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Formulary Update

At A Glance

Formulary Additions

- Alvaiz (eltrombopag) Tablet
- Brukinsa (zanubrutinib) Capsule
- Calcipotriene (generic) Cream/Ointment
- Midodrine (generic) Tablet
- Progesterone (generic) Capsule

Prior Authorization (QRM) Additions

- Elfabrio (pegunigalsidase alfa-iwxj) Intravenous Solution
- Lupron Depot-Ped (leuprolide acetate) Intramuscular Syringe Kit
- Sunlenca (lenacapavir) Tablet/Subcutaneous Solution
- Zavzpret (zavegepant) Intranasal Solution

Prior Authorization (QRM) Updates

- Adalimumab Products
- Adbry (tralokinumab) Subcutaneous Solution
- Bosulif (bosutinib) Tablet
- Cosentyx (secukinumab) Intravenous/Subcutaneous Solution
- Demser (metyrosine) Capsule
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- Enzyme Replacement Therapies
- Fabrazyme (agalsidase beta) Injection
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- Gonadotropin Releasing Hormone Agonists
- Gonadotropin Releasing Hormone (GnRH) Receptor Antagonists
- Herceptin (trastuzumab) Intravenous Solution
- Kevzara (sarilumab) Intravenous/Subcutaneous Solution
- Mounjaro (tirzepatide) Subcutaneous Solution
- Nexletol (bempedoic acid)/Nexlizet (bempedoic acid and ezetimibe) Tablet
- Olumiant (baricitinib) Tablet
- Orfadin (nitisinone) Capsule/Oral Suspension
- Otezla (apremilast) Tablet
- PCSK-9 Inhibitors
- Rozlytrek (entrectinib) Capsule/Oral Pellet
- Voxzogo (vosoritide) Subcutaneous Solution

A PUBLICATION OF THE GEORGIA PHARMACY AND THERAPEUTICS (P&T) COMMITTEE. The Formulary Update contains information regarding formulary additions, deletions, exclusions, brief descriptions of products, and current drug related news. It also lists items to be discussed at upcoming P&T meetings. Please refer to the web pages: KP Georgia Formulary and Drug Lists OR Drug Formulary for Practitioners for the full KPGA Drug Formulary.

Commercial HMO/Closed Formulary Additions

The following medications will be ADDED to the Commercial Formulary effective March 13, 2024:

Note: Commercial Formulary additions may result in tier changes on the QHP (ACA)/Open Formulary.

- **Alvaiz (eltrombopag) Tablet:** Indicated for treatment of chronic immune thrombocytopenia (ITP) in children >6 years, adolescents, and adults, and for treatment of severe aplastic anemia and chronic hepatitis C infection in adult patients.
- **Brukinsa (zanubrutinib) Capsule:** Indicated for treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), mantle cell lymphoma (MCL) (relapsed or refractory), marginal zone lymphoma (MZL) (relapsed or refractory) and Waldenstrom macroglobulinemia (WM).
- **Calcipotriene (generic) Cream/Ointment:** Indicated for treatment of plaque psoriasis in adults.
- **Midodrine (generic) Capsule:** Indicated for treatment of symptomatic orthostatic hypotension.
- **Progesterone (generic) Capsule:** Indicated for treatment of secondary amenorrhea, dysfunctional premenopausal bleeding, postmenopausal hormone replacement therapy (HRT), maintenance of pregnancy, and for assisted reproductive technology (ART).

Commercial HMO/Closed Formulary Removal

The following medication will be REMOVED from the Commercial Formulary effective January 1, 2025:

- **Vectical (calcitriol) Ointment:** Indicated for treatment of mild to moderate plaque psoriasis.

QHP-ACA/Open Formulary Tier Changes

The following medications will have tier changes effective March 13, 2024:

- **Calcipotriene (generic) Cream/Ointment:** Down-tier to Preferred Generic Tier 2
- **Midodrine (generic) Capsule:** Down-tier to Preferred Generic Tier 2
- **Progesterone (generic) Capsule:** Down-tier to Preferred Generic Tier 2

QHP-ACA/Open Formulary Step Therapy Additions

The following medication will have step therapy added effective IMMEDIATELY:

- **Lagevrio (molnupiravir) Tablet:** Indicated for treatment of adults with mild to moderate COVID-19 who are at high risk for progression to severe COVID-19.

Interregional Treatment Algorithms

The following IR Treatment Algorithm was recently updated:

- **Inflammatory Bowel Disease Practice Recommendations:** treatment algorithms and recommendations were updated based on clinical guidelines and clinical practice.

Interregional Practice Recommendations

The Emerging Therapeutics Strategy Program (ETSP) is a centralized effort that applies our evidence-based model to develop interregional practice recommendations with KP physician specialists, coordinates KP HealthConnect clinical content for decision support, and monitors outcomes to measure uptake of the clinical and strategy recommendations. Through the collaboration of Pharmacy, Permanente physicians, and Federation partners, the ETSP offers a unified approach in the provision and management of specialty drugs to help ensure that our members derive the greatest value from these products.

The following IR Practice Recommendation ADDITION was recently approved:

- **Zurzuvae (zuranolone):** Indicated for the treatment of severe postpartum depression in adult patients.

The following IR Practice Recommendation UPDATES have been recently approved:

- **hATTR-PN drugs (patisiran-vutrisiran-inotersen-eplontersen):** updated to 1) include Wainua (eplontersen), a recently approved therapy for hATTR-PN and 2) clarify that dual therapy with tafamidis and a hATTR-PN therapy can be considered on a case-by-case basis.
- **Tepezza (teprotumumab):** updated to 1) recommend hearing assessments throughout treatment, 2) include the addition of a photograph of the patient's full face in KPHC for baseline assessments, and 3) recommend a complete eye exam, including clinical activity score, every 6-12 months for 3 years after treatment initiation for monitoring response.
- **Voxzogo (vosoritide):** updated to incorporate the FDA approved expanded indication for pediatric patients younger than 5 years old.

ETSP recommendations as well as pipeline candidates can be found here: https://sp-cloud.kp.org/sites/teams-emergingtsc/SitePages/Home.aspx. Please note: Newly marketed medications requiring ETSP review will also receive prior authorization (PA) review. These medications will not be eligible for consideration of drug benefit coverage until completion of drug specific ETSP and PA criteria review processes.

Upcoming Formulary Items

An important aspect of the formulary process is the involvement of all practitioners. Please contact your P&T Committee representative or your clinical service chief by March 22, if you wish to comment on any of the medications, class re views, or other agenda items under consideration.

To make formulary addition requests, you must submit a Formulary Additions/Deletions Form and Conflict of Interest Form to Drug Information Services or call (404) 439-4417.

Removals from the QRM Prior Authorization Review List of Medications for the Commercial/HMO Closed Formularies & QHP-ACA/Open Formularies

Note: The updates below DO NOT APPLY to Medicare Part D or Dual Choice Prescription Benefit Plans. Optum and MedImpact are the external PBMs for each of these plans, respectively, externally administering all non-formulary or prior authorization criteria and coverage review.

Prior authorization restrictions will be removed effective March 13, 2024:

- **Brukinsa (zanubrutinib) Capsule:** Indicated for treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), mantle cell lymphoma (MCL) (relapsed or refractory), marginal zone lymphoma (MZL) (relapsed or refractory) and Waldenstrom macroglobulinemia (WM).
- **Signifor LAR (pasireotide) Injection:** Indicated for the treatment of acromegaly and Cushing disease when there is inadequate response to surgery and/or surgery is not an option.

Additions to the QRM Prior Authorization Review List of Medications for the Commercial/HMO Closed Formularies & QHP-ACA/Open Formularies

Note: The updates below DO NOT APPLY to Medicare Part D or Dual Choice Prescription Benefit Plans. Optum and MedImpact are the external PBMs for each of these plans, respectively, externally administering all non-formulary or prior authorization criteria and coverage review.

The following QRM additions will be effective March 13, 2024:

- **Elfabrio (pegunigalsidase alfa-iwxj) Intravenous Solution:** Indicated for treatment of Fabry disease.
- **Sunlenca (lenacapavir) Tablet/Subcutaneous Solution:** Indicated for treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.
- **Zavzpret (zavegepant) Intranasal Solution:** Indicated for treatment of acute treatment of migraine with or without aura in adults.

The following QRM addition will be effective June 12, 2024:

- **Lupron-Depot Ped (leuprolide acetate) Intramuscular Syringe Kit:** FDA indicated for treatment of central precocious puberty. Lupron-Depot (equivalent to Lupron-Depot Ped) remains the KP preferred therapy for central precocious puberty.

QRM Prior Authorization Review Criteria Updates

Note: The updates below DO NOT APPLY to Medicare Part D or Dual Choice Prescription Benefit Plans. Optum and MedImpact are the external PBMs for each of these plans, respectively, externally administering all non-formulary or prior authorization criteria and coverage review.

- **Adalimumab products:** Criteria updated to 1) add unbranded adalimumab-adbm to the list of non-preferred products, 2) clarify that a trial of a nonbiologic DMARD is not required if the patient has been on a biologic DMARD or JAK inhibitor for rheumatology indications, and 3) require a trial and failure of preferred Amjevita before continued approval of a non-preferred product.
- **Adbry (tralokinumab):** Criteria updated to 1) change the age requirement from 18 years to 12 years or older for the treatment of moderate-to-severe atopic dermatitis and 2) allow continuation of Adbry for new members who are clinically stable on Dupixent or Adbry.
- **Bosulif (bosutinib):** Criteria updated to include the expanded indication for pediatric patients age 1 year and older for the treatment of Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML).
- **Cosentyx (secukinumab):** Criteria updated to 1) incorporate the new intravenous infusion formulation, 2) highlight the subcutaneous formulation is preferred over the IV formulation, 3) add statement that the approval of the IV infusion formulation requires a significant non-modifiable barrier that prohibits subcutaneous administration, and 4) clarify that a trial of an NSAID and/or nonbiologic DMARD is not required if a patient has been on a biologic DMARD or JAK inhibitor for a rheumatology indication.
- **Demser (metyrosine):** Criteria updated to clarify 1) indications for use, 2) the requirement to trial an alpha-adrenergic and beta-adrenergic blocker in combination, and 3) the duration of initial approval and continued approval based on indication.
- **Enbrel (etanercept):** Criteria updated to clarify that a trial of an NSAID and/or nonbiologic DMARD is not required if a patient has been on a biologic DMARD or JAK inhibitor for the same condition.
- **Entyvio (vedolizumab):** Criteria updated to 1) add the subcutaneous formulation to the QRM PA review criteria, 2) clarify that an infliximab and adalimumab product must be trialed for at least 3 months, and 3) clarify the requirement for a negative TB test to align with criteria for other biologics.

Information Concerning Coverage Determinations

Medicare Part D: Medicare Part D Plan Non Formulary and Prior Authorization criteria and coverage determination are made externally by the Pharmacy Benefit Manager Optum Rx.

Prescriber completes the .NFRequestForm when entering drug order. Your documentation is used by OptumRx to determine whether the prescribed drug is eligible for drug benefit coverage. No documentation = No coverage.

The KP Pharmacy Consult Service will send your documentation to OptumRx for their coverage determination decision within the labeled time frame (standard: 72 hours; urgent: 24 hours). If not received by the deadline, the PBM will deny the request. If OptumRx has further questions, you will be contacted for responses. You may phone OptumRx at **1-888-791-7255** to address any patient / drug coverage specific questions. To see the MPD Formulary, please visit: Medicare Part D Formulary

Dual Choice: Dual Choice Plan Non Formulary and Prior Authorization criteria and coverage determination are made externally by the Pharmacy Benefit Manager MedImpact.

Prescriber completes the .NFRequestForm when entering drug order. Your documentation is used by MedImpact to determine whether the prescribed drug is eligible for drug benefit coverage. No documentation = No coverage.

The KP Pharmacy Consult Service will send your documentation to MedImpact for their coverage determination decision within the labeled time frame (standard: 72 hours; urgent: 24 hours). If not received by the deadline, the PBM will deny the request. If MedImpact has further questions, you will be contacted to provide responses. You may phone MedImpact at **1-888-336-2676** to address any patient / drug coverage specific questions. The Dual Choice formulary differs from the KPHC formulary (i.e. DOACs, ADHD, asthma). Please visit: Choice Formulary

Questions and Concerns?

If you have any questions or concerns, please contact any of the following P&T Committee members and designated alternates:

P&T Committee Voting Members:

Debbi Baker, PharmD, BCPS
Clinical Pharmacy

Karen Bolden, RN, BSN
Clinical Services

Hector Clarke, PharmD, BCOP
Ambulatory Pharmacy

Halima Daboiko, MD
Obstetrics and Gynecology

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Jennifer Rodriguez, MD
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Daniel Robitshek, MD
CDU/Hospital Services

Designated Alternates:

Jacqueline Anglade, MD
Obstetrics and Gynecology

Lesia Jackson, RN
Clinical Services

Satya Jayanthi, MD
Hospitalist

QRM Prior Authorization Review Criteria Updates (Continued)

- **Enzyme Replacement Therapies- Cerezyme, Elelyso, and Vpriv:** Criteria updated to (1) change the preferred therapy to Elelyso and (2) clarify criteria parameters that define symptomatic for Gaucher's disease.
- **Fabrazyme (agalsidase beta):** Criteria updated to add geneticists and nephrologists as prescribers.
- **Fintepla (fenfluramine):** Criteria updated to 1) add FDA approved indication of Lennox-Gastaut Syndrome (LGS), 2) clarify which antiepileptic drugs should be trialed prior to approval based on indication, 3) remove REMS enrollment as a review criteria requirement, and 4) require a trial of Epidiolex and/or Diacomit prior to approval based on indication.
- **Glucagon-like Peptide-1 (GLP-1) Receptor Agonists for Type 2 Diabetes:** Criteria updated to 1) add a statement clarifying why Victoza 1.2 mg daily is the maximum recommended dose, 2) add Jardiance adherence requirement, 3) change the continued approval criteria to require an A1c decrease of 0.5% if using insulin, and 4) clarify that an A1c above 7% is considered an A1c above target for members with ASCVD.
- **Gonadotropin Releasing Hormone Agonists – Vantas and Supprelin LA implants:** Criteria updated to 1) remove Vantas as it is no longer on the market, 2) add pediatric endocrinologists as prescribers, and 3) require a trial of Eligard prior to approval.
- **Gonadotropin Releasing Hormone (GnRH) Receptor Antagonists – Myfembree, Oriahnn, and Orilissa:** Criteria updated to 1) add the FDA approved indication for moderate to severe pain with endometriosis for approval of Myfembree and 2) reduce the amount of trial agents required for approval.
- **Herceptin (trastuzumab):** Criteria updated to require PA review to all Herceptin biosimilars except for Kanjinti.
- **Kevzara (sarilumab):** Criteria updated to clarify that a trial of a nonbiologic DMARD is not required if a patient has been on a biologic DMARD or JAK inhibitor for the same condition.
- **Mounjaro (tirzepatide):** Criteria updated to 1) clarify that trials of Ozempic and Jardiance require at least 80% adherence for 3 months, 2) require documentation of a trial and failure or contraindication to Victoza and Rybelsus if a patient fails Ozempic, 3) remove the requirement of trialing a non-preferred GLP-1 prior to approval if unable to tolerate Ozempic, and 4) add continued approval criteria for members initiated on Mounjaro outside of KPGA.
- **Nexletol (bempedoic acid)/Nexlizet (bempedoic acid and ezetimibe):** Criteria updated to 1) add criteria for high risk and very high risk patients, 2) remove trial of PCSK-9 inhibitors as a requirement for approval, and 3) clarify criteria surrounding required trial of statins and ezetimibe prior to approval.
- **Olumiant (baricitinib):** Criteria updated to clarify that a trial of a nonbiologic DMARD is not required if a patient has been on a biologic DMARD or JAK inhibitor for the same condition.
- **Orfadin (nitisinone):** Criteria updated to remove brand name Nityr tablets from the QRM PA review criteria. QRM PA review is not required for Nityr tablets.
- **Otezla (apremilast):** Criteria updated to clarify that a trial of a nonbiologic DMARD is not required if a patient has been on a biologic DMARD or JAK inhibitor for a rheumatology indication.
- **PCSK-9 Inhibitors- Praluent and Repatha:** Criteria updated to 1) to require LDL not at goal within the past 3 months and 2) clarify that a trial of ezetimibe is not required if the patient requires >25% LDL lowering.
- **Rozlytrek (entrectinib):** Criteria updated to 1) add the FDA approved expanded indication for use in pediatric patients 1 month of age or older, 2) add symptomatic heart failure, myocardial infarction, unstable angina, and coronary artery bypass graft in the past 3 months as reasons for non-coverage, and 3) update pediatric dosing and administration information.
- **Voxzogo (vosoritide):** Criteria updated to 1) incorporate the new FDA approved expanded indication for patients younger than 5 years old and 2) update the dosing and administration information.

Approved Floor Stock List Changes

(Effective 3.13.2024)

Medication	Department
Approved Floor Stock List Additions	
Dextrose 25% in Water IV Syringe	ACC-CDU
Priorix (measles, mumps, and rubella, live vaccine)	Adult Primary Care
	Family Practice
	Hematology/Oncology
	Infectious Disease
	Pediatrics
Approved Floor Stock List Removals	
M-M-R II (measles, mumps, and rubella, live vaccine)	Adult Primary Care
	Family Practice
	Hematology/Oncology
	Infectious Disease
	Pediatrics
	Women's Health

Medicare Part D Formulary Changes

Kaiser Permanente has a National Medicare Part D (MPD) Formulary. Each regional P&T Committee reviews drugs and decides on tier status. The National Medicare Part D Pharmacy and Therapeutics Committee is charged with reconciling regional differences in MPD Formulary recommendations through consensus building in order to maintain one National MPD Formulary for Kaiser Permanente..

Medicare Part D Initial Tier Placement

Initial Tier Placements- Recently launched and approved medications

Drug Name	Tier Status	Implementation Date
zilucoplan sodium 16.6 mg, 23 mg, 32.4 mg injection (Zilbrysq)	Specialty Tier 5	1/4/2024
vamorolone 40 mg/mL oral suspension (Agamree)	Specialty Tier 5	1/4/2024
bosutinib 50 mg, 100 mg capsules (Bosulif)	Specialty Tier 5	1/4/2024
eplontersen 45 mg/0.8 mL injection (Wainua)	Specialty Tier 5	12/27/2023
oxaprozin 300 mg capsules (generic)	Specialty Tier 5	12/21/2023
eflornithine HCL 192 mg tablets (Iwilfin)	Specialty Tier 5	12/21/2023
adalimumab-adaz 80mg/0.8 mL autoinjection (Hyrimoz)	Specialty Tier 5	12/20/2023
risperidone 25 mg, 37.5 mg, 50 mg extended-release microspheres injection (generic)	Specialty Tier 5	12/13/2023
cyclosporine 0.1% ophthalmic solution (Vevye)	Specialty Tier 5	12/8/2023
iptacopan HCL 200 mg capsules (Fabhalta)	Specialty Tier 5	12/8/2023
oxaprozin 300 mg capsules (Coxanto)	Specialty Tier 5	12/4/2023
adamts13 recombinant-krhn 500 units, 1500 units injection kit (Adzynma)	Specialty Tier 5	11/29/2023
alpha-1 proteinase inhibitor (Human) 4000 mg, 5000 mg injection (Zemaira)	Specialty Tier 5	11/29/2023
nirogacestat hydrobromide 50 mg tablets (Ogsiveo)	Specialty Tier 5	11/29/2023
toripalimab-tpzi 240 mg/6mL injection (Loqtorzi)	Specialty Tier 5	11/28/2023
reprotectinib 40 mg capsules (Augtyro)	Specialty Tier 5	11/27/2023
adalimumab-atto 40 mg/0.4mL, 80 mg/0.8mL, 20 mg/0.2mL, 40 mg/0.4mL autoinjector	Brand Tier 3	11/23/2023

Class Review

April 2024:

Medication Class Review
Stimulants/ADHD/Anti-Obesity/Anorexiants
Antianxiety Agents
Antiasthmatic and bronchodilator agents
Anticonvulsants
Antidepressants
Antimyasthenics/cholinergic agents
Antiparkinsons
Antipsychotics/Antimanic Agents
Genitourinary – Misc.
Hematological Agents – Misc.
Hypnotics/sedatives/sleep disorder agents
Migraine Products
Neuromuscular Blockers
Psychotherapeutics – Misc.
Urinary Antiinfectives
Urinary Antispasmodics

Medicare Part D Formulary Removal of Brand Drugs

During the year, Kaiser Permanente may make changes to our Medicare Part D Formulary (Drug List). The list below is intended to inform you of these changes. The following table lists all products recently removed from the Medicare Part D Formulary to be replaced with the generic.

Brand Medication	Brand Drug Tier	Generic Alternative	Generic Drug Tier	Effective Date
Votrient 200 mg tablets	5	pazopanib 200 mg tablets	5	2/1/2024
Symbicort 80-4.5 mcg/act aerosol inhaler	3	Breyna 80-4.5 mcg/act aerosol inhaler	2	2/1/2024
Symbicort 160-4.5 mcg/act aerosol inhaler	3	Breyna 160-4.5 mcg/act aerosol inhaler	2	2/1/2024
Lialda 1.2 g tablets	2	mesalamine 1.2 g tablets	2	3/1/2024
Vascepa 0.5 g capsules	2	icosapent ethyl 0.5 g capsules	2	4/1/2024
Vascepa 1 g capsules	2	icosapent ethyl 1 g capsules	2	4/1/2024

In the News....

FDA Approves Label Expansion for "Genentech/Novartis" Xolair

On February 16, 2024, the U.S. Food and Drug Administration approved Genentech and Novartis' Xolair (omalizumab), a subcutaneous anti-immunoglobulin E (anti-IgE) antibody injection, for the reduction of Type 1 allergic reactions including anaphylaxis. This is the only approved antibody for adults and pediatric patients 1 year of age and older with an immunoglobulin E (IgE)-mediated food allergy with an accidental exposure to one or more foods. Xolair was first approved in 2003 and is also indicated for the treatment of moderate to severe asthma in adults and pediatric patients 6 years of age and older, the treatment of chronic spontaneous urticaria in adults and adolescents 12 years and older, and as add-on maintenance treatment for chronic rhinosinusitis with nasal polyps in adult patients only.[1]

The expanded approval for Xolair is based on a Phase 3, double-blind, randomized, placebo-controlled trial titled OUtMATCH (NCT03881696). Patients with a food allergy to peanuts and at least two other foods (including milk, egg, wheat, cashew, hazelnut, or walnut) were included. Enrolled patients were unable to tolerate ≤ 100 mg of peanut and ≤ 300 mg of another food without the occurrence of severe allergic symptoms such as whole-body hives, persistent coughing, or vomiting. Treatment with Xolair for 16 to 20 weeks led to 68% of stud y participants achieving the primary endpoint of tolerating at least 600 mg of peanut protein without moderate or severe allergic symptoms compared to 5% in the placebo group. A statistically higher proportion of participants who received Xolair compared to placebo also achieved secondary endpoints, that included tolerating protein from milk, egg, or cashew without moderate or severe allergic symptoms. Xolair's safety findings remain consistent with previously conducted clinical trials across other indications.[2]

More than 40% of children and more than half of adults with food allergies have experienced a severe reaction at least once. While Xolair will not eliminate food allergies or allow patients to consume food allergens freely, its repeated use will help reduce the negative health impact of severe allergic reactions if accidental exposure occurs. At KPGA, Xolair currently requires QRM prior authorization review. [1]

1. FDA approves First Medication to Help Reduce Allergic Reactions to Multiple Foods After Accidental Exposure. U.S. Food and Drug Administration. FDA Approves First Medication to Help Reduce Allergic Reactions to Multiple Foods After Accidental Exposure | FDA. Accessed February 23, 2024.
2. Xolair. [package insert]. South San Francisco, CA. Genentech, Inc; 2024.

Eohilia (budesonide): The First FDA-Approved Oral Agent for Eosinophilic Esophagitis

On February 9, 2024, the U.S. Food and Drug Administration (FDA) approved Eohilia (budesonide oral suspension) for the treatment of eosinophilic esophagitis (EoE), an inflammatory condition of the esophagus that can cause pain and difficulty swallowing.[1,2] Eohilia enters the market as the first and only oral therapy that is FDA-approved for the treatment of EoE. It is currently approved for the short-term treatment of EoE in adult and pediatric patients 11 years of age and older. Notably, the FDA only recommends treatment with Eohilia for up to 12 weeks, as Eohilia has not been shown to be safe and effective beyond 12 weeks.[1]

Approval of Eohilia was based on two safety and efficacy trials, Study 1 (NCT02605837, n=318) and Study 2 (NCT01642212, n=92). Both studies included pediatric and adult subjects who experienced esophageal inflammation following treatment with a proton pump inhibitor (PPI) and experienced at least 4 days of dysphagia (as measured by the Dysphagia Symptom Questionnaire [DSQ]) over a 2-week period prior to randomization. Participants were randomized to receive either Eohilia 2 mg twice daily or placebo. Both studies achieved the efficacy endpoints of histologic remission in the Eohilia group (Study 1: 53.1%; Study 2: 38%) compared to placebo (Study 1: 1%; Study 2: 2.4%) and reduction in the patient-reported DSQ combined score in the Eohilia group (Study 1: −10.2; Study 2: −14.5) compared to placebo (Study 1: −6.5; Study 2: −5.9). The most common adverse reactions reported with Eohilia were respiratory tract infection (13%), gastrointestinal mucosal candidiasis (8%), headache (5%), gastroenteritis (3%), throat irritation (3%), adrenal suppression (2%), and erosive esophagitis (2%).[1]

Eohilia is anticipated to have a wholesale acquisition cost of $1875 per 30-day supply. Due to use in a specific population, recommended limitation on duration of therapy, and relatively high cost, Eohilia will likely require prior authorization or step therapy criteria review for coverage.

1. Eohilia [package insert]. Lexington, MA: Takeda Pharmaceuticals; 2024
2. Dellon ES, Gonsalves N, Hirano I, et al. ACG clinical guideline: Evidenced based approach to the diagnosis and management of esophageal eosinophilia and eosinophilic esophagitis (EoE). Am J Gastroenterol. 2013;108(5):679-693. doi:10.1038/ajg.2013.71