the following: initiation of systemic corticosteroids, increased doses of systemic corticosteroids from baseline, doubling of inhaled corticosteroids, emergency room visit, or hospitalization.
	• Acute flare of significant systemic disease (infection, hematologic, renal, hepatic, cardiovascular diseases, or gastrointestinal diseases), or a recent hospitalization because of their disease within the previous two months.
	
	Initial Approval:
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	• **Pre-filled Syringe or Autoinjector:** 3-month approval in a monitored setting (i.e., KP Complex Nurse Clinic [CNC], back office) to monitor effectiveness and safety.
	
	First Continued Approval:
	• **Pre-filled Syringe or Autoinjector:** 9-months (after first 3-month approval) to be dispensed via the outpatient pharmacy benefit or via administration in the KP CNC**.**
	
	Continued Approval:
	For existing members who previously met the full criteria above: 12 months for prefilled syringe or autoinjector to be dispensed via the outpatient pharmacy benefit or via administration in the KP CNC if the patient has experienced any of the following:
	• **For moderate to severe persistent asthma:**
	• Reduction in the frequency of asthma exacerbations and reduction in the use of rescue medications or inhaled corticosteroids.
	• Reevaluate asthma control at one, three, and six-month intervals or as necessary and reassess the need for continued therapy based on the patient's disease severity and level of asthma control. There is limited data regarding the safety of using omalizumab long term.
	• **For chronic idiopathic urticaria:**
	  ○ Reduction in the frequency of symptoms (wheals, pruritus).
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	
	For new members who were initiated on Xolair outside of KPGA: Confirm patient meets all the above diagnosis and medication trial criteria without reasons for non-coverage. Confirm patient is documented as clinically stable by a specialist in the past 6 months.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**

Drug	Prior Authorization Criteria

	• **Pre-filled Syringe and Autoinjector:** approve 12 months to be dispensed via the outpatient pharmacy benefit or via administration in the KP CNC
	
	Criteria for use of Xolair for diagnosis of nasal polyposis:
	• Prescribed by Otolaryngologist
	• Adults 18 years of age or older≥
	• Otolaryngologist documentation of bilateral nasal polyposis after full endoscopic sinus surgery
	• History of failure, intolerance, or contraindication to all of the following after full endoscopic sinus surgery:
	  ○ Two or more short courses of systemic corticosteroids in the last 12 months
	  ○ Intranasal steroid spray or rinse (i.e., fluticasone, triamcinolone, mometasone spray and/or budesonide rinse) for 3 months
	  ○ Montelukast for 3 months
	  ○ **Dupixent for 6 months AND THEN Nucala for 6 months**
	• Patient has a documented IgE of at least 30 IU/mL in the last 12 months.
	• Not currently receiving any of the following:Dupixent, Nucala, Fasenra, Tezspire, Cinqair, or Adbry
	• Patient will continue a nasal corticosteroid with Xolair unless contraindicated or intolerance to nasal corticosteroids.
	
	Initial Approval Duration:
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service).**
	• **Pre-filled Syringe or Autoinjector:** 3-month approval in a monitored setting (i.e., KP Complex Nurse Clinic [CNC], back office) to monitor effectiveness and safety.
	
	First Continued Approval:
	• **Pre-filled Syringe or Autoinjector:** 9-months (after first 3-month approval) to be dispensed via the outpatient pharmacy benefit or via administration in the KP CNC
	
	Continued Approval: 12 months for prefilled syringe or autoinjector to be dispensed via the outpatient pharmacy benefit or via administration in the KP CNC if the patient has experienced the following:
	
	• **For new members who were initiated on Xolair outside of KPGA:** confirm patient meets all the above criteria without reasons for non-coverage.
	• **For existing members who previously met the full criteria above:** patient must have completed an appointment with an Otolaryngologist with documented clinically significant benefit within the last 12 months.
	• **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.**
	
	Criteria for use of Xolair in patients with IgE-mediated food allergy:
	• Prescribed by an allergy specialist.
	• Pre-filled Syringe: age ≥ 1 year of age or older; Autoinjector: ≥ 12 years of age or older
	• Weight ≥ 10 kg (22 lbs) AND IgE level ≥ 30 IU/mL

Drug	Prior Authorization Criteria
	• Documented food allergy to one or more of the following: peanuts, milk, eggs, wheat, cashew, hazelnut, or walnut as demonstrated by meeting the criteria below • Positive skin prick test (SPT), > 4 mm wheal greater than saline control • Positive food specific IgE (≥ 6 kUA/L). • According to the prescriber, the patient has a history of allergic reaction to a food that meets each of the following: • Patient demonstrated signs and symptoms of a significant systemic allergic reaction; AND ***NOTE:** signs and symptoms of a significant systemic allergic reaction include hives, swelling, wheezing, hypotension, and GI symptoms. • This reaction occurred within a short period of time following a known ingestion of the food; AND • The prescriber deemed this reaction significant enough to require a prescription for an epinephrine autoinjector ***NOTE:** examples of epinephrine autoinjectors include EpiPen, EpiPen Jr., Auvi-Q, and generic epinephrine autoinjectors. • Documented use in conjunction with food allergen avoidance. • Patient has a prescription for epinephrine for emergent use. • NOT currently receiving Palforzia. Initial Approval Duration: • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** • **Patients < 18 years of age:** 12 months or until age 18. May be approved for healthcare provider administration and then transitioned to outpatient self-administration OR administration in the KP Complex Nurse Clinic (CNC) at age 18. • **Adults for Pre-filled Syringe and Autoinjector:** 3-month approval in a monitored setting (i.e., KP CNC, back office) to monitor effectiveness and safety. First Continued Approval for Adults: 9-months to be dispensed via the outpatient pharmacy benefit or via administration in the KP CNC. Continued Approval: 12 months to be dispensed via the outpatient pharmacy benefit (ages ≥ 18 years) or via administration in the KP CNC if has experienced the following. age • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** • Pre-filled Syringe and Autoinjector: ○ **Adult new members who were initiated on Xolair outside of KPGA**: confirm patient meets all the above coverage criteria. ○ **Adult existing members who previously met the full criteria above:** Documented clinically significant benefit from allergist. Patient must have completed an appointment with documented clinically significant benefit with an allergist within the last 12 months. ○ **Patients < 18 years of age** may be approved for continued healthcare provider administration and then transitioned to outpatient self-administration OR administration in the KP CNC at age 18.
Xolremdi	**Candidates for treatment with Xolremdi should meet ALL the following criteria:**

Drug	Prior Authorization Criteria
(Mavorixafor)	• Age ≥ 12 years • Prescribed by an allergist/immunologist • Patient is diagnosed with WHIM (warts, hypogammaglobulinemia, infections, and myelokathexis) syndrome • Documentation of symptoms and complications associated with WHIM Syndrome Reasons for Non-coverage: • Concomitant use with drugs highly dependent on CYP2D6 (i.e., amitriptyline, codeine, fluoxetine, paroxetine, etc.) • Pregnancy or lactation • Severe renal impairment (CrCl 15-30 mL/min) or End-stage renal disease (less than 15 mL/min) • Moderate to severe hepatic impairment (Child-Pugh Group B and C) Initial Approval: 3 months • Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service). Continued Approval: 12 months if the patient meets all criteria above in addition to the following: • Documentation of sustained improvement in absolute lymphocyte count (ALC) and absolute neutrophil count (ALC) • Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service). Ordering Information: • Xolremdi is available through PANTHERx Specialty Pharmacy. • Prescriber completes X4Connect Enrollment Form, PANTHERx will verify coverage, and once approved, Xolremdi will be shipped directly to the patient.
Xospata (Gilteritinib)	**Candidates for Xospata should meet ALL the following criteria:** Diagnosis of acute myeloid leukemia (AML): • Prescribed by an oncologist or hematologist. • Age ≥ 18 years • Patient has a diagnosis of relapsed or refractory acute myeloid leukemia (AML) • Documented tyrosine kinase 3 (FLT3) receptor mutation • Patient has a documented treatment failure or intolerance to midostaurin (Rydapt) Diagnosis of myeloid/lymphoid neoplasms: 1. Prescribed by an oncologist or hematologist. 2. Age ≥ 18 years 3. Patient has a diagnosis of a myeloid or lymphoid neoplasm. 4. Documented tyrosine kinase 3 (FLT3) receptor mutation 5. Patient has a documented treatment failure or intolerance to midostaurin (Rydapt) Initial Approval: 12 months with a quantity limit of 90 tablets per 30 days.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Continued Approval: 12 months with a quantity limit of 90 tablets per 30 days. For continued approval for treatment with Xospata, patient should meet ALL the following criteria: • Patient continues to meet the above criteria. • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. For new members who were initiated on Xospata outside of KPGA: Patient should meet ALL the following criteria: • Prescribed by an oncologist or hematologist. • Age ≥ 18 years • Patient has a diagnosis of relapsed or refractory AML with a documented FLT3 mutation OR a myeloid/lymphoid neoplasm with a documented FLT3 mutation. • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. • Quantity limit of 90 tablets per 30 days

Xphozah
(Tenapanor)
	Candidates for treatment with Xphozah must meet ALL the following criteria:
	
	• Age ≥ 18 years
	• Prescribed by nephrologist
	• Documentation of chronic kidney disease on dialysis with hyperphosphatemia
	  ○ Phosphate level > 5.5 mg/dL
	• Documented adequate therapeutic trial (>3 months) with inadequate response, contraindication and/or intolerance to **ALL** phosphate lowering agents listed below:
	  ○ Sevelamer carbonate or sevelamer HCL
	  ○ Lanthanum carbonate
	  ○ Calcium acetate
	  ○ Auryxia (ferric citrate)
	  ○ Velphoro (sucroferric oxyhydroxide)
	
	Reasons for Non-coverage:
	• Patient with known or suspected mechanical gastrointestinal obstruction
	• Concurrent use of stool softeners or laxatives
	
	Initial Approval: 6 months (Pharmacy Benefit Override Required Also)
	
	Continued Approval: 12 months. (Pharmacy Benefit Override Required Also) Patient must meet all criteria above without reasons for non-coverage in addition to:
	• Phosphate levels within range (3.5 mg/dL to 5.5 mg/dL) and improvement from baseline
	• Continue approval if patient has documented a clinically significant benefit from medication

Xpovio (Selinexor)	**Candidates for treatment with Xpovio should meet ALL the following criteria:** • Age ≥ 18 years • The patient has relapsed or refractory multiple myeloma (RRMM) • The patient has received at least four prior therapies

Drug	Prior Authorization Criteria

	• The patient is refractory to ALL the following:
	  ○ Two proteasome inhibitors (e.g., bortezomib, carfilzomib, ixazomib)
	  ○ Two immunomodulatory agents (e.g., lenalidomide, pomalidomide, thalidomide)
	  ○ An anti-CD38 monoclonal antibody (e.g., daratumumab)
	• The medication will be used in combination with dexamethasone
	• Negative pregnancy test in a female of childbearing potential
	• Patients of reproductive potential have been counseled regarding effective contraception and fetal risks during Xpovio therapy and for 1 week after the last dose
	• Prescribed by an oncologist
	
	Approval Period:
	• Initial approval: 12 months
	• Continued Approval: 12 months if the patient does not show evidence of progressive disease or unacceptable toxicity while on Xpovio therapy.

Xromi
(Hydroxyurea)
	Hydroxyurea capsules are the preferred hydroxyurea formulation at KP and are available on the KPGA formulary without prior authorization or step therapy.
	
	Candidates for treatment with Xromi (hydroxyurea) should meet ALL of the following criteria:
	
	• Prescribed by a hematologist, oncologist, or provider that specializes in the treatment of sickle cell disease
	• Documentation patient is unable to swallow solid oral dosage forms
	• Patient has diagnosis of ONE of the following:
	  ○ Acute myeloid leukemia
	  ○ Chromic myeloid leukemia
	  ○ Chromic myelomonocytic leukemia
	  ○ Differentiation syndrome
	  ○ Essential thrombocythemia
	  ○ Head and neck carcinoma
	  ○ Hypereosinophilic syndrome
	  ○ Meningioma
	  ○ Myelofibrosis
	  ○ Polycythemia vera
	  ○ Sickle cell anemia
	
	Reasons for Non-coverage:
	• Pregnancy
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. For continued approval for treatment, patient should meet ALL the following criteria:
	• Patient is responding positively to therapy
	• Documentation patient is unable to swallow solid dosage forms

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

Xtandi
(Enzalutamide)
	Candidates for treatment with Xtandi must meet ALL the following criteria:
	
	• Patient is male.
	• Prescribed by an oncologist or urologist.
	• Age ≥18 years
	• Diagnosis of prostate cancer that meets ONE of the following:
	  ○ Non-metastatic, castration resistant AND PSA doubling time is ≤10 months
	  ○ Non-metastatic, castration sensitive with high-risk biochemical recurrence
	  ○ Metastatic, castration sensitive in patients with low volume disease AND ECOG PS 0-2 with documented intolerance, contraindication*, or treatment failure with abiraterone + prednisone (KP's preferred 1st line)
	  ○ Metastatic, castration sensitive in patients with high volume disease AND ECOG PS 2 with documented intolerant, contraindication*, or treatment failure with abiraterone + prednisone (KP's preferred 1st line)
	  ○ Metastatic, castration resistant with documented intolerance, contraindication*, or treatment failure to Abiraterone + prednisone (KP's preferred 1st line)
	  Note: Relative contraindication to abiraterone defined as: type 2 diabetes with A1c>7%, patient is on insulin, severe liver disease (Child-Pugh Class C), cardiovascular risk clearly documented by oncologist (e.g., heart failure with LVEF <50%; recent MI, or ventricular arrhythmia)
	• Prescribed in combination with ONE of the following:
	  ○ Gonadotropin-releasing hormone (GnRH) agonist or antagonist (e.g., leuprolide [Lupron])
	  ○ Patient has had a bilateral orchiectomy.
	
	Initial Approval: 12 months
	
	Continued Approval: 12 months. For continued approval for treatment with Xtandi, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria.
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	
	For new members who were initiated on Xtandi outside of KPGA: Patient should meet ALL of the following criteria:
	• Patient is male.
	• Prescribed by an oncologist.
	• Age ≥ 18 years
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.

Xyrem (Sodium Oxybate) Preferred: Sodium oxybate (generic Xyrem) Non-Preferred: Brand Xyrem	**Candidates for treatment with Xyrem should meet ALL the following criteria:** • Prescribing restricted to sleep specialists AND • Patient is not currently drinking alcohol or have a current substance abuse comorbidity (12 months of full remission) or currently taking sedative hypnotic agents AND • Patient is negative for succinic semialdehyde dehydrogenase deficiency if clinical suspicion exists for inborn errors in metabolism AND • Documented diagnosis of cataplexy associated with narcolepsy OR excessive daytime sleepiness associated with narcolepsy OR idiopathic hypersomnia

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	○ If diagnosed with excessive daytime sleepiness associated with narcolepsy, patient must have documentation of all the following: ▪ Patient has Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10 ▪ Patient's self-reported sleep log demonstrates adequate sleep opportunity per Sleep Specialist (7 to 9 hours for most patients) ▪ Documented trial and failure of, or contraindication to at least three wake promoting agents or stimulants i.e., maximum tolerated dose of modafinil, traditional wake-promoting agent (e.g., amphetamine sulfate, methylphenidate, etc.) AND solriamfetol (Sunosi) ○ If diagnosed with cataplexy associated with narcolepsy, patient must have documentation of the following: ▪ Patient has tried and failed venlafaxine and at least one other agent for the treatment of cataplexy such as an SSRI (e.g., fluoxetine) or trial of pitolisant (Wakix) prior to KP. ***Note:** Xyrem is preferred to Wakix at KP ○ If diagnosed with idiopathic hypersomnia, must have documentation of the following: ▪ Patient's self-reported sleep log demonstrates adequate sleep opportunity per Sleep Specialist (7 to 9 hours for most patients) ▪ Trial and failure of, or contraindication to at least three wake promoting agents or stimulants (i.e maximum tolerated dose of modafinil, methylphenidate, dextroamphetamine, and amphetamines) Initial Approval: 12 months Continued Approval: 12 months if the following criteria are met: For new members initiated on sodium oxybate outside of KPGA: • Documented beneficial effect from therapy during sleep specialist follow up in the last 6 months AND • For narcolepsy with EDS and idiopathic hypersomnia, patient has a history of trial and failure of at least three wake- promoting agents or stimulants (e.g., amphetamine-dextroamphetamine, methylphenidate, modafinil or armodafinil) OR • For narcolepsy with cataplexy, patient has a history of trial and failure of venlafaxine For existing members who have previously met the full criteria above: approve if documented beneficial effect from therapy during sleep specialist follow up in the last 6 months. Ordering Information: • Xyrem is dispensed by ESSDS / Accredo Specialty Pharmacy. • If approved, target reviewer should call Accredo at 855-525-7995 to communicate approval.

Drug	Prior Authorization Criteria
	• Each provider must complete a Xywav REMS provider enrollment form AND submit a patient enrollment form (Prescribers | XYWAV and XYREM REMS). • After obtaining QRM approval, providers may email KP Benefits at ga-pharmacybenefits@kp.org to communicate approval with the specialty pharmacy.

Xywav
(Oxybate Salts: Calcium, Magnesium, Potassium, and Sodium)
	Candidates for treatment with Xywav should meet ALL the following criteria PLUS the individual disease state criteria that follows:
	
	• Prescribed by a sleep specialist
	• Patient may NOT be on any sedative-hypnotic agents (e.g., zolpidem), benzodiazepines (e.g., alprazolam or lorazepam), or drinking alcohol. If history of substance abuse, patient must have 12 months of full remission.
	• Patient is unable to take sodium oxybate (generic Xyrem) as demonstrated by ONE of the following:
	  ○ Documented cardiovascular disease requiring sodium restriction such as congestive heart failure or refractory hypertension (on 3 or more antihypertensives or failed multiple antihypertensives)
	  ○ Adequate trial (≥ 2 months) of sodium oxybate (generic Xyrem) with treatment failure or intolerance documented
	
	<u>For diagnosis of cataplexy in narcolepsy:</u>
	
	• Age ≥ 7 years
	• Patient has tried and failed venlafaxine AND at least one other agent for the treatment of cataplexy such as an SSRI (e.g., fluoxetine) or trial of pitolisant (Wakix) prior to KP. *Note Xyrem is preferred to Wakix at KP.
	
	<u>For diagnosis of excessive daytime sleepiness in narcolepsy:</u>
	
	• Age ≥ 7 years
	• Patient has Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
	• Patient's self-reported sleep log demonstrates adequate sleep opportunity per Sleep Specialist (7 to 9 hours for most patients)
	• Documented trial and failure of, or contraindication to at least three wake-promoting agents or stimulants (i.e., maximum tolerated dose of modafinil, traditional wake-promoting agent (e.g., amphetamine sulfate, methylphenidate, etc.)) AND solriamfetol (Sunosi)
	
	<u>For diagnosis of idiopathic hypersomnia:</u>
	
	• Age ≥ 18 years

Drug	Prior Authorization Criteria
	• Patient must have documented trial and failure of, or contraindication to at least three wake promoting agents or stimulants (i.e maximum tolerated dose of modafinil, methylphenidate, dextroamphetamine, and amphetamines). Reasons for Non-coverage: • Documented succinic semialdehyde dehydrogenase deficiency Initial Approval: 12 months Continued approval: 12 months. Approve if patient has seen a sleep specialist in the last 6 months with documented clinical benefit. For new members initiated on Xywav outside of KPGA: • Documented beneficial effect from therapy during sleep specialist follow up in the last 6 months • Documented cardiovascular disease requiring sodium restriction such as congestive heart failure or refractory hypertension (on 3 or more antihypertensives or failed multiple antihypertensives) hence the patient is unable to take sodium oxybate (Xyrem) • For narcolepsy with EDS or idiopathic hypersomnia, patient has a history of trial and failure of at least three wake-promoting agents or stimulants (e.g., amphetamine-dextroamphetamine, methylphenidate, modafinil or armodafinil) OR • For narcolepsy with cataplexy, patient has a history of trial and failure of venlafaxine Ordering Information: • Xywav is dispensed by ESSDS / Accredo Specialty Pharmacy. • If approved, target reviewer should call Accredo at 855-525-7995 to communicate approval. • Each clinician must complete a Xywav REMS provider enrollment form AND submit a patient enrollment form (Prescribers | XYWAV and XYREM REMS). • After obtaining QRM approval, providers may email KP Benefits at ga-pharmacybenefits@kp.org to communicate approval with the specialty pharmacy.
CAR-T Therapy **Yescarta** (Axicabtagene ciloleucel)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** **Candidates for treatment with Yescarta should meet ALL the following criteria:** • **MUST verify member's benefit information. If member's coverage is through Target, CLOSE the request.** Member must go through Aradigm for this therapy. • Prescribed by an Oncologist with expertise in malignant hematology • Age ≥ 18 years • Histologically confirmed lymphoma consistent with an FDA approved indication for the specific CAR-T therapy. • Chemotherapy-refractory disease, defined as one or more of the following:

Drug	Prior Authorization Criteria
	○ Refractory to two or more lines of therapy with less than partial response to last line of therapy OR ○ Refractory post-autologous hematopoietic stem cell transplantation (HSCT) • Subjects must have received adequate prior therapy including at a minimum: ○ anti-CD20 monoclonal antibody unless tumor is CD20-negative AND ○ an anthracycline containing chemotherapy regimen ○ For subjects with transformed FL must have received prior chemotherapy for follicular lymphoma and subsequently have chemo-refractory disease after transformation to DLBCL • Absolute neutrophil count ≥500/µL • Absolute lymphocyte count >100/µL • Platelet count ≥ 50,000/µL • Adequate organ function defined as (patients with borderline organ function may still be eligible based on center of excellence standards): ○ Left Ventricular Ejection Fraction ≥ 45% ○ Creatinine clearance ≥ 40 mL/min ○ ALT ≤ 5 times the upper limit of normal (ULN) for age ○ Total bilirubin < 2 mg/dL ○ Baseline oxygen saturation >91% on room air Reasons for Non-coverage: • Presence of fungal, bacterial, viral, or other infection that is uncontrolled or requiring intravenous (IV) antimicrobials for management. Simple urinary tract infection (UTI) and uncomplicated bacterial pharyngitis are permitted if responding to active treatment. • Known infection with HIV (detectable viral load) • Hepatitis B (HBsAG positive and detectable viral load) • Hepatitis C virus (anti-HCV positive and detectable viral load) Initial Approval: ONE TIME DOSE ONLY. At this time, CAR-T therapy is intended as a one-time (single infusion) treatment. Repeat treatment of any CAR-T therapy is considered investigational and is not recommended outside of enrollment in a clinical trial. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval** Continued Approval: Not applicable. CAR-T is intended as a one-time (single infusion) treatment. Dosing and Administration: • **KP members will be referred out to institutions that are certified to administer CAR-T therapies.** • **Yescarta is available only through restricted programs under a Risk Evaluation and Mitigation Strategy (REMS) Yescarta REMS/Kymriah REMS.**

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td>Yartemlea
(Narsoplimab-wuug)</td><td>
Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval

Candidates for treatment with Yartemlea (narsoplimab-wuug) should meet ALL the following criteria:

• Patients ≥2 years of age
• Prescribed by hematologist/oncologist
• Diagnosed with hematopoietic cell transplant-associated thrombotic microangiopathy and meets both of the following:
  ○ Platelet count < 150,000/mL or a decrease in platelet count > 50% from the highest value obtained following transplant.
  ○ Evidence of microangiopathic hemolysis (e.g., presence of schistocytes, serum lactate dehydrogenase [LDH] > upper limit of normal ([ULN], or haptoglobin < lower limit of normal [LLN])

Initial Approval: 12weeks
• Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval
• Yartemlea is intended for short-term use only (2-16 weeks). If continued use is needed after 12 weeks, candidates must meet initial approval criteria again.

Dosage and Administration:
<table>
<tr><th>Weight (kg)</th><th>Recommended Dosage</th></tr>
<tr><td>Greater than or equal to 50 kg</td><td>370 mg given as an intravenous infusion over 30 minutes once weekly. Increase frequency to twice weekly if there is inadequate improvement in TA-TMA signs and symptoms. (2.1)</td></tr>
<tr><td>Less than 50 kg</td><td>4 mg/kg given as an intravenous infusion over 30 minutes once weekly. Increase frequency to twice weekly if there is inadequate improvement in TA-TMA signs and symptoms. (2.1)</td></tr>
</table>
* Chart copied from Yartemlea. Prescribing information. Omeros Corporation. Accessed January 29, 2026. https://pi.omeros.com/us/yartemlea-uspi.pdf
</td></tr>
<tr><td>Yorvipath
(Palopegteriparatide)</td><td>
**Please note: Reviewers must obtain approval from the Physician Program Director of QRM OR AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)

Candidates for treatment with Yorvipath (palopegteriparatide) must meet ALL the following criteria:

• Patient is ≥18 years of age
• Prescribed by an endocrinologist
</td></tr>
</table>

Drug	Prior Authorization Criteria

	• Diagnosed with chronic hypoparathyroidism (HP) of postsurgical, autoimmune, genetic, or idiopathic origins, for at least 26 weeks, based on hypocalcemia in the setting of inappropriately low serum PTH levels
	• Documentation that hypoparthyroidism is NOT due to impaired responsiveness to parathyroid hormone or a history of disease that affects calcium metabolism or calcium-phosphate homeostasis
	• Persistent symptomatic hypocalcemia despite 12-week trial of conventional therapy: activated vitamin D (e.g., calcitriol) and calcium
	• Provider attestation that the patient's disease cannot be adequately controlled on conventional therapy (i.e., symptomatic hypocalcemia, hyperphosphatemia, renal insufficiency, hypercalciuria, or poor quality of life)
	• Documented recent (within last 4 weeks)
	  ○ serum 25 (OH) vitamin D in normal range (20-80 ng/mL) and
	  ○ albumin-adjusted serum calcium >7.8 mg/dL and
	  ○ eGFR ≥ 30 mL/min
	
	<u>Reasons for Non-Coverage:</u>
	
	• Diagnosis of acute postsurgical HP
	• Patient at increased risk of osteosarcoma (examples below).
	  ○ Open epiphyses
	  ○ Metabolic bone diseases other than hypoparathyroidism, including Paget's disease
	  ○ Unexplained elevations of alkaline phosphatase,
	  ○ Bone metastases or history of skeletal malignancies,
	  ○ History of external beam or implant radiation involving the skeleton
	  ○ Hereditary disorders predisposing to osteosarcoma
	• Pregnancy
	
	<u>Initial Approval:</u> 6 months
	
	• Reviewers must obtain approval from the Physician Program Director of QRM OR AAMD prior to providing QRM PA approval.
	• Approve for coverage via the pharmacy outpatient benefit only
	
	<u>Continued Approval</u>: 12 months. Continued approval for treatment with Yorvipath (palopegteriparatide) should meet ALL of the criteria above in addition to the criteria below:
	• Documentation of a recent albumin-corrected serum calcium in the lower-half of the normal reference range or just below the normal reference range (~8–9 mg/dL) AND ONE of the following:
	  ○ Patient no longer requires active vitamin D or therapeutic doses of calcium **OR**
	  ○ Patient has had a significant reduction in required dosages and is still actively titrating doses of Yorvipath
	• Reviewers must obtain approval from the Physician Program Director of QRM OR AAMD prior to providing QRM PA approval.

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	• Approve for coverage via the pharmacy outpatient benefit only Ordering Information: • Yorvipath is only available through PantherRx Rare Pharmacy (pantherxrare.com) or Orsini Specialty Pharmacy (orsinispecialtypharmacy.com)
Yuviwel (Navepegritide)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval.** **Candidates for Yuviwel (navepegritide) should meet ALL of the following criteria:** • Prescribed by Geneticist and/or Pediatric Endocrinologist • Patient is ≥2 years of age • Patient has open epiphyses • Confirmed diagnosis of achondroplasia through genetic testing confirming FGFR3 gene mutation associated with achondroplasia • Provider attestation that the patient does not have planned or expected limb-lengthening surgery • Documentation of recent annualized growth velocity (AGV) • Documentation of trial and failure or contraindication to Voxzogo (vosoritide) Reasons for Non-coverage: • Concurrent use with another C-type natriuretic peptide (CNP) (e.g., Voxzogo [vosoritide]) • Hypochondroplasia or short stature condition other than achondroplasia • eGFR <60 mL/min/1.73 m^2 Initial Approval: 12 months Continued Approval: 12 months. Confirm patient continues to meet the above criteria AND the following: • Patient has experienced an improvement in annual growth velocity since baseline (at least 1 cm annually) • Patient's epiphyses remain open Ordering Information: Yuviwel is only available via Specialty Pharmacy: Anovo. Instructions on how to obtain Yuviwel is available at: Starting a Patient | YUVIWEL® (navepegritide)
Zavesca (Miglustat)	**Candidates for treatment with Zavesca should meet ALL the following criteria:** Criteria for Niemann-Pick disease type C (NPC) • Diagnosed with Niemann-Pick disease type C (NPC) • Age ≥ 2 years • Prescribed by or in consultation with a neurologist or geneticist AND • Used in combination with arimoclomol (Miplyffa)

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Criteria for Gaucher's disease • Documented diagnosis of Type 1 Gaucher's Disease and anemia • Patient is symptomatic (i.e., radiologic evidence of skeletal disease, platelet count <60,000 microL, liver >2.5 times normal size, spleen > 15 times normal size) • Age ≥ 18 years • Patient has been evaluated by a Geneticist • Tried and failed or unable to tolerate enzyme replacement therapy (Cerezyme, Vpriv, Elelyso) enzyme replacement therapy for at least 6 months. • Tried and failed or unable to tolerate eliglustat (Cerdelga) Initial Approval Period: 6 months Continued Approval: 12 months. Confirm patient meets all above criteria. In addition, continue approval if patient is responding to treatment (improving platelet count, decreased hepatomegaly and splenomegaly) Monitoring: • Neurologic evaluations baseline and repeat every 6 months Ordering information: • Zavesca is only dispensed by Accredo. For more information, visit ZAVESCA® (miglustat): For the treatment of type 1 Gaucher Disease

Zavzpret
(Zavegepant)
	Candidates for treatment with Zavzpret (zavegepant) should meet the following criteria:
	
	• Age ≥ 18 years
	• Prescribed by a Neurologist, or providers in the Department of Neurology who specialize in headache management
	• Documentation of one of the following:
	  ○ Persistent or severe nausea or vomiting during migraine attack AND inadequate response, intolerance or contraindication to ALL of the following alternatives: an antiemetic (e.g., prochlorperazine), sumatriptan nasal spray and zolmitriptan nasal spray
	  ○ Inadequate response and/or intolerance to Nurtec ODT (rimegepant) and Ubrelvy (ubrogepant) AND one of the following:
	  ▪ Documented contraindication to treatment with triptans, such as coronary artery disease, history of stroke, peripheral vascular disease, ischemic bowel disease, basilar or hemiplegic migraine, unstable angina, and uncontrolled hypertension
	  ▪ Documented inadequate response and/or intolerance to three different triptans or triptan dosage forms e.g., sumatriptan tablet, naratriptan tablet, rizatriptan ODT, sumatriptan intranasal
	
	Initial Approval: 6 months
	
	Continued Approval: 12 months. Continue approval if the following criteria are met:

Drug	Prior Authorization Criteria

	• For new members who were initiated on Zavzpret outside of KPGA, approve if patient has previously tried and failed two preferred alternatives:
	  ○ Oral preferred alternatives: Ubrelvy, Nurtec ODT
	  ○ Intranasal preferred alternatives: sumatriptan nasal spray, zolmitriptan nasal spray
	• Documented beneficial effect and tolerance of the medication

Zejula
(Niraparib)
	Candidate for treatment with Zejula for oncologic indications should meet all of the following:
	• Prescribed by a hematologist/oncologist OR Gynecologic Oncologist
	• Age ≥ 18 years
	• If female of childbearing potential, baseline negative pregnancy test
	• Patient has a diagnosis of ONE of the following:
	  ▪ Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer
	  ▪ Patient does NOT have BRCA1/2 mutation OR BRCA mutation status is unknown AND
	  ▪ Used as maintenance treatment AND
	  ▪ Complete or partial response to FIRST LINE platinum-based chemotherapy (e.g., regimens containing cisplatin, carboplatin, OR oxaliplatin) AND
	  ▪ Bevacizumab was not used during primary therapy
	  ▪ Advanced or Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer
	  ▪ Deleterious or suspected deleterious germline BRCA-mutated (gBRCAmut) cancer AND
	  ▪ Used as maintenance treatment AND
	  ▪ Complete or partial response to platinum-based chemotherapy (e.g., regimens containing cisplatin, carboplatin, OR oxaliplatin) AND
	Patient has a documented treatment failure (e.g., intolerance, allergic reaction, disease progression) to KP's preferred PARP inhibitor, Olaparib (Lynparza)
	
	<u>Approval Period:</u> 12 months
	
	<u>Continued Approval:</u> 12 months. Patient must meet all the following:
	• Patient continues to meet the above criteria; AND
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread; AND
	• Absence of unacceptable toxicity from therapy (any ≥ grade 3 toxicity that does not improve with dose reduction and/or holding therapy)
	• Females of reproductive potential only: patient will be advised to use effective contraception during therapy and for 6 months after the last dose

Zepatier (Elbasvir and Grazoprevir)	**Candidates for treatment with Zepatier should meet ALL the following criteria:** • Prescribed by Gastroenterologist or Infectious Disease specialist • Documented Hepatitis C virus (HCV) infection demonstrated by detectable quantitative HCV RNA level in previous 12 months • Documented HCV genotype is 1 or 4 ○ For genotype 1a: documented baseline RAS with no NS5A resistance identified

Drug	Prior Authorization Criteria
	• Direct-acting antiviral (DAA)-naïve patients with documented intolerance or contraindication to the authorized generic for Epclusa (sofosbuvir/velpatasvir). • Do not approve if documented decompensated cirrhosis [Child-Turcotte-Pugh (CTP) class B or C] Initial Approval: 12 weeks Continued approval for new members who were initiated on Zepatier outside of KPGA: confirm diagnosed with hepatitis C and Zepatier initiation date. Approve for a total of 12 weeks.
Zeposia (Ozanimod)	**Candidates for treatment with Zeposia must meet ALL the following criteria PLUS the individual disease state criteria that follows:** • Females of childbearing potential (12 to 50 years) should have a baseline negative pregnancy test within the past month AND either a prescription for birth control (IUD or other contraceptive) or documentation of the patient declining contraception and being counseled of the potential risk of pregnancy. • Physician has addressed varicella zoster virus (VZV) immunogenicity (i.e., reported history of VZV, documented VZV antibodies or VZV vaccination) via chart note documentation. • Documented baseline CBC with differential, ophthalmologic exam, LFTs, serum bilirubin, and EKG in the past 6 months. • No history of myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or class III or IV heart failure in the last 6 months. • No history or presence of Mobitz type II second-degree or third-degree atrioventricular block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker. • Not prescribed in combination with another biologic agent for the same indication or advanced small molecule (e.g., tofacitinib, upadacitinib) for the same indication • Not currently prescribed monoamine oxidase inhibitor (i.e., phenelzine, selegiline) • Then follow the disease state specific criteria below, based on diagnosis: **Criteria for the Diagnosis of Relapsing Forms of Multiple Sclerosis** • Documented diagnosis of relapsing-remitting multiple sclerosis (RRMS) or active secondary progressive multiple sclerosis (active SPMS). • Prescribed by a neurologist. • Zeposia is being prescribed as monotherapy for treatment of MS • Documented trial and intolerance to fingolimod (Gilenya) that is expected to be reduced with ozanimod (Zeposia). • Documented clinical barrier, therapeutic failure or intolerance to rituximab product (Riabni is the preferred product if rituximab has never been tried). **Criteria for the Diagnosis of Ulcerative Colitis** • Age ≥ 18 years • Documented moderately to severely active ulcerative colitis • Prescribed by gastroenterologist

Drug	Prior Authorization Criteria

	• Documented inadequate response (of at least a 3-month trial), intolerance, or contraindication to ALL the following:
	  ○ Infliximab product (e.g., Inflectra [preferred])
	  ○ Ustekinumab product (e.g., Yesintek [preferred])
	  ○ Tofacitinib (preferred JAK-inhibitor) OR Rinvoq (upadacitinib). If patient is pregnant, tofacitinib or Rinvoq trial is NOT required
	  ○ Tremfya (guselkumab)
	
	Initial Approval: 12 months
	
	Continued approval: 12 months
	
	For Multiple Sclerosis diagnosis:
	
	For new members who were initiated on Zeposia outside of KPGA:
	• Patient has had a visit with a KPGA MS Specialist (*please note: Dual Choice members may see either a KPGA or an external MS Specialist)
	• Patient has tried and failed the preferred alternatives rituximab AND fingolimod (Gilenya)
	• Patient is confirmed to be stable on the therapy.
	
	For existing members who previously met the full criteria:
	• Documented beneficial effect from therapy during Neurology follow-up in the past 12 months.
	
	For Ulcerative Colitis diagnosis:
	• For new members and existing members: Documented clinical benefit (asymptomatic or in remission) from therapy, during a Gastroenterology follow-up in the past 12 months.
	
	Ordering Information:
	• Ozanimod is only available through AmeriSource Bergen Specialty Pharmacy.

Zilbrysq (Zilucoplan)	**Candidates for treatment with Zilbrysq (zilucoplan) must meet ALL the following criteria:** Criteria for Generalized Myasthenia Gravis: • Prescribed by or in consultation with a Neurologist with specialty in neuromuscular disorders • Diagnosis of generalized myasthenia gravis (gMG) • Patient is 18 years or older • Confirmed anti-acetylcholine receptor (AChR) antibody positive • No history of thymoma or thymic neoplasm OR patient has history of thymoma and has had a thymectomy that was completed over 3 months ago • Patient has a Myasthenia Gravis Activities of Daily Living (MG-ADL) scale score of 5 or higher

Drug	Prior Authorization Criteria

	• Patient is currently taking pyridostigmine for symptomatic management as prescribed unless there is a severe intolerance or contraindication
	• Trial of corticosteroid for at least 3 months and patient experienced inadequate disease control or patient has an intolerance or contraindication to corticosteroid therapy
	• Trial of at least one non-steroidal immunosuppressive therapy for the duration indicated:
	  ○ Azathioprine or mycophenolate for at least 12 months
	  ○ Rituximab for at least 12 months
	  ○ Other disease modifying therapy (e.g., cyclophosphamide, cyclosporine, tacrolimus, methotrexate) for at least 6 months
	• Patient has tried and failed or has a contraindication to chronic IV immune globulin (IVIG)
	• Patient has tried and failed or has a contraindication to efgartigimod (Vyvgart)
	
	Reasons for Non-coverage:
	• Patient is prescribed concomitant efgartigimod (Vyvgart) or monoclonal antibody therapy for myasthenia gravis such as Ultomiris, Soliris or Rystiggo
	• Unresolved serious Neisseria meningitidis infection
	• Not vaccinated against Neisseria meningitidis, unless risk of treatment delay outweighs infection risk
	
	Initial Approval: 6 months
	
	Continued Approval: 12 months.
	
	For new members who were initiated on zilucoplan (Zilbrysq) outside of KPGA, approve if ALL the following criteria are met:
	
	• Patient has had a visit with a Neurologist with specialty in neuromuscular disorder to discuss consideration of chronic IVIG as an alternative treatment option
	• Patient has tried and failed a corticosteroid AND at least one non-steroidal immunosuppressive therapy as listed above
	• Patient confirmed to be stable on therapy by Neurologist
	
	For first renewal of zilucoplan (Zilbrysq): documented improvement of at least 2-points on the Myasthenia Gravis-Activities of Daily Living scale (MG-ADL)
	
	For subsequent renewals after first renewal: documented maintenance of stable MG-ADL score or documented beneficial effect from therapy during Neurology follow up in the last 12 months

Zokinvy
(Lonafarnib)
	Candidates for treatment with Zokinvy should meet ALL the following criteria:
	
	• Prescribed by a geneticist or by another specialist in consultation with a geneticist
	• Age ≥ 12 months
	• Documentation of diagnosis
	  ○ Hutchinson-Gilford Progeria Syndrome (HGPS) OR
	  ○ Processing-deficient Progeroid Laminopathies with LMNA or ZMPSTE24
	
	Reasons for Non-coverage:
	• Progeroid syndromes

Drug	Prior Authorization Criteria
	• Processing-proficient Progeroid Laminopathies • Concomitant use with strong or moderate CY3A inhibitors or inducers, midazolam, lovastatin, simvastatin or atorvastatin Initial Approval: 12 months Continued Approval: 12 months. Continue approval based on adherence to specialist follow-up appointments.

Zolgensma (Onasemnogene abeparvovec-xioi)	**Please note: Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval**
	
	Candidates for treatment with Zolgensma should meet ALL the following criteria:
	**Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).*
	
	• **MUST verify member's benefit information. If member's coverage is through Target, CLOSE the request.** Member must go through Aradigm for this therapy.
	• Diagnosis of SMA based on documented gene mutation analysis with bi-allelic SMN1 mutations (deletion or point mutations) and confirmatory testing.
	• Documentation of 1, 2, or 3 copies of SMN2 gene.
	• Treatment WILL be administered no later than age 6 months, regardless if patient is symptomatic or not symptomatic.
	• Parent/family agrees to adhere to follow-up assessments and/or medical treatment plan
	• Anti-AAV9 antibody titer ≤1:50 within 14 days prior to onasemnogene abeparvovec infusion.
	• Patient is afebrile at time of treatment and no known active viral infection (including HIV, hepatitis B or C).
	• Documented completion of baseline labs:
	  ○ Liver function tests [aspartate aminotransferase (AST) and alanine aminotransferase (ALT), gamma-glutamyl transpeptidase (GGT), total bilirubin, and prothrombin time]
	  ○ Troponin-I
	  ○ HIV, hepatitis B, hepatitis C
	• Prescribed by Pediatric Neurologist or designated Neurologist or other physician specialist with expertise in managing infantile SMA.
	
	Reasons for Non-coverage:
	• Use of invasive ventilatory support (tracheotomy with positive pressure)* or pulse oximetry <95% saturation. *Exception: non-invasive ventilator support (BiPAP) for less than 10 hours a day.
	• Number of SMN2 gene copies is zero or ≥4
	• Documentation of other types of SMA that do not involve SMN1 mutation

Drug	Prior Authorization Criteria
	• Prior gene therapy for SMA (e.g., participation in trial or prior treatment outside of Kaiser Permanente) Initial Approval: ONE TIME DOSE ONLY • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM AND AAMD prior to providing QRM PA approval** Continued Approval: Not applicable. Onasemnogene abeparvovec is intended as a one-time, single-dose infusion. Repeat dosing has not been studied and is not recommended. Dosing and Administration: • Onasemnogene abeparvovec is a single-dose intravenous infusion given over 60 minutes. • The recommended dosage is 1.1 x 1014 vector genomes (vg) per kg of body weight • Administer a systemic corticosteroid equivalent to oral prednisolone at 1 mg/kg of body weight per day, starting one day prior to onasemnogene abeparvovec infusion and continue daily for a total of 30 days, then if liver status is normal, taper over 28 days • Should be administered in an infusion clinic or inpatient setting.

Zolinza
(Vorinostat)
	Candidates for Zolinza should meet ALL the following criteria:
	Diagnosis of cutaneous T-cell lymphoma:
	• Prescribed by a hematologist or oncologist.
	• Age ≥ 18 years
	• Diagnosis of progressive, persistent or recurrent cutaneous T-cell lymphoma (CTCL)
	• Documented treatment failure, contraindication or intolerance to at least TWO systemic therapies
	  ○ Systemic therapies, include but are not limited to the following: extracorporeal photopheresis (ECP), systemic retinoids, brentuximab vedotin (Adcetris), bexarotene, interferon alpha-db, interferon gamma-1b, methotrexate, denileukin
	
	Diagnosis of Hodgkin lymphoma:
	• Prescribed by a hematologist or oncologist.
	• Age ≥ 18 years
	• Diagnosis of Classic Hodgkin Lymphoma
	• Documented treatment failure or intolerance to at least THREE systemic regimens
	  ○ Examples include: ABVD (doxorubicin, bleomycin, vinblastine & dacarbazine) + rituximab/rituximab biosimilar, CHOP (cyclophosphamide, doxorubicin, vincristine, & prednisone) + rituximab/rituximab biosimilar, CVbP (cyclophosphamide, vinblastine & prednisone) + rituximab/rituximab biosimilar, Adcentris (brentuximab vedotin) + AVD (doxorubicin, vinblastine, dacarbazine)
	• Medication will be used in combination with pembrolizumab (Keytruda)
	
	Initial Approval: 12 months

<table>
<tr><th>Drug</th><th>Prior Authorization Criteria</th></tr>
<tr><td></td><td><u>Continued Approval:</u> 12 months. For continued approval for treatment with Zolinza, patient should meet ALL the following criteria:
Patient continues to meet the above criteria.
Patient is responding positively to therapy based on stabilization of disease or no disease progression</td></tr>
<tr><td>Zoryve
(Roflumilast)</td><td>Candidates for Zoryve should meet ALL of the following criteria:
<u>Criteria for atopic dermatitis:</u>
Documented mild-to-moderate atopic dermatitis (BSA >5%)
Prescribed by a dermatologist
Age <u>≥</u> 2 years and request is for Zoryve 0.05% Cream OR age <u>≥</u> 6 years and request is for Zoryve 0.15% Cream
Documented inadequate response, intolerance or contraindication to ALL of the following:
Topical calcineurin inhibitors [Pimecrolimus (Elidel) or tacrolimus (Protopic)]
Medium to very high potency topical corticosteroid for a minimum of 4 weeks:
<table><tr><th>Medium Potency</th><th>High and Very High Potency</th></tr><tr><td>Triamcinolone acet 0.1%, 0.025% O, C</td><td>Betameth diprop aug 0.05% C</td></tr><tr><td>Betamethasone val 0.1% C</td><td>Fluocinonide 0.05% O, C, G</td></tr><tr><td>Mometasone 0.1% O, C</td><td>Fluocinonide-emollient 0.05% C</td></tr><tr><td>Triamcinolone acet 0.5% C</td><td>Desoximetasone 0.25% C</td></tr><tr><td>Betamethasone diprop 0.05% C</td><td>Betamethasone diprop aug 0.05% O, G</td></tr><tr><td>Betamethasone val 0.1% L</td><td>Clobetasol 0.05% O, C</td></tr></table>O = oint, C = cream, G = gel, L = lotion
Phototherapy (unless documented that pediatric patient is developmentally unable to stand in light unit by him/herself)
Systemic corticosteroids (i.e prednisone, methylprednisolone)
<u>Criteria for plaque psoriasis</u>:
Documented moderate to severe plaque psoriasis
Prescribed by a dermatologist
Age <u>≥</u> 6 years and request is for Zoryve 0.3% Cream OR age <u>≥</u> 12 years and request is for Zoryve 0.3% Foam
Documented history of inadequate response, contraindication, or intolerance to ALL of the following:
High or super-high potency topical corticosteroid for a minimum of 4 weeks:
<table><tr><th>High and Very High Potency</th></tr><tr><td>Betameth diprop aug 0.05% C</td></tr></table></td></tr>
</table>

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria

Fluocinonide 0.05% O, C, G
Fluocinonide-emollient 0.05% C
Desoximetasone 0.25% C
Betamethasone diprop aug 0.05% O, G
Clobetasol 0.05% O, C

  - Topical vitamin D analog [e.g., calcipotriene 0.005% solution, calcitriol 3mcg/g ointment] for a minimum of 6 weeks
  - Topical calcineurin inhibitors [e.g., Pimecrolimus (Elidel) or tacrolimus (Protopic)] for a minimum of 6 weeks
  - Topical retinoid [e.g., tazarotene 0.1% topical cream]
  - Phototherapy (PUVA, UVB with coal tar or dithranol, UVB standard or narrow-band, or home UVB) of at least a 3-month trial, excluding patients with:
    - Involvement of sensitive areas (e.g., hand, feet, face, body folds or genitals)
    - Concomitant use of medications that cause photosensitivity, history of photosensitivity disorder (e.g.,Lupus, Dermatomyositis, Porphyria, Xeroderma pigmentosum), history of melanoma or abnormal moles, history of multiple non-melanoma skin cancers
- If BSA >8% must also have documented history of inadequate response, contraindication, or intolerance to the ALL of following:
  - Preferred Adalimumab product (e.g., Amjevita [preferred]) OR infliximab product (Infliximab-dyyb/Inflectra [preferred])
  - Preferred ustekinumab product (Yesintek [ustekinumab-kfce]

Criteria for seborrheic dermatitis:

- Diagnosis of seborrheic dermatitis (may involve scalp, face, trunk, or intertriginous areas)
- Prescribed by a dermatologist
- Age ≥ 9 years AND request is for Zoryve 0.3% Foam
- Documented history of inadequate response, contraindication, or intolerance to **ALL** of the following:
  - Topical corticosteroid (e.g., betamethasone dipropionate, augmented 0.05% cream, clobetasol propionate 0.05% ointment, lotion, gel) for at least 2 months
  - Topical calcineurin inhibitor (e.g tacrolimus 0.1% ointment) for at least 3 months
  - Topical antifungal (e.g.,ketoconazole, ciclopirox) for at least 3 months

Reason for Non-coverage:

- Moderate to severe liver impairment (Child-Pugh B or C)

Initial Approval: 6 months (with quantity limited to 60 grams (1 tube) per 30 days). If additional quantities are being requested, then the prescriber must document that the affected BSA to be treated is >8%.

Drug	Prior Authorization Criteria
	Continued Approval: 12 months. Confirm patient meets all above coverage criteria. In addition, continued approval if patient has documented a clinically significant benefit from medication documented by the prescriber specialist. For new members who were initiated on Zoryve prior to joining KPGA: Confirm patient meets the full criteria above for approval without reasons for Non-coverage.

Zurzuvae
(Zuranolone)
	Candidates for treatment with Zurzuvae must meet ALL the following criteria:
	
	**Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).*
	
	• Age 18-45 years
	• Prescribed by a psychiatrist and/or OB/GYN in consultation with a psychiatrist
	• Documented diagnosis of postpartum depression
	  ○ onset no earlier than third trimester of pregnancy and no later than four weeks postpartum)
	• Patient is ≤ 12 months postpartum
	• Documentation of moderately severe to severe depression using a validated screening tool for moderate to severe depression, within prior two weeks of treatment initiation
	  ○ Note: examples of validated screening tools include Patient Health Questionnaire-9 (PHQ-9) or Edinburgh Postnatal Depression Scale (EPDS)
	• Documentation of negative serum pregnancy test 1 week prior to start of treatment initiation AND
	  ○ Documentation that patient agrees to use effective contraception during zuranolone treatment and for one week after final dose
	• If patient currently on antidepressants, documentation that dose is stable for approximately two weeks and is not titrated or changed during active treatment with zuranolone (except for cases of adverse reactions)
	
	Reasons for Non-coverage:
	• Pregnancy*
	  a. *Note: Pregnancy tests may show positive within 4 weeks postpartum
	• Active psychosis
	• Diagnosis of bipolar disorder, schizophrenia, or schizoaffective disorder
	• Active alcohol or drug abuse within prior 30 days
	• Significant risk of suicide as determined by the provider.
	• Concomitant use of opioids, benzodiazepines, anxiolytic, and sleep aids
	• Concomitant use with CYP3A4 inducers (i.e., phenobarbital, phenytoin, rifampin, St. John's wort)
	
	Approval: ONE-TIME approval for 14 days

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
Zusduri (Mitomycin)	**Candidates for treatment with Zusduri should meet ALL the following criteria:** • Age ≥ 18 years • Prescribed by oncologist or urologist • Patient has a diagnosis of low-grade, non-muscle-invasive bladder cancer (LG-NMIBC) • Patient has a documented treatment failure to generically available mitomycin [J9280] instilled intravesically • Patient has <u>at least one</u> of the following indicating intermediate-risk disease: a. Presence of multiple tumors b. Solitary tumor >3 cm c. Early or frequent recurrence defined as >1 occurrence of low-grade NMIBC within 1 year of the current diagnosis • Patient as ONE of the following: a. Documented recurrence after prior transurethral resection of bladder tumor (TURBT) **OR** b. Documentation patient is ineligible for TURBT due to one of the following: high anesthesia risk, complex anatomy, or prior complications with resection • Therapy will be used for intravesical installation only. • Will not be used concurrently with other mitomycin formulation (e.g., Jelmyto) • Patient has not received intravesical BCG treatment within the previous 6 months of starting therapy (except for a single dose post TURBT) for high-grade NMIBC <u>Reasons for non-coverage:</u> • Pregnant • Low-risk NMIBC • High-risk NMIBC <u>Initial approval period:</u> Approve one 6-week course in a 3-month window. Approve for back-office administration ONLY. <u>Continued approval</u>: Not applicable. <u>Dosing and Administration:</u> • 75 mg (56 mL) once weekly for 6 weeks. • Administer by intravesical instillation only. Do not administer by pyelocalyceal instillation or by other route.
Zycubo (Copper histidinate)	***Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** **Candidates for treatment with Zycubo (copper histidinate) should meet ALL the following criteria:** • Must be prescribed by Neurologist • Patient is <18 years of age • Diagnosis of Menkes Disease by ONE of the following:

Drug	Prior Authorization Criteria
	○ Biochemical abnormalities (elevated DOPAC: DHPG ratio OR elevated dopamine: norepinephrine ratio) ○ ATP7A mutation consistent with severe Menkes Disease phenotype ○ IF biochemical/genetic diagnosis genetic results are pending and delay of treatment may result in harm, may accept documentation of clinical signs and symptoms including characteristic Menkes kinky hair, skin abnormalities, progressive neurologic impairment, growth and developmental delays, and multisystem complications affecting the brain, bones, and connective tissues that are strongly consistent with Menkes Disease as initial diagnostic criteria • Documentation of low baseline serum copper level and ceruloplasmin level Reasons for Non-coverage: • Diagnosed with Occipital Horn Syndrome (OHS) Initial Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Continued Approval: 6 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • Must have documented positive therapeutic response (e.g., improved survival, attainment of developmental milestones, physical gains, and/ or normalization of copper-related biomarkers) at an appointment within the past 6 months • If genetic or biochemical testing was not available at initial approval, patient must now have genetic or biochemical testing to confirm Menkes Disease diagnosis Ordering Information: • Zycubo is only distributed through Biologics by McKesson • Providers must fax completed enrollment form to Sentynl Cares ZYCUBO-Sentynl-Cares-Enrollment-Form.pdf
Zydelig (Idelalisib)	**Candidates for Zydelig should meet ALL the following criteria:** • Prescribed by a hematologist or oncologist. • Diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) • Patient has a documented treatment failure or intolerance to at least one BTK inhibitor (e.g., zanubrutinib (Brukinsa), acalbrutinib (Calquence), ibrutinib (Imbruvica), pirobrutinib (Jaypirca) **AND** venetoclax (Venclexta) • Zydelig will be used in combination with rituximab or rituximab biosimilar product. Initial Approval: 12 months with a quantity limit of 60 tablets per 30 days. Continued Approval: 12 months with a quantity limit of 60 tablets per 30 days. For continued approval for treatment with Zydelig, patient should meet ALL the following criteria: • Patient continues to meet the above criteria. • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.

Drug	Prior Authorization Criteria
	For new members who were initiated on Zydelig outside of KPGA: Patient should meet ALL the following criteria: • Prescribed by a hematologist or oncologist. • Diagnosis of CLL • Medication will be prescribed in combination with rituximab or rituximab biosimilar product. • Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread. • Quantity limit of 60 tablets per 30 days
Zykadia (Ceritinib)	**Candidates for Zykadia should meet ALL the following criteria:** Diagnosis of non-small cell lung cancer: • Prescribed by an oncologist. • Age ≥ 18 years • Patient has a diagnosis of advanced, recurrent, or metastatic non-small cell lung cancer (NSCLC) • Patient must meet ONE of the following: o Patient has an anaplastic lymphoma kinase (ALK) gene rearrangement AND meets **all** of the following: 1. Documented treatment failure due to diffuse progression, intolerance, or contraindication to alectinib (Alecensa) 2. Documented failure due to diffuse progression, intolerance, or contraindication to second line lorlatinib (Lorbrena) o Patient has an ROS1 rearrangement AND patient has a documented treatment failure due to diffuse progression, intolerance, or contraindication to entrectinib (Rozlytrek), repotrectinib (Augtyro), AND lorlatinib (Lorbrena). Diagnosis of Erdheim-Chester Disease: • Prescribed by a hematologist or oncologist • Age ≥18 years • Patient has a diagnosis of ALK-positive Erdheim-Chester Disease Diagnosis of inflammatory myofibroblastic tumor: • Prescribed by a hematologist or oncologist • Age ≥18 years • Patient has a diagnosis of ALK-positive inflammatory myofibroblastic tumor • Patient meets ONE of the following criteria: o Patient has advanced, recurrent, or metastatic disease. o Tumor is inoperable. Diagnosis of relapsed or refractory Anaplastic Large Cell Lymphoma: • Prescribed by a hematologist or oncologist • Age ≥18 years • Patient has a diagnosis of ALK-positive anaplastic large cell lymphoma

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Drug	Prior Authorization Criteria

	• Palliative intent
	• Has failed first line therapy per KP Oncology Treatment Pathways
	
	Initial Approval: 12 months with a quantity limit of 90 tablets per 30 days
	
	Continued Approval: 12 months with a quantity limit of 90 tablets per 30 days. For continued approval for treatment with Zykadia, patient should meet ALL the following criteria:
	• Patient continues to meet the above criteria.
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	
	For new members who were initiated on Zykadia outside of KPGA: Patient should meet ALL the following criteria:
	• Prescribed by a hematologist or oncologist
	• Age ≥18 years
	• Patient has a diagnosis of ONE of the following:
	  ○ Advanced, recurrent, or metastatic NSCLC with ALK or ROS1 gene rearrangement
	  ○ ALK-positive Erdheim-Chester Disease
	  ○ ALK-positive myofibroblastic tumor
	  ○ ALK-positive anaplastic large cell lymphoma
	• Patient is responding positively to therapy based on stabilization of disease and/or decrease in size of tumor or tumor spread.
	• Quantity limit of 90 tablets per 30 days.

Zymfentra (Infliximab-dyyb)	**Candidates for treatment with Zymfentra should meet ALL the following criteria:** • Diagnosis of moderate to severe Crohn's disease (CD) or moderate to severe ulcerative colitis (UC) • Prescribed by Gastroenterology • Age ≥18 years • Inadequate response (of at least a 3 month trial) or intolerance to at least 3 of the following: Infliximab-dyyb (Inflectra), Unbranded infliximab, Infliximab-axxq (Avsola) and Infliximab-abda (Renflexis) • Patient must be considered clinically stable (i.e., asymptomatic) on an infliximab IV maintenance dose, for a minimum of 1 year from 1st induction dose (i.e., dose at week 0) Reasons for Non-coverage: • Patient is not currently being treated with an IV infliximab product (i.e.: unbranded infliximab, Remicade, Renflexis, Avsola) • Patient has an active HBV, TB, or other serious infection • Positive for latent tuberculosis (TB) and not taking TB prophylactic therapy • Taking another biologic immunotherapy or have other risk factors for severe immunosuppression and opportunistic infection • History of severe hypersensitivity to any anti-TNF inhibitor biologic • History of antibody formation to Inflectra, Avsola, Renflexis or Remicade

Drug	Prior Authorization Criteria
	Initial Approval Period: 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for member to fill via the outpatient pharmacy benefit only** Continued Approval Period: 12 months. Confirm patient meets above coverage criteria and patient is in clinical remission. For new members who were initiated on Zymfentra outside of KPGA: • Patients must meet the full criteria above for approval • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for member to fill via the outpatient pharmacy benefit only** For existing members who have previously met the full criteria above: • Adequate response and tolerance to medication documented during specialist follow-up in the last 12 months • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** • **Approve for member to fill via the outpatient pharmacy benefit only** Dosage and Administration: • Zymfentra is indicated as maintenance treatment only, starting at Week 10 and thereafter. Patient must complete an intravenous (IV) induction regimen with an infliximab product. • Week 10 and thereafter: Inject 120 mg subcutaneously once every two weeks. The initial dose should be in place of the next scheduled intravenous infusion.

Zynteglo
(Betibeglogene autotemcel)
	Candidates for Zynteglo should meet ALL of the following criteria:
	
	**Prior to formal QRM review, case-specific information should be reviewed by an Interregional Consultative Panel (required for KP Internal Reviewers only).*
	
	• Prescribed by a Pediatric or Adult Hematology/Oncology Specialist
	• Age < 50 years
	• Confirmed diagnosis of β-thalassemia through genetic testing; and
	• Diagnosis of transfusion dependent beta-thalassemia (TDT) by hematology specialist and with a history of:
	  ○ For age ≤18 years: ≥100 mL/kg/year of packed red blood cells (pRBCs) in prior two years
	  ○ For age >18 years: ≥8 transfusions of pRBCs per year in prior two years
	and
	• Clinically stable and eligible to undergo hematopoietic stem cell therapy (HSCT) in accordance with KP National Transplant Services Blood and Marrow Transplantation Patient Selection Criteria

***Does not apply to Medicare Benefit**

Drug	Prior Authorization Criteria
	Reasons for Non-coverage: • Positive for presence of human immunodeficiency virus type 1 or 2 (HIV-1 and HIV-2), hepatitis B virus (HBV), or hepatitis C (HCV) • Any prior or current malignancy (other than nonmelanoma skin cancer) • Prior HSCT • Prior receipt of gene therapy • Evidence of cardiac or hepatic dysfunction due to iron overload • Pregnancy or breastfeeding • Childbearing potential without adequate contraception • White blood cell (WBC) count <3×109/L, and/or platelet count <100×109/L not related to hypersplenism • Uncorrected bleeding disorder • Immediate family member with a known Familial Cancer Syndrome • Any contraindications to the use of G-CSF and plerixafor during the mobilization of hematopoietic stem cells and any contraindications to the use of busulfan and any other medicinal products required during the Approval Period: ONE-TIME, SINGLE-DOSE INFUSION. Repeat dosing has not been studied and is not recommended. • **Please note: Reviewers must obtain approval from the Physician Program Director of QRM or AAMD prior to providing QRM PA approval (excluding Pharmacy Consult Service)** Dosage and administration: • Zynteglo is a single-dose intravenous infusion provided in one or more infusion bags. • The minimum recommended dose is 5.0 × 106 CD34+ cells/kg. • KP members will be referred out to facilities that are certified to administer Zynteglo.