



# Formulary Update

## Formulary Additions

- Cefadroxil 500mg capsules
- Rifampin 150mg capsules

## Prior Authorization (QRM) Additions/ Removals

- |  |                                     |
|--|-------------------------------------|
| • Tecelra (afamitresgene autoleucel)               | • Tryvio (aprocitentan)             |
| • Niktimvo (axatilimab-csfr)                       | • Yorvipath (palopegteriparatide)   |
| • Bkerv (eculizumab-aeeb)                          | • Revuforj (revumenib)              |
| • Epysqli (eculizumab-aagh)                        | • Opzelura (ruxolitinib)            |
| • Kisunla (donanemab)                              | • Livdelzi (seladelpar)             |
| • Vyvgart (efgartigimod alfa & hyaluronidase-qvfc) | • Journavx (suzetrigine)            |
| • Attruby (acoramidis)                             | • Lodoco (colchicine)               |
| • Crenessity (crinercerfont)                       | • Saizen (somatropin) – REMOVED     |
| • Duvyzat (givinostat)                             | • Saizenprep (somatropin) – REMOVED |

## Prior Authorization (QRM) Updates

- |                                      |   |
|--------------------------------------|---|
| • Abrilada (adalimumab)              | • Trodelvy (sacituzumab govitecan-hziy)             |
| • Vtama (tapinarof)                  | • Padcev (enfortumab vedotin-ejfv)                  |
| • Nemludio (nemolizumab)             | • Onexton (Clindamycin Phosphate/ Benzoyl Peroxide) |
| • Bimzelx (bimekizumab)              | • Anktiva (nogapendekin alfa inbakicept-pmIn)       |
| • Botox (botulinum toxin)            | • Lumakras (sotorasib)                              |
| • Vascepa (icosapent ethyl)          | • Breyanzi (lisocabtagene maraleucel)               |
| • IVIG Various Products              | • Carvykti (Ciltacabtagene autoleucel)              |
| • Dupixent (dupilumab)               | • Fruzaqla (fruquintinib)                           |
| • Nucala (mepolizumab)               | • Jynarque (tolvaptan)                              |
| • Xolair (omalizumab)                | • Yorvipath (palopegteriparatide)                   |
| • Abecma (Idecabtagene vicleucel)    | • Mounjaro (tirzepatide)                            |
| • Amtagvi (Lifileucel)               | • Imbruvica (ibrutinib)                             |
| • Imdelltra (tarlatamab-dlle)        | • Orfadin (nitisinone)                              |
| • Itovebi (Inavolisib)               | • Provenge (sipuleucel-T)                           |
| • Krazati (adagrasib)                | • Rezlidhia (olutasidenib)                          |
| • Kymriah (tisagenlecleucel)         | • Truqap (capivasertib)                             |
| • Lazcluze (lazertinib)              |   |
| • Monjuvi (Tafasitamab-cxix)         |   |
| • Augtyro (repotrecitinib)           |   |
| • Yescarta (Axicabtagene ciloleucel) |   |
| • Vitrakvi (Larotrectinib)           |   |

### Table of Contents

1	Summary of Formulary Changes
2 & 6- 7	Formulary/ Floor Stock Updates
3	IR Practice Recommendations
4-6	QRM Updates
7	Medicare Part D Updates
8	In the News



**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 List](#) OR [Drug Formulary for Practitioners](#) for all KPGA Drug Formularies.

### Upcoming Formulary Items:

An important aspect of the formulary process is the involvement of all clinicians. Please contact your P&T Committee representative or your clinical department chief by July 16, if you wish to comment on any of the medications, class reviews, 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.



### Medication Class Review August 2025

Amebicides

Aminoglycosides

Anthelmintics

Antifungals

Anti-infectives – Misc.

Antimalarials

Antimycobacterial

Antivirals

Biologicals Misc.

Cephalosporins

Dermatological

Fluoroquinolones

Local Anesthetics - IV

Macrolides

Penicillins

Psychotherapeutics & Neurological  
Agents

Sulfonamides

Sulfonamides

Tetracyclines

Toxoids

### Commercial HMO/Closed Formulary Additions

**The following medication will be ADDED to the Commercial Formulary effective July 2, 2025:**

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

Cefadroxil 500mg capsules	Indicated for Group A Streptococcal infections, UTI treatment, skin and soft tissue infections, and prosthetic joint infections.
Rifampin 150mg capsules	Indicated for a variety of clinical conditions but is most used to treat active and latent tuberculosis.

### QHP-ACA/Open Formulary Step Therapy Additions

**The following medications will have step therapy ADDED effective July 2, 2025:**

Aklief (trifarotene)	Indicated for the treatment of acne vulgaris in patients nine years of age and older.
Eysuvis (loteprednol)	For the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease

### QHP-ACA/Open Formulary Tier Changes

**The following medications will have a tier change effective July 2, 2025:**

Drug	Previous Tier	New Tier
Cefadroxil 500mg capsules	Non-Preferred Tier 4	Generic Tier 2
Rifampin 150mg capsules	Non-Preferred Tier 4	Generic Tier 2

### Day Supply Additions

**The following medication will have 30-day supply restrictions effective July 2, 2025:**

Eysuvis (loteprednol)	One box per 365 days
Journavx (suzetrigine)	11 tablets per episode

### Approved Floor Stock List Additions

Medication	Department
Betamethasone Sodium Phosphate & Acetate 6mg/ml, MDV 5ml	Orthopedics



## 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 UPDATES were recently approved:**

<b>Camzyos (mavacamten)</b>	Updated to reflect package insert changes which reduce the required echocardiography monitoring in the maintenance phase and reduce contraindications
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ETSP recommendations as well as pipeline candidates can be found here: [ETSP Home Page](#)

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.



## 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](#).



## 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 medications will be ADDED to the QRM PA Review List effective July 2, 2025. Those marked with an asterisk are pending an effective date.

<b>Niktimvo (axatilimab-csfr)</b>	Indicated for the treatment of chronic graft-versus-host disease (cGVHD) after failure of ≥2 prior lines of systemic therapy.
<b>Bkemv (eculizimab-aeeb) &amp; Epysqli (eculizumab-aagh)</b>	Indicated for: <ul style="list-style-type: none"> <li>• Treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.</li> <li>• Treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.</li> <li>• Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.</li> </ul>
<b>Kisunla (donanemab)</b>	Indicated for the treatment of Alzheimer disease; to be initiated in patients with mild cognitive impairment or mild dementia stage of disease.
<b>Vyvgart (efgartigimod alfa and hyaluronidase-qvfc)</b>	Indicated for the treatment of generalized myasthenia gravis in adults who are anti-acetylcholine receptor antibody positive (AChR+).
<b>Duvyzat (givinostat)</b>	Indicated for treatment of Duchenne muscular dystrophy in patients ≥6 years of age.
<b>Yorvipath (palopegteriparatide)</b>	Indicated for treatment of hypoparathyroidism in adults.
<b>Revuforj (revumenib)</b>	Indicated for treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene ( <i>KMT2A</i> ) translocation in adults and pediatric patients ≥1 year of age.
<b>Opzelura (ruxolitinib)</b>	Indicated for topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.
<b>Livdelzi (seladelpar)</b>	Indicated for treatment of primary biliary cholangitis in combination with ursodeoxycholic acid (UDCA) in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.
<b>Journavx (suzetrigine)</b>	Indicated for treatment of moderate to severe acute pain in adults.
<b>Lodoco (colchicine)</b>	Indicated to help prevent heart attacks, strokes, and other serious heart problems in people who are at high risk for these events due to existing heart disease or multiple risk factors.
<b>Tecelra (afamitresgene autoleucel)*</b>	Indicated for the treatment of unresectable or metastatic synovial sarcoma in adults who have received prior chemotherapy, are <i>HLA-A*02:01P</i> , <i>HLA-A*02:02P</i> , <i>HLA-A*02:03P</i> , or <i>HLA-A*02:06P</i> positive (in blood samples) and whose tumor expresses the melanoma-associated antigen A4 (MAGE-A4) antigen as determined by an approved or cleared companion diagnostic device.
<b>Tryvio (aprocitentan)*</b>	Indicated for use in patients whose BP is not adequately controlled on other antihypertensive medications.
<b>Crenessity (crinecerfont)*</b>	Indicated for the adjunctive treatment to glucocorticoid replacement to control androgens in patients with classic congenital adrenal hyperplasia (FDA approved in ≥4 years and adults).
<b>Attruby (acoramidis)*</b>	Indicated for the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis in adults to reduce cardiovascular death and cardiovascular-related hospitalization.

\* QRM Criteria Pending

## 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.

- **Abrilada (adalimumab):** Criteria updated to list Abrilada (adalimumab-afzb) as a non-preferred product.
- **Vtama (tapinarof):** Criteria updated to add the indication of atopic dermatitis.
- **Nemluvio (nemolizumab):** Criteria updated to add the indication of atopic dermatitis.
- **Bimzelx (bimekizumba):** Criteria updated to add Yesintek (ustekinumab-kfce) as a preferred product. Also, added need to document negative test for tuberculosis within the past 24 months.
- **Botox (botulinum toxin):** Criteria updated to add the diagnosis of hemifacial spasm.
- **Vascepa (icosapent ethyl):** Criteria updated to list icosapent ethyl (generic for Vascepa) as preferred.
- **Intravenous IVIG Various Product:** Criteria updated to include numerous indications for use of IVIG.
- **Dupixent (dupilumab):** Criteria updated to change initial approval duration to 6 months in alignment with the European Position Paper on Rhinosinusitis (EPOS) and the European Forum for Research and Education in Allergy and Airway Diseases (EUFOREA) guidelines.
- **Nucala (mepolizumab):** Criteria updated to change initial approval duration to 6 months in alignment with the EPOS/ EUFOREA guidelines.
- **Xolair (omalizumab):** Nasal polyposis criteria updated to change initial approval duration to 6 months in alignment with the EPOS/ EUFOREA guidelines.
- **Xolair (omalizumab):** Food allergy criteria updated to state patients less than 18 years of age should be approved for continued healthcare office administration.
- **Abecma (Idencabtagene vicleucel):** Criteria updated to remove Eastern Cooperative Oncology Group (ECOG) performance status (PS).
- **Amtagvi (Lifileucel):** Criteria updated to remove ECOG PS.
- **Imdelltra (tarlatamab-dlle):** Criteria updated to remove ECOG PS.
- **Itovebi (Inavolisib):** Criteria updated to remove ECOG PS.
- **Krazati (adagrasib):** Criteria updated to remove ECOG PS.
- **Kymriah (tisagenlecleucel):** Criteria updated to remove ECOG PS.
- **Lazcluze (lazertinib):** Criteria updated to remove concomitant CYP3A4 as a reason for non-coverage and remove ECOG PS.
- **Monjuvi (Tafasitamab-cxix):** Criteria updated to remove ECOG PS.
- **Augtyro (repotrectinib):** Criteria updated to remove ECOG PS.
- **Yescarta (Axicabtagene ciloleucel):** Criteria updated to remove ECOG PS.
- **Vitrakvi (Larotrectinib):** Criteria updated to remove need for negative pregnancy test, remove ECOG PS.
- **Trodelvy (sacituzumab govitecan-hziy):** Criteria updated to remove ECOG PS.
- **Padcev (enfortumab vedotin-ejfv):** Criteria updated to remove need for patient to agree to use of adequate contraception and remove ECOG PS.
- **Onexton (clindamycin phosphate/ benzoyl peroxide):** Criteria updated to list clindamycin phosphate/ benzoyl peroxide (generic for Onexton) as preferred.
- **Anktiva (nogapendekin alfa inbakicept-pmln):** Criteria updated to remove ECOG PS.
- **Breyanzi (lisocabtagene maraleucel):** Criteria updated to remove ECOG PS..
- **Carvykti (ciltacabtagene autoleucel):** Criteria updated to remove ECOG PS.
- **Fruzaqla (fruquintinib):** Criteria updated to remove ECOG PS.
- **Jynarque (tolvaptan):** Criteria updated to clarify that eGFR should be greater than or equal to 25 for approval and remain at that level for continued coverage.
- **Yorvipath (palopegteriparatide):** Criteria for coverage updated to include persistent symptomatic hypocalcemia despite 12-week trial of conventional therapy.
- **Mounjaro (tirzepatide):** Criteria updated to allow prescription from TSPMG Adult Medicine or Family Medicine.
- **Imbruvica (ibrutinib):** Criteria updated to include language about preferred formulation based on daily dose.
- **Lumakras (sotorasib):** Criteria updated to clarify diagnosis and previous treatment regimens.



## QRM Prior Authorization Review Criteria Updates (continued)

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.

- **Orfadin (nitisinone):** Criteria updated to include language about opening capsules and suspending contents in water for patients unable to swallow capsules.
- **Provenge (sipuleucel-T):** Criteria updated to remove ECOG PS..
- **Rezlidhia (olutasidenib):** Criteria updated to remove ECOG PS.
- **Truqap (capivasertib):** Criteria updated to remove concomitant CYP3A4 as a reason for non-coverage and remove ECOG PS.

### Medications Reviewed But Not Accepted to the Commercial HMO Formulary

Note: Medications that can be dispensed via the outpatient pharmacy benefit but are not accepted to the closed Commercial HMO formulary, will be placed on a tier for the QHP-ACA/ Open formularies.

Drug Name	Commercial HMO/Closed Formulary Status	QHP-ACA/ Open Formulary Status
<b>Tecelra (afamitresgene autoleucel)</b>	<ul style="list-style-type: none"> <li>Not accepted – inpatient administered medication</li> <li>Approve for inpatient administration under medical benefit coverage</li> <li>Require QRM PA review*</li> </ul>	
<b>Niktimvo (axatilimab-csfr)</b>	<ul style="list-style-type: none"> <li>Not accepted – clinic administered medication</li> <li>Approve for clinic administration under medical benefit coverage</li> <li>Require QRM PA review</li> </ul>	
<b>Bkemv (eculizimab-aeeb)</b>	<ul style="list-style-type: none"> <li>Not accepted – clinic administered medication</li> <li>Approve for clinic administration under medical benefit coverage</li> <li>Require QRM PA review</li> </ul>	
<b>Epysqli (eculizumab-aagh)</b>	<ul style="list-style-type: none"> <li>Not accepted – clinic administered medication</li> <li>Approve for clinic administration under medical benefit coverage</li> <li>Require QRM PA review</li> </ul>	
<b>Vyvgart (efgartigimod alfa and hyaluronidase-qvfc)</b>	<ul style="list-style-type: none"> <li>Not accepted – clinic administered medication</li> <li>Approve for clinic administration under medical benefit coverage</li> <li>Require QRM PA review</li> </ul>	
<b>Kisunla (donanemab)</b>	<ul style="list-style-type: none"> <li>Not accepted – clinic administered medication</li> <li>Approve for clinic administration under medical benefit coverage</li> <li>Require QRM PA review</li> </ul>	
<b>Attruby (acoramidis)</b>	<ul style="list-style-type: none"> <li>Non-Formulary</li> <li>Require QRM PA review*</li> </ul>	<ul style="list-style-type: none"> <li>Specialty Tier 5</li> <li>Require QRM PA review*</li> </ul>
<b>Crenessity (crinecerfont)</b>	<ul style="list-style-type: none"> <li>Non-Formulary</li> <li>Require QRM PA review*</li> </ul>	<ul style="list-style-type: none"> <li>Specialty Tier 5</li> <li>Require QRM PA review*</li> </ul>
<b>Revuforj (revumenib)</b>	<ul style="list-style-type: none"> <li>Non-Formulary</li> <li>Require QRM PA review</li> </ul>	<ul style="list-style-type: none"> <li>Specialty Tier 5</li> <li>Require QRM PA review</li> </ul>
<b>Duvyzat (givinostat)</b>	<ul style="list-style-type: none"> <li>Non-Formulary</li> <li>Require QRM PA review</li> </ul>	<ul style="list-style-type: none"> <li>Specialty Tier 5</li> <li>Require QRM PA review</li> </ul>
<b>Tryvio (aprocitentan)</b>	<ul style="list-style-type: none"> <li>Non-Formulary</li> <li>Require QRM PA review*</li> </ul>	<ul style="list-style-type: none"> <li>Non-Preferred Tier 4</li> <li>Require QRM PA review*</li> </ul>
<b>Eysuvis (loteprednol)</b>	<ul style="list-style-type: none"> <li>Non-Formulary</li> <li>Apply QL of one box per 365 days</li> </ul>	<ul style="list-style-type: none"> <li>Specialty Tier 5; step therapy</li> <li>Apply QL of one box per 365 days</li> </ul>

\* QRM Criteria Pending

## Medications Reviewed But Not Accepted to the Commercial HMO Formulary (cont.)

Note: Medications that can be dispensed via the outpatient pharmacy benefit but are not accepted to the closed Commercial HMO formulary, will be placed on a tier for the QHP-ACA/ Open formularies.

Drug Name	Commercial HMO/Closed Formulary Status	QHP-ACA/ Open Formulary Status
<b>Yorvipath (palopegteriparatide)</b>	<ul style="list-style-type: none"> <li>Non-Formulary</li> <li>Require QRM PA review</li> </ul>	<ul style="list-style-type: none"> <li>Specialty Tier 5</li> <li>Require QRM PA review</li> </ul>
<b>Revuforj (revumenib)</b>	<ul style="list-style-type: none"> <li>Non-Formulary</li> <li>Require QRM PA review</li> </ul>	<ul style="list-style-type: none"> <li>Specialty Tier 5</li> <li>Require QRM PA review</li> </ul>
<b>Opzelura (ruxolitinib)</b>	<ul style="list-style-type: none"> <li>Non-Formulary</li> <li>Require QRM PA review</li> </ul>	<ul style="list-style-type: none"> <li>Specialty Tier 5</li> <li>Require QRM PA review</li> </ul>
<b>Aklief (trifarotene)</b>	<ul style="list-style-type: none"> <li>Non-Formulary</li> <li>Age limit - for individuals 36 years of age or older; not covered</li> </ul>	<ul style="list-style-type: none"> <li>Non-Preferred Tier 4; step therapy</li> <li>Age limit - for individuals 36 years of age or older; not covered</li> </ul>
<b>Livdelzi (seladelpar)</b>	<ul style="list-style-type: none"> <li>Non-Formulary</li> <li>Require QRM PA review</li> </ul>	<ul style="list-style-type: none"> <li>Specialty Tier 5</li> <li>Require QRM PA review</li> </ul>
<b>Journavx (suzetrigine)</b>	<ul style="list-style-type: none"> <li>Non-Formulary</li> <li>Require QRM PA review</li> <li>Apply QL of 11 tablets per episode</li> </ul>	<ul style="list-style-type: none"> <li>Non-Preferred Tier 4</li> <li>Require QRM PA review</li> <li>Apply QL of 11 tablets per episode</li> </ul>

## 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 for recently launched and approved medications



	Drug Name	Tier Status	Implementation Date
1	Diazoxide Choline 25 mg, 75 mg, 150 mg Extended-Release Tablets (Vykat XR)	Specialty Tier 5	3/31/2025

## 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 Current Tier	Generic Alternative	Generic Drug Tier	Effective Date
PURIXAN SUSP 2000 MG/100ML	5	MERCAPTOPURINE SUSP 2000 MG/100ML	5	6/1/2025
BRILINTA TABS 90 MG	3	TICAGRELOR TABS 90 MG	2	7/1/2025

## FDA clears first blood test for diagnosing Alzheimer's

May 2025 — Last month, the Food and Drug Administration approved the first blood test for diagnosing Alzheimer's disease. The less invasive test, known as Lumipulse manufactured by Fujirebio, uses a blood sample to detect the presence of amyloid plaques in the brain versus current tests which include PET imaging scans of the brain and spinal taps. Lumipulse should help to determine whether memory loss is a result of Alzheimer's while allowing patients earlier access to treatment.

Lumipulse is not intended to be a screening test for healthy individuals. The test is approved for adults 55 or older who have confirmed cognitive impairment. The test measures two proteins, pTau217 and beta-amyloid I-42, and the numerical ratio of the two proteins is associated with the presence or absence of amyloid plaques in the brain. Newer Alzheimer's drugs such as Kisunla and Leqembi target beta-amyloid buildup in the brain, but use has been limited partly due to challenges of diagnosing the disease early enough for the drugs to be effective. Both medications require QRM prior authorization and are administered in the outpatient infusion clinic.

Currently, an estimated 7.2 million Americans age 65 and older are living with Alzheimer's dementia equating to 1 in 9 people age 65 and older having the disease. Dr. Martin A. Makary, the FDA Commissioner said, "Alzheimer's disease impacts too many people, more than breast cancer and prostate cancer combined. Knowing that 10 percent of people aged 65 and older have Alzheimer's, and that by 2050 that number is expected to double, I am hopeful that new medical products such as this one will help patients." Other diagnostic companies have developed tests to screen patients for Alzheimer's, but this is the first one to be cleared by the FDA.

### References:

1. FDA Clears First Blood Test Used in Diagnosing Alzheimer's Disease Available at: <https://www.fda.gov/news-events/press-announcements/fda-clears-first-blood-test-used-diagnosing-alzheimers-disease> - Accessed June 2025.
2. Fujirebio Receives Marketing Clearance for Lumipulse® G pTau 217/β-Amyloid 1-42 Plasma Ratio In-Vitro Diagnostic Test As An Aid To Identify Patients With Amyloid Pathology Associated With Alzheimer's Disease . Available at: <https://www.fujirebio.com/en-us/news-events/fujirebio-receives-marketing-clearance-for-lumipulser-g-ptau-217bamyloid-142-plasma-0> - Accessed June 2025.
3. 2025 Alzheimer's Disease Facts and Figures. Special Report: American Perspectives on Early Detection of Alzheimer's Disease in the Era of Treatment by the Alzheimer's Association. Available at: <https://www.alz.org/getmedia/ef8f48f9-ad36-48ea-87f9-b74034635c1e/alzheimers-facts-and-figures.pdf> - Accessed June 2025.

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

Hector Clarke, PharmD, BCOP  
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Pediatrics

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Stanley Allen III, MD  
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Felicia Martin, PharmD  
Pharmacy/Geriatrics

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### P&T Committee Non-Voting Physician Members

Elizabeth Greco, MD  
Physician Lead, Pharmacy Safety and Systems

Daniel Robitshek, MD  
CDU/Hospital Services

### Designated Alternates:

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