

P&T Committee Meeting Minutes
Medicaid
September 19, 2023

<p>Present (via Teams): Bret Yarczower, MD, MBA – Chair Amir Antonius, Pharm.D. Emily Antosh, Pharm.D. Kristen Bender, Pharm.D. Alyssa Cilia, RPh Michael Dubartell, MD Rajneel Farley, Pharm.D. Kelly Faust, Pharm.D. Tricia Heitzman, Pharm.D. Emily Hughes, Pharm.D. Derek Hunt, Pharm.D. Kerry Ann Kilkenny, MD Philip Krebs, R.EEG T Briana LeBeau, Pharm.D. Ted Marines, Pharm.D. Lisa Mazonkey, RPh Tyreese McCrea, Pharm.D. Jamie Miller, RPh Mark Mowery, Pharm.D. Austin Paisley, Pharm.D. Kimberly Reichard, Pharm.D. Melissa Sartori, Pharm.D. Angela Scarantino Kristen Scheib, Pharm.D. Leslie Shumlas, Pharm.D. Aubrielle Smith Pharm.D. Kirsten Smith, Pharm.D. Michael Spishock, RPh Kevin Szczecina, RPh Amanda Taylor, MD Ariana Wendoloski, Pharm.D. Brandon Whiteash, Pharm.D. Margaret Whiteash, Pharm.D. Morgan Casciole (pharmacy resident) Daniele Francisko (pharmacy resident) Kirsten Mascaritola (pharmacy resident) Benjamin Andrick, Pharm.D. (non-voting participant) Birju Bhatt, MD (non-voting participant) Abigail Chua, DO (non-voting participant) Alfred Denio, MD (non-voting participant) Jeremy Garris, Pharm.D. (non-voting participant)</p>	<p>Absent: Jeremy Bennett, MD Holly Bones, Pharm.D. Kim Castelnovo, RPh Kimberly Clark, Pharm.D. Bhargavi Degapudi, MD Michael Evans, RPh Nichole Hossler, MD Jason Howay, Pharm.D. Keith Hunsicker, Pharm.D. Kelli Hunsicker, Pharm.D. Perry Meadows, MD Jonas Pearson, RPh William Seavey, Pharm.D. Michael Shepherd, MD Todd Sponenberg, Pharm.D. Jill Stone, Pharm.D. Robert Strony, MD MBA Luke Sullivan, DO</p>
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Call to Order: Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, September 19, 2023.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the July 18, 2023 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Cuvrior (trientine tetrahydrochloride)

Review: Cuvrior is a copper chelator indicated for the treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine. Trientine is a copper chelator that eliminates absorbed copper from the body by forming a stable complex that is then eliminated through urinary excretion. Trientine also chelates copper in the intestinal tract. The treatment of Wilson disease is lifetime and aimed at targeting copper overload. Treatment is broken into two phases: removing the tissue copper that has accumulated and preventing the reaccumulation. Copper removal is achieved by the administration of potent chelators. The primary chelator that is used is D-penicillamine. However, 30% of patients do not tolerate D-penicillamine long term. Penicillamine products for Wilson's disease include Cuprimine and Depend both are available generically. Also, it may not be the treatment of choice in patients with neurologic symptoms. Trientine has been used as a second-line agent for those intolerant of D-penicillamine, but it is also a reasonable option for primary therapy and may be preferred due to lower incidence of adverse events. Syprine (trientine hcl) is available generically. Prevention of reaccumulation can be achieved with chelators or by use of oral zinc. To prevent further accumulation or reaccumulation of copper, patients with Wilson disease should also be maintained on a low copper diet to avoid copper-rich foods. Treatment should never be discontinued altogether without careful monitoring. Patients who stop therapy for Wilson disease are at risk for development of hepatic decompensation and acute liver failure. Although Syprine and Cuvrior are both trientine-based products, the indications differ. Cuvrior is approved in penicillamine-tolerant patients and Syprine in penicillamine-intolerant patients. Further, Syprine needs to be refrigerated, whereas Cuvrior can be stored at room temperature.

Clinical Discussion: Aubrielle confirmed that members must be tolerant of penicillamine prior to approval. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: There was one vote to reject, all other votes were in favor to accept the recommendations.

Outcome: Cuvrior will be a pharmacy benefit. It is recommended to not add Cuvrior to formulary. The following prior authorization criteria will apply.

- Medical record documentation that the member is 18 years of age or older AND
- Medical record documentation of a diagnosis of Wilson's disease AND
- Medical record documentation of controlled Wilson's disease as evident by serum non-ceruloplasmin copper (NCC) level between ≥ 25 and ≤ 150 mcg/L AND
- Medical record documentation that the member is tolerant to penicillamine and that penicillamine will be discontinued prior to therapy with Cuvrior AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to trientine

GPI Level: GPI-12

Require RPH Sign off: Yes

Other Formulary Policy Recommendations

Penicillamine capsules: It is recommended to add to the Generic tier of the pharmacy formulary. No prior authorization criteria will apply.

Trientine capsules: It is recommended to add to the Generic tier of the pharmacy formulary. No prior authorization criteria will apply.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Joenja (leniolisib)

Review: Joenja is a kinase inhibitor indicated for the treatment of activated phosphoinositide 3-kinase delta (*PI3Kδ*) syndrome (APDS) in adult and pediatric patients 12 years of age and older. APDS, previously known as p110δ-activating mutation causing senescent T cells, lymphadenopathy, and immunodeficiency (PASLI) disease, is an ultra-rare disease state caused by mutations in the phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit δ (*PIK3CD*) or the phosphoinositide-3-kinase regulatory subunit 1 (*PIK3R1*) gene. APDS is a genetic disorder that can be diagnosed at any age, but usually is identified in early childhood. Patients with APDS present with symptoms including mild developmental delay, bronchitis, bronchiectasis, immune cytopenias, splenomegaly, and/or lymphadenopathy, with earliest reported and most common symptoms including severe/frequent infections of the ears, sinuses, and upper and lower respiratory tracts.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Joenja is a pharmacy benefit that will be managed by GHP and should be added to the GHP Family pharmacy formulary at the Brand tier. The following prior authorization criteria should apply:

- Medical record documentation of age 12 years or older **AND**
- Medical record documentation of a diagnosis of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) **AND**
- Medical record documentation of weight greater than or equal to 45 kg **AND**
- Medical record documentation of a mutation in *PIK3CD* OR *PIK3R1* gene.

GPI Level: GPI-12

Authorization Duration: Initial approval will be for 6 months.

Reauthorization info: Subsequent approvals will be for an additional 12 months and will require medical record documentation of clinical improvement or lack of progression in symptoms of APDS on Joenja therapy.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Columvi (glotitamb-gxbm)

Review: Columvi is a bi-specific CD20-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractor diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two lines of therapy. This was an accelerated approval based on response rate and durability of response.

Clinical Discussion: Does Epkinly have a better safety profile or is it similar to Columvi. Adverse reactions and warnings are similar. Believe it does have a more expanded indication than Columvi. We do not see an advantage of one over the other. The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Columvi is a medical benefit that will be managed by GHP and will require a prior authorization. The following prior authorization criteria will apply:

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Columvi is written by a hematologist or oncologist AND
- Medical record documentation of a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, or large B-cell lymphoma (LBCL) arising from follicular lymphoma AND
- Medical record documentation of prior therapy with at least two lines of systemic therapy

Authorization Duration: Initial approval of Columvi will be for 6 months or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Columvi for the treatment of relapsed or refractor diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma should not exceed the FDA-approved treatment duration of 12 cycles. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Lumryz (sodium oxybate)

Review: Lumryz is a once nightly Central Nervous System (CNS) depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy. Lumryz is the first FDA-approved extended-release formulation of sodium oxybate, which is a derivative of gamma-hydroxybutyrate and metabolite of the neurotransmitter GABA. Although the exact mechanism of action of Lumryz is unknown, it is suggested that Lumryz acts through GABA at noradrenergic and dopaminergic neurons, as well as thalamocortical neurons. Lumryz is available as 4.5 gram, 6 gram, 7.5 gram, or 9 gram oral powder packets to be prepared for oral suspension. Prior to ingestion, the Lumryz oral packet should be suspended in water, ingested within 30 minutes of mixing, and taken at least 2 hours after eating. Patients should take Lumryz while in bed and lie down immediately after ingestion. The recommended initial dosing of Lumryz is 4.5 grams per night. The dosage should be increased by 1.5 grams per night in weekly intervals and titrated to the recommended dosage range of 6 grams to 9 grams per night based on efficacy and tolerability. Patients may be switched to Lumryz from immediate-release sodium oxybate at the nearest equivalent dosage in grams per night.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Lumryz is a pharmacy benefit managed by GHP and should not be added to the pharmacy formulary. The following prior authorization criteria should apply:

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of one of the following:
 1. Diagnosis of excessive daytime sleepiness associated with narcolepsy OR
 2. Diagnosis of cataplexy with narcolepsy AND
- Medical record documentation that Lumryz is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Xyrem OR Xywav

AUTHORIZATION DURATION: 12 months

Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following is required:

- Medical record documentation of reduction in frequency of cataplexy attacks OR
- Medical record documentation of reduction in symptoms of excessive daytime sleepiness

After the initial 12 month approval, subsequent approvals will be for a duration of 12 months. Reevaluation will be every 12 months requiring the following:

- Medical record documentation of continued or sustained reduction in frequency of cataplexy attacks OR
- Medical record documentation of continued or sustained reduction in symptoms of excessive daytime sleepiness

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Tembexa (brincidofovir)

Review: Tembexa (brincidofovir) is indicated for the treatment of human smallpox disease in adult and pediatric patients, including neonates. Smallpox is a serious infectious disease that is caused by the variola virus. In the United States, the last natural outbreak of smallpox occurred in 1949. Smallpox was eradicated and no cases of naturally occurring smallpox have happened since 1977. The World Health Assembly declared smallpox eradicated in 1980. Smallpox was contagious and people with the disease had a fever along with a distinctive, progressive skin rash. Currently, smallpox vaccines are not recommended for the general public because smallpox has been eradicated. If there were a smallpox outbreak, health officials would use smallpox vaccines to control it. There are 3 primary antiviral therapies (tecovirimat, brincidofovir, cidofovir) that have shown effectiveness against orthopoxviruses including variola in animal and in vitro studies. While some antiviral drugs may help treat smallpox disease, there is no treatment for smallpox that has been tested in people who are sick with the disease and proven effective. Due to concerns that variola virus might be used as an agent of bioterrorism, the U.S. government has stockpiled enough smallpox vaccine to vaccinate everyone who would need it if a smallpox outbreak were to occur.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Elfabrio is a medical benefit that will be managed by GHP and will require a prior authorization. The following prior authorization criteria will apply:

- Medical record documentation of a diagnosis of Fabry disease AND
- Prescribed by a metabolic specialist with experience in treating Fabry disease

GPI Level: GPI-12

Authorization Duration: Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Require RPH Sign off: Yes. RPH Sign off will be required for Elfabrio to ensure appropriate utilization.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Filspari (sparsenten)

Review: Filspari is a novel dual endothelin angiotensin receptor antagonist (DEARA) that inhibits both endothelin receptor type A (ET_AR) and angiotensin II receptor type 1 (AT₁R). In kidney diseases like IgAN and focal segmental glomerulosclerosis (FSGS), blockade of both ET_A and AT₁ pathways have been shown to reduce proteinuria, protect podocytes, and prevent glomerulosclerosis and mesangial cell proliferation. Filspari is now the first and only non-immunosuppressive agent approved for the treatment of IgAN.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Tembexa will be non-formulary for GHP Family as it will not be commercially available. If Tembexa becomes commercially available, it should be added to the Brand Tier with no prior authorization required.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Veozah (fezolinetant)

Review: Veozah (fezolinetant) is an oral, non-hormonal therapy approved on May 12, 2023, for the treatment of moderate to severe vasomotor symptoms (VMS), or hot flashes, caused by menopause. It is supplied as a 45 mg tablet to be taken once daily and is first in its class. Veozah (fezolinetant) works as a selective NK3(neurokinin) receptor antagonist that blocks NKB binding on the KNDy neuron, which is thought to restore normal temperature sensitivity of the thermoregulatory center.

Clinical Discussion: Dr. Yarczower asked if you have moderate to severe symptoms, based on clinical trials it will not reduce the severity of symptoms, but it will reduce the frequency of symptoms by approximately 25%. Tyreese confirmed. The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Veozah (fezolinetant) is a pharmacy benefit non-PDL managed and is recommended not to be added to the Medicaid formularies and will require a prior authorization:

- Medical record documentation of age greater than 18 years AND
- Medical record documentation of diagnosis of menopause with moderate to severe vasomotor symptoms (VMS) AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three 3 different medications from at least two of the following categories: i. Estrogens, ii. Non-Hormonal Agents

Formulary Alternatives: Hormonal: Alora Patch, Angeliq Tablet, Climara Pro Patch, Combipatch, Delestrogen Vial, Depo-Estradiol Vial, Elestrin Gel, Estradiol Cream/Tablet/Vaginal Tablet, Estradiol Patch (Once-Weekly), Estradiol Patch (Twice-Weekly), Estradiol Valerate Vial, Estring Vaginal Ring, Femring Vaginal Ring, Fyavolv Tablet, Jinteli Tablet, Medroxyprogesterone Acetate Syringe/Vial, Norethindrone-Ethinyl Estradiol Tablet (generic Femhrt Tablet), Premarin Cream/Tablet, Premphase Tablet, Prempro Tablet, Vagifem Vaginal Tablet, Yuvaferm Vaginal Tablet (Non-Hormonal) Agents: Paroxetine, Escitalopram, Citalopram Solution/Tablet, Desvenlafaxine Succinate ER Tablet, Gabapentin Capsule/Solution/Tablet, Venlafaxine Tablet, Venlafaxine HCl ER Capsule/Tablet

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Furoscix (furosemide injection)

Review: Furoscix is indicated for the treatment of congestion due to fluid overload in adult patients with New York Heart Association (NYHA) Class II and Class III chronic heart failure. Furoscix is not indicated for use in emergency situations or in patients with acute pulmonary edema. Furoscix is supplied as a single-use, on body Infusor with a 80 mg/10 mL prefilled cartridge to deliver 20 mg of Furoscix over the first hour followed by 12.5 mg per hour for the subsequent 4 hours. Furoscix is not for chronic use and should be replaced with oral diuretics as soon as possible. The infusion will last about 5 hours, so patients should limit activity during this time. The adhesive on-body infusor is applied to the stomach on either side of the belly button then a blue start button is pressed to begin the fusion. A small needle will be inserted just under the skin and start the infusion. The on-body infusor should remain on the skin until the delivery is complete, after which the on-body Infusor should be removed and discarded into a sharps container. The site of administration should be rotated with each administration.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: Keith asked to confirm what we are currently doing for these members. Are we doubling oral dose, admitting for IV diuretics, etc.? Could ultimately be cost effective if avoiding an admission. Dr.'s Kilkenny and Dubartell commented that typically the oral dose is doubled and if no relief, member is admitted or brought in for IM furosemide. Mobile paramedics are also sometimes dispatched to the home to administered IM furosemide. Medical directors do not feel it's appropriate to require trial/failure of any other agents prior to approval. One Committee member voted to reject the recommendation, the remaining members voted to accept.

Outcome: Furoscix is a pharmacy benefit that will be managed by GHP and should not be added to the GHP Family formulary. The following prior authorization criteria should be added.

- Medical record documentation that Furoscix is prescribed by or in consultation with a cardiologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of New York Heart Association (NYHA) Class II or Class III chronic heart failure AND
- Medical record documentation of congestion due to fluid overload AND
- Medical record documentation that member is stable on background loop diuretic therapy AND
- Medical record documentation of provider attestation that member will use Furoscix for short-term use only and will be transitioned to oral diuretics as soon as practical

GPI Level: GPI-14

Authorization Duration: 1 month

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Vowst (fecal microbiota spores, live-brpk)

Review: Vowst is an oral FDA approved fecal microbiome agent used in individuals 18 years of age or older to prevent the recurrence of Clostridium difficile infection (CDI) following antibacterial treatment for recurrent CDI. Vowst is not indicated for the treatment of CDI. Administered in capsule formulation, Vowst is manufactured from human fecal matter sourced from qualified donors and routinely tested for a panel of transmittable pathogens. There is potential for food allergens within Vowst therapy as donors do not have dietary restrictions. The fecal microbiota suspension is the filtrate generated by processing the fecal matter in a pre-defined ratio with a solution of polyethylene glycol (PEG) 3350 and saline. Each capsule of Vowst contains between 1×10^6 and 3×10^7 colony forming units in $92 \pm 4\%$ (w/w) glycerol in saline. At present, the mechanism of action of Vowst is unknown.

Clinical Discussion: Dr. Kilkenny asked how often Vowst can be used. There are no recommendations currently about re-treatment. Would only approve for one course at this time. The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Vowst will be a pharmacy benefit managed by GHP that should be added to the GHP Family formulary at the Brand tier. The following prior authorization criteria will apply:

- Documentation of age greater than or equal to 18 years AND
- Prescribed by or in consultation with an infectious disease specialist or gastroenterologist AND
- Medical record documentation that Vowst will be used for the prevention of recurrence of C. difficile infections AND
- Medical record documentation of a diagnosis of recurrent C. difficile infection based on the results of an appropriate laboratory stool test within 30 days of prior authorization request AND
- Medical record documentation that an appropriate standard-of-care antibacterial regimen was used for the treatment of recurrent C. difficile infection (e.g., oral fidaxomicin, oral vancomycin, oral metronidazole) AND

- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Rebyota

Authorization Duration: If approved, authorization shall be for the authorization of 1 treatment course of Vowst with an authorization duration of 30 days.

Note to Reviewer: Vowst is not indicated for the treatment of *C. difficile* infection infections. There is no information currently available indicating that an individual is unable to receive more than one treatment course of Vowst

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Ticovac (Tick-Borne Encephalitis Vaccine)

Review: Ticovac was approved in the United States 2021 and is a vaccine indicated for active immunization to prevent tick-borne encephalitis (TBE). Ticovac is approved for use in individuals 1 year of age and older. This vaccine has been used for over 20 years in Europe.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Ticovac will be a medical benefit managed by GHP. No prior authorization criteria with regards to cost will apply.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Arexvy and Abrysvo (Respiratory Syncytial Virus Vaccine)

Review: Arexvy and Abrysvo are both indicated for the prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older. Abrysvo also received approval for the additional indication for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD cause by respiratory syncytial virus (RSV) in infants from birth through 6 months of age.

Clinical Discussion: Doesn't seem like this would impact children who qualify for Synagis if pre-term. Does this in anyway impact the need for Synagis in children who's mother received the vaccine during pregnancy. Do not believe that this will impact Synagis utilization in those that receive the vaccine. Recommend reviewing these vaccines with experts. Abrysvo – Only criterion is to ensure that member is pregnant and that the vaccine will be administered between 32-36 weeks. Criterion is based on FDA approved indication. Recommend updating to end criterion after gestational age. Should this be administered with each pregnancy? Unknown at this time if a dose is required with each pregnancy. Recommend removing QL for the time being until the vaccine schedule is clarified.

Dr. Sullivan asked if this is this administered regardless of seasonality? At this time it appears it should be administered to any pregnant woman between 32-36 weeks pregnant regardless of season. No additional comments or questions. The committee unanimously voted to accept the recommendations as amended.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Arexvy and Abrysvo will be medical or pharmacy benefits and should be added to the Brand tier of the GHP Family formulary. Arexvy will not require a prior authorization but will have the following limits:

Age Limit: 60 years to 999 years

Quantity Limit: 0.5 mL / 999 days

Abrysvo will not require a prior authorization for patients 60 years of age and older. For members over 19 years of age to under 60 years of age, the following prior authorization criteria will apply:

- Medical record documentation that Abrysvo will be used for active immunization of pregnant individuals at 32 through 36 weeks gestational age

For members under 19 years of age, Abrysvo will not be covered as these members are required to receive the vaccine from their MD through the VFC program.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Beyfortus (nirsevimab-alip)

Review: Beyfortus is a respiratory syncytial virus (RSV) F protein-directed fusion inhibitor indicated for the prevention of RSV lower respiratory tract disease in neonates and infants born during or entering their first RSV season and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. It is a human immunoglobulin G1 kappa (IgG1κ) monoclonal antibody produced by recombinant DNA technology with anti-RSV activity.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Beyfortus is a medical benefit that will be managed by the PDL and will not require a prior authorization for patients under 8 months of age. For patients greater than 8 months of age up to 24 months of age, a prior authorization will be required. The following prior authorization criteria will apply:

- Infants \leq 12 months of age, and born before < 29 weeks gestation at the onset of RSV season
- Infants < 12 months of age, who have a diagnosis of a congenital abnormality of the airway or a diagnosis of a neuromuscular condition that compromises handling of respiratory secretions
- Infants and children < 24 months of age who will be profoundly immunocompromised during the RSV season (e.g., severe combined immunodeficiency or severe acquired immunodeficiency syndrome)
- Infants < 12 months of age, born at < 32 weeks gestation, with chronic lung disease of prematurity, defined as > 21% oxygen for at least 28 days after birth
- Infants and children < 24 months of age with chronic lung disease (CLD) who have required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic steroid use, bronchodilator use or diuretic use)
- Infants < 12 months of age with hemodynamically significant acyanotic heart disease who:

- are receiving medication to control congestive heart failure; or
 - have moderate to severe pulmonary hypertension
- Infants < 12 months of age with cyanotic heart disease who have been evaluated and recommended for treatment by a cardiologist
 - Infants or children who have been receiving prophylaxis and undergo cardiopulmonary bypass during RSV season should receive an additional dose of Beyfortus post-operatively as soon as possible after procedure (even if sooner than a month from previous dose) when medically stable (serum concentrations decrease by a mean of 58% following by-pass)
 - Children less than two years of age who undergo cardiac transplantation during the RSV season
 - Infants in the first year of life with CF and clinical evidence of CLD and/or nutritional compromise
 - Infants in the second year of life with CF and who have severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or whose weight for length is less than the 10th percentile.

The following additional prior authorization criteria will apply to Beyfortus:

- Medical record documentation that member has not received Synagis during the current RSV season.

AUTHORIZATION DURATION:

Prophylaxis of 1 dose should be initiated on November 1 (prior to RSV season). Listed indications would need to be met on November 1 of the calendar year that prophylaxis is initiated. Members born after November 1 during RSV season who meet criteria will receive one dose of prophylaxis.

In the event of an atypical RSV season (i.e. unpredicted, early, or late, high rates of RSV circulation), prophylaxis of 1 dose should be initiated on dates deemed appropriate by Geisinger Health Plan in conjunction with guidance from the American Academy of Pediatrics (AAP) and other applicable clinical resources. Members born after the start of the atypical RSV season who meet criteria will receive 1 dose on the date deemed appropriate by Geisinger Health Plan in conjunction with guidance from the American Academy of Pediatrics (AAP) and other applicable clinical resources.

Dosing beyond 1 dose will be reviewed on a case-by case basis based on CDC surveillance reports, state/local health department recommendations, and other current medical literature.

Other Recommendations

The following prior authorization should be added the Synagis MBP Policy 2.0 and Part D Policy 428.0D

- Medical record documentation that member has not received Beyfortus during the current RSV season

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Fast Facts

Leqembi

Updated Indication: On July 10th 2023, Leqembi received full FDA approval for the treatment of Alzheimer’s disease. The prescribing information now states “Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.” Dosing recommendations have not changed compared to previous recommendations, which are for Leqembi 10mg/kg to be given over approximately one hour, once every two weeks.

Recommendation: It is recommended to modify existing prior authorization criteria as outlined below. Leqembi (lecanemab-irmb) will be considered medically necessary for the Medicaid line of business when ALL of the following criteria are met:

- Medical record documentation that Leqembi (lecanemab-irmb) is prescribed by or in consultation with a dementia specialist (e.g., neurologist, psychiatrist, geriatric psychiatrist, neuropsychiatrist, geriatrician, or gerontologist) **AND**
- Medical record documentation that the dementia specialist will monitor the beneficiary at **least once every 3 months appropriate intervals (prescribing information states MRI is to be obtained prior to the 5th, 7th, and 14th infusions)** **AND**
- Medical record documentation of a diagnosis of Mild Cognitive Impairment (MCI) due to Alzheimer’s Disease (AD) or mild dementia due to Alzheimer’s Disease (AD) [diagnosis codes may include: G30, G30.0, G30.1, G30.8, G30.9, G31.84] **AND**
- Medical record documentation of no medical or neurological conditions (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary’s cognitive impairment **AND**
- Medical record documentation of no contraindications to Magnetic Resonance Imaging (MRI) (e.g. cardiac pacemaker/defibrillator or ferromagnetic metal implants) **AND**
- Medical record documentation of MRI obtained within one year prior to initiating treatment with Leqembi (lecanemab-irmb) **AND**
- Medical record documentation of positron emission tomography (PET) scan positive for brain amyloid plaques OR cerebrospinal fluid (CSF) biomarker testing positive for beta-amyloid plaques (as indicated by reduced amyloid beta 42 [A β 42] levels OR reduced amyloid beta 42 amyloid beta 40 ratio [A β 42/A β 40 ratio] in CSF **OR elevated total tau amyloid beta 1-42 ratio [t-tau/A β 1-42])** **AND**
- Medical record documentation of at least two (2) of the following:
 - Mini-Mental State Examination (MMSE) score of greater than or equal to 22,
 - Montreal Cognitive Assessment (MoCA) score greater than or equal to 17,
 - Clinical Dementia Rating-Global Score (CDR-GS) of 0.5 or 1,
 - Clinical Dementia Rating-Sum of Boxes (CDR-SB) score less than or equal to 9,
 - Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) score less than or equal to 85, and/or
 - Quick Dementia Rating System (QDRS) score less than or equal to 12**AND**
- Medical record documentation that member does not have any exclusions to treatment with Leqembi (lecanemab-irmb), including all of the following:
 - A history of stroke, transient ischemic attack (TIA), or seizures in the past year **AND**
 - A bleeding disorder that is not under adequate control (e.g. a platelet count <50,000 or international normalized ratio [INR] >1.5) **AND**
 - A brain MRI at screening showing any of the following significant pathological findings:
 - More than 4 microhemorrhages (defined as 10 millimeter [mm] or less at the greatest diameter),

- A single macrohemorrhage >10 mm at greatest diameter,
- An area of superficial siderosis,
- Evidence of vasogenic edema,
- Evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions,
- Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease,
- Space occupying lesions, and
- Brain tumors (excludes lesions diagnosed as meningiomas or arachnoid cysts and less than 1 cm at their greatest diameter)

AND

- Medical record documentation of a dose that is consistent with FDA-approved package labeling.

AUTHORIZATION DURATION: Approval will be given for an initial duration of twelve (12) months or less if the reviewing provider feels it is medically appropriate. After the initial twelve (12) month approval, subsequent approvals will be for a duration of twelve (12) months or less if the reviewing provider feels it is medically appropriate, and will require:

- Medical record documentation that member continues to experience medical benefit from and tolerability to Leqembi (lecanemab-irmb) based on the prescriber's assessment **AND**
- Medical record documentation Leqembi (lecanemab-irmb) is prescribed by or in consultation with a dementia specialist (e.g., neurologist, psychiatrist, geriatric psychiatrist, neuropsychiatrist, geriatrician, or gerontologist) **AND**
- Medical record documentation that the member was, and will continue to be, monitored and assessed by the prescribing dementia specialist at **least every 3 months appropriate intervals** **AND**
- Medical record documentation of no medical or neurological conditions (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment **AND**
- Medical record documentation of no contraindications to Magnetic Resonance Imaging (MRI) (e.g. cardiac pacemaker/defibrillator or ferromagnetic metal implants) **AND**
- Medical record documentation of continuing treatment with Leqembi (lecanemab-irmb) based on recent MRI results as recommended in the FDA-approved package labeling (e.g. MRI to be obtained prior to the 5th, 7th, and 14th infusions) **AND**
- Medical record documentation of repeat testing **AND** documented results of at least two of the following:
 - Mini-Mental State Examination (MMSE),
 - Montreal Cognitive Assessment (MoCA),
 - Clinical Dementia Rating-Global Score (CDR-GS),
 - Clinical Dementia Rating-Sum of Boxes (CDR-SB),
 - Repeatable Battery for the Assessment of Neuropsychological Status (RBANS), and/or
 - Quick Dementia Rating System (QDRS)

AND

- Medical record documentation that member does not have any exclusions to treatment with Leqembi (lecanemab-irmb), including all of the following:
 - A history of stroke, transient ischemic attack (TIA), or seizures in the past year **AND**
 - A bleeding disorder that is not under adequate control (e.g. a platelet count <50,000 or international normalized ration [INR] >1.5) **AND**
 - A brain MRI at screening showing any of the following significant pathological findings:

- Evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions,
- Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease,
- Space occupying lesions, and
- Brain tumors (excludes lesions diagnosed as meningiomas or arachnoid cysts and less than 1 cm at their greatest diameter)

AND

- Medical record documentation of a dose that is consistent with FDA-approved package labeling.

Leqembi (lecanemab-irmb) will be considered medically necessary for the Commercial/Exchange/CHIP lines of business when ALL of the following criteria are met:

- Medical record documentation of enrollment in a prospective comparative study and/or a registry that collects information regarding treatment with Leqembi, which can include, but is not limited to, the Alzheimer's Network for Treatment and Diagnostics (ALZ-NET) **AND**
- Medical record documentation Leqembi (lecanemab-irmb) is prescribed by or in consultation with a dementia specialist (e.g., neurologist, psychiatrist, geriatric psychiatrist, neuropsychiatrist, geriatrician, or gerontologist) **AND**
- Medical record documentation that the dementia specialist will monitor the beneficiary at appropriate intervals (prescribing information states MRI is to be obtained prior to the 5th, 7th, and 14th infusions) **AND**
- Medical record documentation of a diagnosis of Mild Cognitive Impairment (MCI) due to Alzheimer's Disease (AD) or mild dementia due to Alzheimer's Disease (AD) [diagnosis codes may include: G30, G30.0, G30.1, G30.8, G30.9, G31.84] **AND**
- Medical record documentation of no medical or neurological conditions (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment **AND**
- Medical record documentation of no contraindications to Magnetic Resonance Imaging (MRI) (e.g. cardiac pacemaker/defibrillator or ferromagnetic metal implants) **AND**
- Medical record documentation of MRI obtained within one year prior to initiating treatment with Leqembi (lecanemab-irmb) **AND**
- Medical record documentation of positron emission tomography (PET) scan positive for brain amyloid plaques OR cerebrospinal fluid (CSF) biomarker testing positive for beta-amyloid plaques (as indicated by reduced amyloid beta 42 [A β 42] levels OR reduced amyloid beta 42 amyloid beta 40 ratio [A β 42/A β 40 ratio] in CSF OR elevated total tau amyloid beta 1-42 ratio [t-tau/A β 1-42]) **AND**
- Medical record documentation of at least two (2) of the following:
 - Mini-Mental State Examination (MMSE) score of greater than or equal to 22,
 - Montreal Cognitive Assessment (MoCA) score greater than or equal to 17,
 - Clinical Dementia Rating-Global Score (CDR-GS) of 0.5 or 1,

- Clinical Dementia Rating-Sum of Boxes (CDR-SB) score less than or equal to 9,
- Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) score less than or equal to 85, and/or
- Quick Dementia Rating System (QDRS) score less than or equal to 12 **AND**
- Medical record documentation that member does not have any exclusions to treatment with Leqembi (lecanemab-irmb), including all of the following:
 - A history of stroke, transient ischemic attack (TIA), or seizures in the past year **AND**
 - A bleeding disorder that is not under adequate control (e.g. a platelet count <50,000 or international normalized ratio [INR] >1.5) **AND**
 - A brain MRI at screening showing any of the following significant pathological findings:
 - More than 4 microhemorrhages (defined as 10 millimeter [mm] or less at the greatest diameter),
 - A single macrohemorrhage >10 mm at greatest diameter,
 - An area of superficial siderosis,
 - Evidence of vasogenic edema,
 - Evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions,
 - Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease,
 - Space occupying lesions, and
 - Brain tumors (excludes lesions diagnosed as meningiomas or arachnoid cysts and less than 1 cm at their greatest diameter) **AND**
- Medical record documentation of a dose that is consistent with FDA-approved package labeling.

GPI Level: GPI-12

Authorization Duration & Reauthorization Criteria: Approval will be given for an initial duration of **twelve (12) months** or less if the reviewing provider feels it is medically appropriate. After the initial twelve (12) month approval, subsequent approvals will be for a duration of **twelve (12) months** or less if the reviewing provider feels it is medically appropriate, and will require:

- Medical record documentation that member continues to experience medical benefit from and tolerability to Leqembi (lecanemab-irmb) based on the prescriber's assessment **AND**
- Medical record documentation of continued enrollment in a prospective comparative study and/or a registry that collects information regarding treatment with Leqembi, which can include, but is not limited to, the Alzheimer's Network for Treatment and Diagnostics (ALZ-NET) **AND**
- Medical record documentation Leqembi (lecanemab-irmb) is prescribed by or in consultation with a

- dementia specialist (e.g., neurologist, psychiatrist, geriatric psychiatrist, neuropsychiatrist, geriatrician, or gerontologist) **AND**
- Medical record documentation that the member was, and will continue to be, monitored and assessed by the prescribing dementia specialist at appropriate intervals **AND**
 - Medical record documentation of no medical or neurological conditions (other than Alzheimer's disease) that might be a significant contributing cause of the beneficiary's cognitive impairment **AND**
 - Medical record documentation of no contraindications to Magnetic Resonance Imaging (MRI) (e.g. cardiac pacemaker/defibrillator or ferromagnetic metal implants) **AND**
 - Medical record documentation of continuing treatment with Leqembi (lecanemab-irmb) based on recent MRI results as recommended in the FDA-approved package labeling (e.g. MRI to be obtained prior to the 5th, 7th, and 14th infusions) **AND**
 - Medical record documentation of repeat testing **AND** documented results of at least two of the following:
 - Mini-Mental State Examination (MMSE),
 - Montreal Cognitive Assessment (MoCA),
 - Clinical Dementia Rating-Global Score (CDR-GS),
 - Clinical Dementia Rating-Sum of Boxes (CDR-SB),
 - Repeatable Battery for the Assessment of Neuropsychological Status (RBANS), and/or
 - Quick Dementia Rating System (QDRS) **AND**
 - Medical record documentation that member does not have any exclusions to treatment with Leqembi (lecanemab-irmb), including all of the following:
 - A history of stroke, transient ischemic attack (TIA), or seizures in the past year **AND**
 - A bleeding disorder that is not under adequate control (e.g. a platelet count <50,000 or international normalized ration [INR] >1.5) **AND**
 - A brain MRI at screening showing any of the following significant pathological findings:
 - Evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infective lesions,
 - Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease,
 - Space occupying lesions, and
 - Brain tumors (excludes lesions diagnosed as meningiomas or arachnoid cysts and less than 1 cm at their greatest diameter); **AND**
 - Medical record documentation of a dose that is consistent with FDA-approved package labeling.

Outcome: There was one vote to reject, all other votes were in favor to accept the recommendation

Paxlovid

Recommendation: It is recommended that Paxlovid be added to the Brand tier for the GHP Family formularies. It will not require a prior authorization. The following QL will apply:

- Paxlovid 150/100 Therapy Pack: 20 tablets per fill
- Paxlovid 300/100 Therapy Packs: 30 tablets per fill

Outcome: The committee unanimously voted to accept the recommendation

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Paxlovid

Recommendation: It is recommended that the following be approved to be in line with DHS' recommendations:

MBP 209.0 Padcev (enfortumab vedotin-ejfv)

- Medical record documentation that member has received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy ~~in the neoadjuvant/adjuvant, locally advanced or metastatic setting~~ **OR**

MBP 119.0 Keytruda (pembrolizumab)

1. Microsatellite Instability-High Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors **OR** colorectal cancer **AND**
- For solid tumors:
 - Medical record documentation of progression following prior treatment(s) **AND**
 - Medical record documentation of no satisfactory alternative treatment options
- ~~• For colorectal cancer:
 - Medical record documentation Keytruda will be used as first-line treatment **OR**
 - Medical record documentation of progression following treatment with fluoropyrimidine, oxaliplatin, and irinotecan~~

MBP 290.0 Epkinly (epcoritamab-bysp)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Epkinly is written by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, **and high-grade B-cell lymphoma** **AND**
- Medical record documentation of prior therapy with at least two lines of systemic therapy

MBP 286.0 Hemgenix (etranacogene dezaparvovec-drlb)

- Prescription written by or in consultation with a hematologist **AND**
- Medical record documentation that the member is a male based on assigned sex at birth and age greater than or equal to 18 years **AND**

- Medical record documentation of a diagnosis of moderate or severe hemophilia B with Factor IX level < 2 IU/dL or ≤ 2% of normal **AND**
- Medical record documentation of one of the following:
 - Member has current use of Factor IX prophylaxis therapy for at least 2 months with > 150 exposure days^ of treatment with Factor IX protein **OR**
 - Member has current of historical life-threatening hemorrhage **OR**
 - Member has repeated, serious spontaneous bleeding episodes
- AND**
- Medical record documentation that the member has a recent negative inhibitor status to Factor IX prior to administration of Hemgenix **AND**
- Medical record documentation that the member does not have an active hepatitis B or hepatitis C infection* assessed within the last 6 months **AND**
- Medical record documentation that the member does not have uncontrolled HIV** assessed within the last 6 months **AND**
- Medical record documentation that the member does not have evidence of advanced cirrhosis*** assessed within the last 6 months **AND**
- Medical record documentation that the member has not received any previous gene therapy for hemophilia B **AND**
- Medical record documentation that Hemgenix is being dosed according to the Food and Drug Administration approved labeling**** **AND**
- Medical record documentation of the frequency of bleeds within the previous 12 months **AND**
- ~~Medical record documentation of therapeutic failure on Factor IX prophylaxis therapy~~

Outcome: The committee unanimously voted to accept the recommendation

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

DUR Update

Recommendation: The September 2023 P&T DUR/Adherence Update was submitted to the Committee for review.

Outcome: The committee unanimously voted to accept the recommendation

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

August ELECTRONIC VOTE

An electronic vote was held from August 15, 2023, to August 25, 2023. Responses were received from 26 members (out of 50 members) and all voted to approve. Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Hyqvia

Updated Indication: Hyqvia is now indicated for the treatment of Primary Immunodeficiency (PI) in adult and pediatric patients 2 years of age and older. Previously, it was only indicated for adults.

Outcome: There are no changes recommended to the formulary placement, authorization duration, or prior authorization criteria since the policy does not specify approved ages for any individual IVIG product.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Livmarli

Updated Indication: Livmarli is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 3 months of age and older. It was previously indicated in patients 1 year of age and older.

Outcome: There are no changes to formulary status, quantity limits, or authorization duration. It is recommended to update policy 1552.0F to remove age requirement.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

GHP Family Update

Discussion: During a recent review of policies by DHS it was requested that the noted changes noted below be made to be consistent with the drug's indication and/or be approved.

Recommendation: It is recommended the Committee approve the following changes:

Prior authorization of Kerendia will be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of chronic kidney disease associated with type 2 diabetes **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of serum potassium ≤ 5.0 mEq/L or ≤ 5.5 mEq/L if previously established on therapy **AND**
- Medical record documentation of persistent albuminuria (albumin to creatinine ratio consistently greater than 30 mg/g) despite treatment with both of the following:
 - Maximally tolerated angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) OR medical record documentation of contraindication or intolerance to one angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) **AND**
 - One sodium-glucose co-transporter 2 (SGLT-2) inhibitor with proven kidney or cardiovascular benefit OR medical record documentation of contraindication or intolerance to one sodium-glucose co-transporter 2 (SGLT-2) inhibitor with proven kidney or cardiovascular benefit

Prior authorization of Pyrukynd will be made for members who meet the following criteria:

- Medical record documentation of age 18 years or older **AND**
- Medical record documentation of diagnosis of pyruvate kinase deficiency (PKD) **AND**
- Medical record documentation of at least 2 mutant alleles in the PKLR gene, with at least 1 being a missense mutation **AND**
- Medical record documentation that the member is not homozygous for the R479H mutation **AND**
- Medical record documentation that Pyrukynd is being prescribed by or in consultation with a hematologist **AND**
- ~~Medical record documentation that the member required red blood cell (RBC) transfusions for hemolytic anemia due to PKD within the last 12 months **AND**~~

- Medical record documentation of hemoglobin level less than or equal to 10 g/dL **OR the member is receiving regular RBC transfusions AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Meeting adjourned at 5:02 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on November 21, 2023 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams