Geisinger

# P&T Committee Meeting Minutes
# Commercial/Marketplace/CHIP
# September 19th, 2023

| Present (via Teams): | Absent: |
|---|---|
| Bret Yarczower, MD, MBA – Chair | Jeremy Bennett, MD |
| Amir Antonius, Pharm.D. | Alyssa Cilia, RPh |
| Emily Antosh, Pharm.D. | Michael Evans, RPh |
| Kristen Bender, Pharm.D. | Nichole Hossler, MD |
| Kim Castelnovo, RPh | Jason Howay, Pharm.D. |
| Kimberly Clark, Pharm.D. | Perry Meadows, MD |
| Bhargavi Degapudi, MD | Jonas Pearson, RPh |
| Michael Dubartell, MD | William Seavey, Pharm.D. |
| Rajneel Farley, Pharm.D. | Robert Strony, MD MBA |
| Kelly Faust, Pharm.D. | Jeremy Garris, Pharm.D. (non-voting participant) |
| Tricia Heitzman, Pharm.D. | |
| Keith Hunsicker, Pharm.D. | |
| Kelli Hunsicker, Pharm.D. | |
| Derek Hunt, Pharm.D. | |
| Emily Jacobson, 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. | |
| Michael Shepherd, MD | |
| Leslie Shumlas, Pharm.D. | |
| Aubrielle Smith Pharm.D. | |
| Kirsten Smith, Pharm.D. | |
| Michael Spishock, RPh | |
| Todd Sponenberg, Pharm.D. | |
| Jill Stone, Pharm.D. | |
| Luke Sullivan, DO | |
| Kevin Szczecina, RPh | |

| | |
|---|---|
| Amanda Taylor, MD<br>Ariana Wendoloski, Pharm.D.<br>Brandon Whiteash, Pharm.D.<br>Margaret Whiteash, Pharm.D.<br>Morgan Casciole (pharmacy resident)<br>Daniele Francisko (pharmacy resident)<br>Hailey Knittle (pharmacy resident)<br>Kirsten Mascaritola (pharmacy resident)<br>Nichole Varela Gonzalez (pharmacy resident)<br>Birju Bhatt, MD (non-voting participant)<br>Alfred Denio, MD (non-voting participant)<br>Mahakdip Gill, Pharmacy Student<br>Yuliya Gonchar, Pharmacy Student | |

**Call to Order:**
Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, September 19th, 2023.

**Review and Approval of Minutes:**
Dr. Bret Yarczower asked for a motion or approval to accept the July 18th, 2023 and August 2023 e-vote 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. Wilson disease is an autosomal recessive genetic disorder that leads to impaired function of the intracellular copper transporter ATP7B. Reduced biliary excretion of copper results in its accumulation in the liver and other tissues (e.g. brain, cornea). 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. The primary chelator that is used is D-penicillamine. 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. 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.

Cuvrior is available as 300 mg of trientine tetrahydrochloride (equivalent to 150 mg of trientine). The recommended starting total daily dose of Cuvrior in patients is 300 mg up to 3,000 mg taken orally in divided doses (two times daily). The total daily dose should not exceed 3,000 mg. If on penicillamine, that should be discontinued before starting Cuvrior. The total daily dose of Cuvrior should be adjusted according to clinical assessment and laboratory monitoring of copper.

Cuvrior was studied in a randomized, active-controlled, multi-center, non-inferiority in 53 adult patients with Wilson's disease. All patients had been receiving penicillamine for at least 1 year prior to study entry, were adequately controlled and tolerating penicillamine. At the start of the study, patients entered a 12-week baseline period and continued to receive their established total daily dosage of penicillamine. At Week 12, patients were randomized to either remain on penicillamine (N=27) or switch to Cuvrior (N=26) for the 24-week post-randomization period. The primary efficacy endpoint was the mean serum NCC level at Week 36. Prior to initiation of randomized treatment, the mean NCC levels in the penicillamine and Cuvrior arms were 77 mcg/L (66; 88) and 66 mcg/L (55; 76), respectively. At Week 36, the mean NCC levels in the penicillamine and Cuvrior arms were 46 mcg/L (35; 58) and 56 mcg/L (44; 67), respectively. The mean 24-hour urinary copper excretion (UCE) at Week 36 was lower in patients receiving Cuvrior as compared to patients receiving penicillamine. All patients in both treatment arms were considered clinically stable as determined by an adjudication committee at Week 36.

Cuvrior is contraindicated in patients with a hypersensitivity to trientine or to any of the excipients. Worsening of clinical symptoms, including neurological deterioration, may occur at the beginning of Cuvrior therapy due to mobilization of excess stores of copper. Copper deficiency and iron deficiency may develop following treatment with Cuvrior. The most common adverse reactions (≥ 5%) are abdominal pain, change of bowel habits, rash, alopecia, and mood swings. The safety and effectiveness of Cuvrior in pediatric patients have not been established.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** Aubrielle confirmed that members must be tolerant of penicillamine prior to approval. No additional comments or questions. The committee voted by majority to accept the recommendations as presented.

**Financial Discussion:** No comments or questions. The committee voted by majority to accept the recommendations as presented.

**Outcome:** Cuvrior will be a pharmacy benefit that will not be added to the 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

**QUANTITY LIMIT:** 10 tablets per day

**GPI LEVEL:** GPI-12

**RPH SIGNOFF REQUIRED:** Yes

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

Penicillamine tablets: Penicillamine tablets will remain at the Generic tier of the pharmacy formulary and will require a prior authorization.

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to penicillamine capsules

Trientine capsules: It is recommended to add to the Generic tier of the pharmacy formulary. It is recommended to remove the prior authorization.

**Discussion:** No comments or questions. The committee voted by majority to accept the recommendations as presented.

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.

There are fewer than 250 people diagnosed with APDS as of 2020, with a median diagnostic delay of 7 years. APDS is a primary immunodeficiency (PID), which is a group of more than 400 genetic disorders that are characterized by gene mutations that cause proteins to be missing or dysfunctional, leading to improper immune system function. Diagnosis of APDS can be made definitively by gene sequencing PIK3CD and/or PIK3R1. Patients may be misdiagnosed with other autoimmune disorders before suspecting a PID. Other PIDs, such as common variable immune deficiency (CVID), hyper IgM syndrome (HIGM), or autoimmune lymphoproliferative syndrome (ALPS), may also be misdiagnosed before correctly diagnosing APDS in patients.

Joenja is the first FDA-approved treatment for APDS. Joenja is a small-molecule inhibitor of the hyperactive p110δ subunit of PI3K. Joenja inhibits signaling pathways that downstream cause hyperactivity of the mTOR/AKT pathway and cause dysregulation of B and T cells. Joenja targets the root cause of APDS, unlike prior treatment options that were only supportive treatments. The supportive therapies that are used in APDS for symptom management include long-term antibiotic prophylaxis and immunoglobulin replacement therapy. Rituximab and rapamycin have been used to reduce lymphoproliferation and in very severe cases a hematopoietic stem cell transplant (HSCT) may be curative for some patients. However, HSCT have serious risks and potential for complications and are not effective in all patients with APDS and are therefore uncommon with an estimated fewer than 10% of APDS patients having received a HSCT.

Joenja is supplied as a 70 mg oral tablet. The recommended dosage is 70 mg orally twice daily, approximately 12 hours apart, with or without food. Joenja is approved in adult and pediatric patients 12 years of age and older weighing greater than or equal to 45 kg. Pregnancy status should be verified in females prior to starting treatment.

Joenja was evaluated in a triple-blind, randomized, placebo-controlled phase 3 clinical trial. Patients included 31 adult and pediatric patients 12 years of age and older with confirmed APDS-associated genetic PI3Kδ mutation, with a documented variant in either PIK3CD or PIK3R1. During the 12-week study period patients were randomized 2:1 to be treated with either Joenja 70 mg (N=21) or placebo (N=10) every 12 hours. Patients included needed to have nodal and/or extranodal lymphoproliferation, clinical findings and manifestations compatible with APDS/PASLI such as a history of repeated oto-sino-pulmonary infections and/or organ dysfunction (e.g. lung, liver), and at least 1 or more measurable nodal lesion on CT or MRI scan. Patients were excluded if they were previously treated with or concurrently using immunosuppressive medications. They were also excluded for current use of strong inhibitors of CYP3A, moderate or strong inducers of CYP3A, or medications metabolized by CYP1A2 with a narrow therapeutic index. Live vaccines were unable to be administered starting 6 weeks before study, during the study, and up to 7 days after the last dose of Joenja.

The co-primary efficacy endpoints were improvement in lymphoproliferation (measured by difference in index lymph node size from baseline shown by MRI or CT-scan) and normalization of immunophenotype (measured by percentage of naïve B cells in peripheral blood shown by flow cytometry). The difference in adjusted mean change (95% CI) between Joenja and placebo for lymph node size was -0.25 (−0.38, −0.12; P = 0.006; N = 26) and for percentage of naïve B cells was 37.30 (24.06, 50.54; P = 0.0002; N = 13). Both primary endpoints were met and Joenja showed significant reduction in lymphadenopathy.

The most common adverse reactions (>10%) to Joenja were headache, sinusitis, and atopic dermatitis. Joenja may cause fetal harm; the potential risk to a fetus should be advised to patients and education on using effective contraception. Pregnancy status should be verified before initiating treatment. Women should be advised not to breastfeed during treatment and for 1 week after the last dose due to potential for serious adverse reactions in the child. Joenja may reduce effectiveness of live, attenuated vaccines if administered during treatment. The safety and efficacy of Joenja has not been established in pediatric patients below the age of 12 years. Joenja was not studied in any patients 65 years of age or older so it is unknown if they would respond differently. Joenja is extensively metabolized by the liver and should be avoided in patients with moderate to severe hepatic impairment.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.
**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Joenja is a pharmacy benefit and will be added to the Commercial, Marketplace, and GHP Kids pharmacy formularies at the Specialty tier or Brand Non-Preferred tier for members with a three-tier benefit. The following prior authorization criteria will 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

**AUTHORIZATION DURATION:** Initial approval will be for 6 months. 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.

**QUANTITY LIMIT:** 2 tablets per day

**RPH SIGNOFF REQUIRED:** Yes

**GPI LEVEL:** GPI-12

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

---

**LIQREV (sildenafil)**

**Review:** Liqrev is a phosphodiesterase-5 (PDE-5) inhibitor indicated for the treatment of pulmonary arterial hypertension in adults to improve exercise ability and delay clinical worsening. It is provided in a 122 mL bottle in suspension with the strength being 10mg/mL, so it does not need to be reconstituted. The dosing is 20 mg by mouth three times a day. Liqrev is contraindicated in patients with known hypersensitivity to sildenafil, concomitant use of organic nitrates either regularly or intermittently, and concomitant use of Adempas (riociguat) which is a guanylate cyclase stimulator. Of note, pediatric use information is approved for Viatris Specialty LLC's, REVATIO (sildenafil) tablets. However, because of exclusivity rights, Liqrev is not labeled with those rights.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Liqrev is a pharmacy benefit and will be added to Commercial, Marketplace, or GHP Kids formulary. It will be added to Commercial Policy 167.0 Sildenafil (generic Revatio). It will be added to the brand non-preferred tier and the following prior authorization criteria will apply:

- Medical record documentation that sildenafil is prescribed by a cardiologist or pulmonologist **AND**

- Medical record documentation of a diagnosis of functional class 2, 3, or 4 pulmonary arterial hypertension **AND**
- See no medical record documentation of organic nitrate therapy **AND**
- If for sildenafil 10 mg/mL (generic REVATIO) requests, medical record documentation of a therapeutic failure on, intolerance, or contraindication to Liqrev 10 mg/mL

**RPH SIGNOFF REQUIRED:** No

**GPI LEVEL:** GPI-12

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

---

**COLUMVI (glotitamab-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.

Columvi is administered as an intravenous infusion through a dedicated infusion line that includes a sterile 0.2-micron in-line filter. Columvi is administered by a healthcare professional with immediate access to appropriate medical support, including supportive medications to manage severe CRS. Patients will receive premedications prior to each dose which can include dexamethasone, acetaminophen, and antihistamines. On Cycle 1 Day 1, all patients should be pretreated with a single 1,000 mg dose of Obinutuzumab to deplete circulating and lymphoid tissue B cells. Columvi begins with step up dosing and continues for a maximum of 12 cycles or until disease progression or unacceptable toxicity, whichever comes first.

The efficacy of Columvi was evaluated in the NP30179 trial, an open label, multicohort, single arm clinical trial in patients with relapsed or refractory LBCL after two or more lines of systemic therapy. Patients included in the trial were required to have absolute neutrophil count ≥ 1,500/µL, platelet count ≥ 75,000/µL independent of transfusion, serum creatinine ≤ 1.5 x ULN or CLcr ≥ 50 mL/min, and hepatic transaminases ≤ 3 x ULN. The trial excluded patients with active or previous CNS lymphoma or CNS disease, acute infection, recent infection requiring intravenous antibiotics, or prior allogeneic HSCT. Patients received pretreatment with Obinutuzumab on Cycle 1 Day 1 and then received Columvi by intravenous infusion according to the recommended dosage.

The efficacy population includes 132 patients with de novo DLBCL, NOS (80%) or LBCL arising from follicular lymphoma (20%) who had received at least one dose of Columvi. The median number of prior lines of systemic therapy was 3 (range: 2-7). Most patients (83%) had refractory disease to last therapy, 55% had primary refractory disease, 30% had received CAR-T cell therapy, and 19% had received autologous HSCT. Efficacy was based on objective response rate (ORR) and duration of response (DOR), as determined by Independent Review Committee (IRC) using the 2014 Lugano criteria. The median time to first response was 42 days. Among responders the median follow-up for DOR was 11.6 months.

Columvi includes a black box warning for the risk of Cytokine Release Syndrome (CRS), including serious and fatal reactions. Warnings and precautions for Columvi include Cytokine Release Syndrome, neurologic toxicity, serious infection, tumor flare, and embryo fetal toxicity.

Serious adverse reactions occurred in 48% of patients and included CRS, COVID-19 infection, sepsis, and tumor flare. Fatal adverse reactions occurred in 5% of patients from COVID-19 infection, sepsis, and delirium. Adverse reactions led to permanent discontinuation of Columvi in 7% of patients, including from infection, delirium, neutropenia, and CRS. Adverse reactions led to dose interruptions of Columvi in 19%

of patients, most frequently from neutropenia and thrombocytopenia. The most common adverse reactions were CRS, musculoskeletal pain, rash, and fatigue. The most common laboratory abnormalities are decreased lymphocyte count, phosphate, neutrophil count, and fibrinogen, and increased uric acid. The safety and efficacy of Columvi in pediatric patients have not been established. Of the 145 patients with relapsed or refractory LBCL in Study NP30179, 55% were 65 years of age and older and 23% were 75 years of age or older. There was a higher rate of fatal adverse reactions, primarily from COVID-19, in patients 65 years of age and older compared to younger patients. No overall differences in efficacy were observed between older and younger patients.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**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 at this point in time. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Columvi is a medical benefit drug and will be added to the medical benefit cost share list. When processed at a Specialty Pharmacy, Columvi will process on the Specialty tier or Brand NP tier for members with a three-tier benefit. 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

**RPH SIGNOFF REQUIRED:** Yes

**QUANTITY LIMIT:** 30 mL per 21 days

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.

Narcolepsy affects approximately 1 in 2000 people in the United States. Patients with narcolepsy have excessive daytime sleepiness (EDS), which affects the brain's regulation of the sleep-wake cycle. Some patients with narcolepsy may also have cataplexy (sudden loss of muscle tone and weakness), hallucinations, and sleep paralysis. Current FDA-approved treatment and guidelines for narcolepsy without cataplexy in adults include modafinil, Sunosi, and immediate release amphetamine/dextroamphetamine. For narcolepsy with or without cataplexy in adults, treatment includes Xyrem, Xywav, and Wakix. Xywav has a lower sodium content compared to Xyrem and may be a better therapeutic option for patients with hypertension cardiovascular disease, and kidney disease. The guidelines from American Academy of Sleep Medicine (AASM) 2021 noted that selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs), such as venlafaxine and fluoxetine (which are commonly used off-label for narcolepsy treatment), have insufficient and inconclusive evidence to support recommendations for use.

Efficacy of Lumryz was evaluated in the phase 3 REST-ON study. The REST-ON study was a double-blind, randomized, placebo-controlled, two-arm multicenter study with 212 participants aged 16 to 72 years. All patients were diagnosed with narcolepsy with or without cataplexy. The study lasted 13 weeks with up-titration over a period of eight weeks, stable dosing of 9 grams per night over a period of five weeks, and a follow up period of one week. Three co-primary endpoints were met.

Safety of Lumryz was evaluated in the REST-ON trial. Adverse reactions experienced in 2% or more of Lumryz treated patients were nausea, headache, vomiting, dizziness, enuresis, decreased appetite, anxiety, hyperhidrosis, and decreased weight. Of the patients treated with Lumryz, 15.9% discontinued the trial due to adverse reactions compared to 1.9% of placebo patients.

Like Xyrem, Lumryz has a high sodium content and patients with heart failure, hypertension, or impaired renal function should be monitored. Warnings for usage of Lumryz include respiratory depression and sleep-disordered breathing, depression, suicidal ideation and behavior, parasomnias, and other behavioral and psychiatric adverse reactions. Lumryz is a Schedule III controlled substance and has a black box warning for CNS depression and abuse and misuse. It is contraindicated in combination with alcohol or sedative hypnotics and in patients with succinic semialdehyde dehydrogenase deficiency. Lumryz has restricted access through the Lumryz REMS program and may only be dispensed by certified specialty pharmacies.

Safety and efficacy of Lumryz in pregnant or pediatric patients have not been established. There were an insufficient number of patients aged 65 years and older in the clinical study to establish if geriatric patients respond differently than younger patients. It is recommended that geriatric patients start at a lower dose and be monitored due to the greater chance of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Lumryz should not be started in patients with hepatic impairment because appropriate dosage adjustment strengths are not available. If a patient is on a stable dose of another oxybate product, the patient can be switched to Lumryz if the appropriate dosage strength is available. There have not been any direct studies performed between Lumryz and other FDA-approved treatments for narcolepsy.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Lumryz is a pharmacy benefit and will be added to the Commercial, Exchange, and CHIP formularies at the Specialty and Brand NP tier. The following prior authorization criteria will apply:

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to modafinil, methylphenidate immediate release **OR** amphetamine/dextroamphetamine immediate release

**AUTHORIZATION DURATION:** 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

**GPI LEVEL:** GPI-12

**QUANTITY LIMIT:** 9 grams per day, 30-day supply per fill

**RPH SIGNOFF REQUIRED:** No

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 cause 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.

There is a current, ongoing mpox outbreak in the United States. Treatment should be considered in patients with mpox who have severe disease or involvement of anatomic areas which might result in serious sequelae that include scarring or strictures. Currently there is no treatment approved specifically for mpox virus infections. Brincidofovir is made available from the Strategic National Stockpile (SNS) for treatment of mpox to clinicians who request and obtain an FDA-authorized single-patient emergency use IND (e-IND). Brincidofovir can be considered for use under an e-IND for treatment of human mpox disease in adults and pediatric patients (including neonates) with positive results of human mpox viral testing and meeting certain criteria.

Tembexa is not indicated for the treatment of disease other than human smallpox disease. The effectiveness of Tembexa for the treatment of smallpox disease has not been determined in humans because adequate and well-controlled field trials have not been feasible and inducing smallpox disease in humans to study the drug's efficacy is not ethical. Tembexa efficacy may be reduced in immunocompromised patients based on studies in immune deficient animals. Tembexa will not be available for commercial sale. The manufacturer, Chimerix, will work with governments and public health agencies globally to make Tembexa available in case of smallpox outbreak.

Tembexa is available as 100 mg oral tablets and 10 mg/mL oral suspension. For patients 48 kg and above, the recommended dose is 200 mg once weekly for 2 doses (days 1 and 8). Patients 10 kg to less than 48 kg should receive 4 mg/kg once weekly for 2 doses (days 1 and 8). Patients less than 10 kg should receive 6 mg/kg one weekly for 2 doses (days 1 and 8). Prior to initiating Tembexa, perform hepatic laboratory testing and pregnancy testing as clinically appropriate to inform risk.

The effectiveness of Tembexa for treatment of smallpox disease was established based on results of adequate and well-controlled animal efficacy studies of rabbits and mice infected with species specific non-variola orthopoxviruses. Survival rates observed in the animal studies may not be predictive of survival rates in clinical practice. Efficacy studies were conducted in the rabbitpox model (New Zealand White rabbits infected with rabbitpox virus) and the mousepox model (BALB/c mice infected with ectromelia virus). The primary efficacy endpoint for these studies was survival. Survival was monitored for 4 to 5 times the mean time to death for untreated animals in each model. In the rabbitpox study, rabbits were lethally challenged intradermally with 600 plaque-forming units of rabbitpox virus; brincidofovir was administered orally with a regimen of 20/5/5 mg/kg (administered every 48 hours for 3 doses) with brincidofovir treatment initiated on 3, 4, 5, or 6 days post-challenge. The timing of brincidofovir dosing was intended to assess efficacy when treatment is initiated after animals have developed clinical signs of disease, specifically fever in rabbits. Clinical signs of disease were evident in some animals at Day 3 post-challenge but were evident in all animals by Day 4 post-challenge. In the mousepox study, mice were lethally challenged intranasally with 200 plaque-forming units of ectromelia virus; brincidofovir was administered orally with a regimen of 20/5/5 mg/kg or 10/5/5 mg/kg (administered every 48 hours for 3 doses) with brincidofovir treatment initiated on 4, 5, 6, or 7 days post-challenge. All animals had detectable viremia by 4 days post-challenge. In the mousepox model, a clinically evident sign of disease could not be identified to use as a trigger to initiate treatment. Treatment with brincidofovir resulted in statistically significant improvement in survival relative to placebo, except when the 10/5/5 mg/kg regimen was initiated at Day 6 post-challenge in the mousepox study.

Tembexa has warning and precautions for increased risk for mortality when used for longer duration, elevations in hepatic transaminases and bilirubin, diarrhea and other gastrointestinal adverse events, coadministration with related products (cidofovir), embryo-fetal toxicity, carcinogenicity, and male infertility. The most common adverse reactions (occurring in at least 2% of Tembexa-treated subjects) were diarrhea, nausea, vomiting, and abdominal pain.

As in adults, the effectiveness of Tembexa in smallpox infected pediatric patients, including neonates, is based solely on efficacy studies in animal models of orthopoxvirus disease. The recommended pediatric dosing regimen is expected to produce brincidofovir exposures that are comparable to those in adults

based on a population pharmacokinetic modeling and simulation approach. Of the 392 subjects in the controlled clinical studies, 21% were ≥65 years of age and 1% were ≥75 years of age. The nature and severity of adverse events was comparable between subjects older and younger than 65 years. No alteration of dosing is recommended for patients ≥ 65 years of age.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** Dr. Yarczower asked Leslie to confirm that no prior authorization would be required. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Tembexa will be non-formulary for Commercial, Exchange and CHIP as it will not be commercially available. If Tembexa becomes commercially available, it will added to the Brand Non-Preferred Tier with no prior authorization required.

**GPI LEVEL:** GPI-10

**QUANTITY LIMIT:**

- 100 mg Oral Tablets: 4 tablets per 365 days.
- 10 mg/mL Oral Suspension: 65 mL per 365 days.

**RPH SIGNOFF REQUIRED:** No

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

---

**LITFULO (ritlecitinib)**

**Review:** Alopecia areata (AA) is an autoimmune disease typically characterized by nonscarring hair loss. The common presentation of AA is one or more coin-shaped or ovoid patches of alopecia which could be accompanied by total scalp or body hair loss. Patients can also develop more severe cases being alopecia totalis (AT), which is when all hair is lost on the scalp, or alopecia univeralis (AU), this is the case where all hair is lost on the scalp as well as the body. Patients typically do not have other symptoms but can experience burning, itching, and or inflammation in the affected area(s). Limited AA (hair loss of <20% of the scalp surface area) can be seen to be unpredictable in terms of remission and relapse of disease whereas moderate to severe AA can be seen to be as more chronic course with little to no periods of remission.1

AA is thought to be a genetic disease that is not directly caused by stress but can often time be a trigger for disease flare ups or relapses. Other than stress reduction and allowing time for the body to resolve AA naturally there are very limited therapies that can treat or prevent AA in terms of non-pharmacological methods. Some examples of non-pharmacological treatment that have been tried but not proven are photochemotherapy with psoralen plus ultraviolet A (PUVA) or intralesional injections of autologous platelet-rich plasma, however evidence is limited.

In June 2022 the drug Olumiant was approved by the FDA which is an oral JAK ½ inhibitor for the treatment of adults with severe AA. This was the first FDA-approved treatment as there was none before this time. Topical, intralesional, and systemic immunomodulator agents are often used in off-label indication to promote hair growth.

Topical and intralesional treatments can be used in patients with limited hair loss (<25%) intralesional corticosteroid injections are the preferred first-line treatment, however for those with larger patches of hair loss and for patients that can not tolerate injections topical corticosteroids can be an alternative first line treatment option.

Patients with extensive hair loss can also utilize topical immunotherapy such as diphenylcyclopropenone (DPCP) or squaric acid dibutyl ester (SADBE) which is first line for extensive hair loss. These topical agents trigger an immune reaction to promote hair growth but typically takes about 3 months for effects to be seen. These agents are not commercially available and must be purchased through a chemical distributor to be compounded into a solution of the appropriate strength which is typically 2%.

Systemic treatments are used for patients that cannot use the topical and intralesional treatments. Currently only Olumiant and Litfulo are the only FDA approved systemic treatments for AA. There are off label treatments that can be used such as oral immunomodulators (methotrexate, azathioprine) and oral corticosteroids can also be used for short periods of time to regain quick control of the disease. These off-label medications will most likely still be seen to play a role in AA management due to the high cost and variable payer coverage for Olumiant and Litfulo despite the limited efficacy and side effect possibilities.1

Prescribers and experts will often time use the Severity of Alopecia Tool (SALT) as a standardized tool to be able to put a number to the amount of hair loss in a patient, this is the tool used in clinical trials and practice. SALT scores range from 0 (no scalp hair loss) to 100 (total scalp hair loss), a decrease in SALT score reflects hair regrowth. An example of this is a SALT score of 80 equals 20% scalp hair coverage. SALT scores also indicate the severity of disease following the following ranges: no hair loss = 0, limited hair loss = 1-20, moderate hair loss = 21-49, severe = 50-94, and very severe = 94-100.1

Litfulo is a kinase inhibitor. Litfulo irreversibly inhibits Janus kinase 3 (JAK3) and the tyrosine kinase expressed in hepatocellular carcinoma (TEC) kinase family by blocking the adenosine triphosphate (ATP) binding site. In cellular settings, Litfulo inhibits cytokine induced STAT phosphorylation mediated by JAK3-dependent receptors. Additionally, Litfulo inhibits signaling of immune receptors dependent on TEC kinase family members. The relevance of inhibition of specific JAK or TEC family enzymes to therapeutic effectiveness is not currently known.

The recommended dosage of Litfulo is 50 mg orally once daily with or without food.2

The most common adverse reactions seen taking Litfulo include headache, diarrhea, acne, rash, urticaria, folliculitis, pyrexia, atopic dermatitis, dizziness, blood creatine phosphokinase increased, herpes zoster, red blood cell count decreased, stomatitis.2

Litfulo is a JAK inhibitor, which contains the same boxed warnings as other JAK inhibitors including risks for serious infections, mortality, malignancy, major cardiovascular events, and thrombosis. Litfulo must not be taken with other drugs of the same class (JAK inhibitors). Live vaccinations should also be avoided during or shortly prior to initiation of Litfulo treatment. There are currently no dose adjustments required for patients >65 years of age. Patients with a Child Pugh C score which indicate severe hepatic impairment is not recommended to take Litfulo however mild to moderate impairment has no dose adjustment required (Child Pugh B, C).2

Prior to initiating Litfulo absolute lymphocyte count (ALC) and platelet counts must be performed due to Litfulo being associated with increased incidence of liver enzyme elevations and creatine phosphokinase elevations.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Coverage of Litfulo for the treatment of alopecia areata is not a covered service under the pharmacy benefit. Litfulo 50 mg capsules will be excluded under the pharmacy benefit.

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.

VMS, or hot flashes, are believed to be caused by changes in estrogen levels and increased neurokinin B (NKB) activity in the hypothalamus, the region of the brain responsible for thermoregulation. Kisspeptin, neurokinin B and dynorphin A (KNDy) neurons contribute to body temperature control in the thermoregulatory center. KNDy neurons are inhibited by estrogen and stimulated by NKB at the neurokinin 3 (NK3) receptor. Estrogen decline during menopause leads to uninhibited NKB-mediated stimulation of KNDy neurons, leading to dysregulation of the thermoregulatory center. VMS and/or night sweats, are the most common symptoms reported with menopause, occurring in 75%–80% of menopausal women.

Hot flashes typically begin as a sudden sensation of heat centered on the upper chest and face, which spreads throughout the body and often lasts 2 to 4 minutes. Hot flashes are often accompanied by profuse sweating, and are sometimes followed by chills, shivers, and anxiety. When symptoms occur at night, they can disrupt sleep. The frequency of VMS episodes can range from one per day to one per hour. The intensity of VMS can be classified as mild (sensation of heat without sweating), moderate (sensation of heat with sweating), or severe (sensation of heat with sweating, causing cessation of activity). VMS can vary in duration, with a median total VMS duration of approximately 7.4 years. However, intensity and duration of VMS can differ by ethnicity and race, with African American women experiencing longer and more intense symptoms. VMS can have a significant impact on quality of life, including sleep, mood, and productivity.

The 2023 hormone therapy position statement of The North American Menopause Society list treatment of choice for menopausal symptoms, including VMS, as menopausal hormonal therapy (MHT). MHT is appropriate for women who are less than 60 years old, less than 10 years from the onset of menopause and those that do not have a history of cardiovascular disease or hormone dependent cancers. In addition to MHT, non-hormonal treatment therapy for VMS includes SSRis/SNRis such as paroxetine or venlafaxine. According to the therapy position statement, Veozah (fezolinetant), can be considered an effective treatment for VMS symptoms as well.

The effectiveness of Veozah (fezolinetant) was determined in the Bright Sky Clinical Trial Program, which evaluated the efficacy of Veozah (fezolinetant) across two studies, Skylight 1 NCT04003155 (SKYLIGHT 1/Trial 1) and Skylight 2 NCT04003142 (SKYLIGHT 2/Trial 2). Skylight trial 1 and 2 were conducted as a 12-week, randomized, double-blind placebo-controlled trials followed by a 40-week extension period to evaluate safety. There were three arms in each trial, placebo, Veozah (fezolinetant) 30 mg and Veozah (fezolinetant) 45 mg in which participants were randomized in a 1:1:1 ratio. The primary endpoints of Skylight 1 and 2 measured the frequency and severity of vasomotor symptoms at 4 weeks and 12 weeks compared to baseline at week 0. The primary endpoint results for Veozah (fezolinetant) 45mg concluded a statistically significant change from baseline in frequency of hot flashes, in which participants experienced a 48% and 53% reduction from baseline in frequency of VMS at 4 weeks across both trials

and a 61% and 63% reduction at 12 weeks. Compared to placebo, there was a 31% reduction in frequency from baseline at 4 weeks in both trials. There was a 37% and 42% reduction in frequency at 12 weeks in the placebo arm across both trials. Feozah (fezolinetant) 30 mg results were not submitted to the FDA for approval, as the results were statistically significant but not significant when compared to the results of Veozah (fezolinetant) 45 mg tablet. In terms of reduction in severity, Feozah (Fezolinetant) 45 mg arm demonstrated across both trials a 20 % and 25% reduction of severity compared to baseline at weeks 4 and 12 respectively. In comparison to placebo, the severity endpoint was 12% and 16% at weeks 4 and 12. Another study included in the Bright Sky program included clinical trial Skylight 4 which was conducted as an endometrial safety requirement by the FDA for any treatment used to alleviate menopause symptoms. This trial was conducted over 52 weeks and showed the incidence of endometrial hyperplasia or endometrial malignancy in fezolinetant-treated participants the results were within pre-specified limits, according to FDA guidance.

Common adverse effects for this medication include abdominal pain, diarrhea, insomnia, back pain, hot flush, and hepatic transaminase elevation. Prior to starting therapy, baseline liver function test should be conducted. Veozah (fezolinetant) should not be started in patients with elevated bilirubin or those whose AST and ALT are 2x the ULN. Monitoring should include liver function test at baseline and at 3, 6 and 9 months after starting Veozah (fezolinetant) or when symptoms suggest liver injury (I.e., yellowing of the skin, nausea and vomiting.) Veozah (fezolinetant) is contraindicated in patients with liver cirrhosis, end stage renal disease and concomitant use of CYP1A2 inhibitors.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**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. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Veozah (fezolinetant) is a pharmacy benefit and will not to be added to the Commercial/Exchange/CHIP 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

**GPI LEVEL:** GPI-12

**QUANTITY LIMIT:** 1 tablet per day

**RPH SIGNOFF REQUIRED:** No

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. Furosix 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.

The approval of Furoscix was supported by results of a phase 2/3 crossover pharmacokinetic/ pharmacodynamic (PK/PD) study, which compared the PK and bioavailability of Furoscix with the same dose of furosemide administered IV in patients with chronic HF, to establish IV equivalency. Results showed a bioavailability of 99.6% compared to 80 mg of IV furosemide. The most common adverse reactions were injection site bruising, discomfort, and dizziness.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**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. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Furoscix is a pharmacy benefit and will not be added to the Commercial, Marketplace, and GHP Kids formularies. The following prior authorization criteria will be required.

- 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

**AUTHORIZATION DURATION:** 1 month

**GPI LEVEL:** GPI-14

**RPH SIGNOFF REQUIRED:** Yes

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 in 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.

Vowst is an oral medication taken 2 to 4 days after the completion of antibacterial treatment for CDI. Prior to the first dose patients are to administer bowel prep consisting of drinking 296 mL (10 oz) of magnesium citrate on the day before and at least 8 hours prior to taking the first dose. Although, not approved for this indication, patients with impaired kidney function received polyethylene glycol electrolyte solution (250 mL GoLYTELY) a bowel prep in clinical studies. Patients taking Vowst should also refrain from eating or drinking, except for a small amount of water, for at least 8 hours prior to taking the first dose. Vowst is dosed as 4 capsules taken orally daily for 3 consecutive days. Each dose is to be taken on an empty stomach prior to the first meal of the day.

Vowst met the prespecified success criterion of the upper bound of the two-sided 95% CI of the CDI relative risk lower than 0.83, indicating superiority to placebo. Statistically significant benefit was maintained through 24 weeks of follow-up.

In Vowst treated patients, there were lower rates or recurrence in all stratified subpopulations evaluated. Those included participants 65 years of age and older and those less than 65 years old as well as those initially treated with vancomycin or fidaxomicin.

There are no contraindications are listed on the product label for Vowst. Vowst is manufactured from human fecal matter, it may carry a risk of transmitting infectious agents. If an infection is suspected by a healthcare provider possibly to have been transmitted by this product, the occurrence should be reported by the provider to the manufacturer. Vowst may contain food allergens. The potential for adverse reactions related to food allergen is unknown.

The most common adverse reactions (reported in ≥5% of participants) were abdominal distension (31.1%), fatigue (22.2%), constipation (14.4%), chills (11.1%), and diarrhea (10.0%). Vowst contains bacterial spore; therefore, antibacterials should not be administered concurrently.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**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. No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Vowst is a pharmacy benefit that will be added to the Commercial/Exchange/CHIP formularies at the Specialty tier or the Brand Non-Preferred for members with a three-tier benefit. 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

**QUANTITY LIMIT:** 12 capsules per 30 days

**AUTHORIZATION DURATION: A**uthorization shall be for the authorization of 1 treatment course of Vowst with an authorization duration of 30 days.

**GPI LEVEL:** GPI-12

**RPH SIGNOFF REQUIRED:** Yes

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

---

**INPEFA (sotagliflozin)**

**Review:** Inpefa is indicated for reducing the risk of cardiovascular (CV) death, hospitalization for heart failure (HF), and urgent heart failure (HF) visits in adults with HF or type 2 diabetes mellitus (T2DM), chronic kidney disease (CKD), and other CV risk factors. Inpefa is the first oral medication of dual inhibitor of proteins sodium glucose cotransporter types 1 and 2 (SGLT1 and SGLT2). The FDA labeling includes all left ventricular HF and patients with or without diabetes mellitus. Inpefa is available as an oral once daily tablet. The initial dose is 200 mg daily and can be titrated to 400 mg daily.

Inpefa has two phase 3 randomized, double-blinded, placebo-controlled trials, SOLOIST and SCORED. In the SOLOIST trial, when compared to placebo, Inpefa showed a significant 33% reduction in the rate of deaths from CV causes and hospitalizations and urgent visits for HF during a median 9 month of follow-up. Most common adverse events that occurred were hypotension, urinary tract infections, and diarrhea. The SCORED trial compared Inpefa with placebo in patients with T2DM with a glycated hemoglobin level of 7% or higher, CKD, and additional CV risks. The goal of the trial was to assess the safety and efficacy of Inpefa in reducing CV events. The trial was stopped early as a result of loss of funding due to COVID-19 Pandemic and the primary endpoint was changed to composite endpoint of total CV deaths, hospitalizations of HF, and urgent HF visits. Inpefa was superior ($p < 0.001$) to placebo in reducing the risk of the primary composite endpoint. SGLT2 inhibitors approved for heart failure are Farxiga and Jardiance. Current 2022 AHA/ACC/HFSA guidelines and for treating patients with heart failure and the 2023 ACC expert consensus statement do not recommend one SGLT2 inhibitor over the other.

Inpefa is contraindicated in patients with hypersensitivity reaction to Inpefa. Warnings and safety precautions include diabetic ketoacidosis in patients with type one diabetes mellitus and other ketoacidosis, volume depletion, urosepsis and pyelonephritis, hypoglycemia with concomitant use of insulin, Fournier's Gangrene, and genital mycotic infections. Due to the medication working in the kidneys the most reported side effects are urinary tract infections, volume depletion, diarrhea, and hypoglycemia.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** Confirmed with rebate vendor that we do receive rebates on Farxiga and Jardiance. This is in line with the rebate recommendations. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Inpefa will be a pharmacy benefit and will not be added to the Commercial/Exchange/CHIP formularies. Inpefa will require a prior authorization with the following criteria:

- Medical record documentation of one of the following:
    - Medical record documentation of a diagnosis of heart failure **OR**
    - Medical record documentation of a diagnosis of type 2 diabetes mellitus (T2DM), chronic kidney disease (CKD), or other cardiovascular (CV) risk factors **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Jardiance **AND** Farxiga

**QUANTITY LIMIT:** 1 tablet per day

**GPI LEVEL:** GPI-12

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.

Ticovac is prepared from TBE virus propagated in chick embryo fibroblast cells. The harvested virus suspension is inactivated by treatment with formaldehyde, purified by sucrose gradient centrifugation and adsorbed onto aluminum hydroxide. Following administration, Ticovac induces TBEV-neutralizing antibodies, which are believed to provide protection. A protective antibody level has not been defined.

The United States Advisory Committee on Immunization Practices (ACIP) approved recommendations for use of Ticovac for people who are moving or traveling to a TBE-endemic area and will have extensive exposure to ticks based on their planned outdoor activities and itinerary. Additionally, Ticovac may be considered for people traveling or moving to a TBE-endemic area who might engage in outdoor activities in areas ticks are likely to be found. The decision to vaccinate should be based on an assessment of their planned activities and itinerary, rick factors for a poorer medical outcome, and personal perception and tolerance of risk.

TBE is caused by the tick-borne encephalitis virus, a member of the Flaviviridae family, and is transmitted through the bite of a tick in the Ixodidae family, which act as the viral carrier of the disease. Three different viral subtypes have been characterized, including the European or Western tick-borne encephalitis virus, Siberian tick-borne encephalitis virus, and Far Eastern tick-borne encephalitis virus. Less common modes of transportation include the consumption of raw milk from infected livestock, maternal-fetal transmission, and through laboratory exposure.

TBE affects people most often in rural, forested locations in eastern, central, and northern Europe, as well as northern China, Mongolia, and Russia. According to the World Health organization, 10,000-12,000 cases of TBE are reported annually. TBE does not occur in the United States. Between 2000 and 2017, the CDC recorded only 8 cases in the United States, and all cases involved patients who had recently traveled to an endemic country.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Ticovac will be a medical benefit if the member's specific plan allows for coverage of travel vaccines. Ticovac will be excluded from the Commercial Pharmacy Formulary. Ticovac will not be added to the medical benefit cost share list. 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.

---

**ZONISADE (zonisamide)**

**Review:** Zonisade (zonisamide) is an oral suspension, FDA approved for adjunctive therapy in the treatment of partial (focal) onset seizures in adults and adolescents 16 years of age and older. While the mechanism of action is not fully known, it is believed that Zonisade works by inactivating voltage gated sodium channels to prevent neuron firing.

Zonisade is available as a 100 mg per 5 mL oral suspension. Initial dosing for the treatment of partial onset seizures begins at 100 mg by mouth once daily. Based on clinical response and tolerability, Zonisade can be titrated by 100 mg every two weeks up to 400 mg once daily. The maximum dose for Zonisade is 600 mg once daily. However, there has been no clinical evidence showing increased benefit in doses over 400 mg daily. Increased incidence of side effects has been reported in doses above 300 mg daily.

For the treatment of focal onset seizures, first line therapy options include lamotrigine and levetiracetam. Zonisade can be used as adjunct therapy if additional response is needed. While zonisamide has shown efficacy as monotherapy, it is not recommended by the American Academy of Neurology and National Institute for Health and Clinical Excellence guidelines to be used as first line treatment of focal onset seizures.

Zonisamide use in pregnant patients may cause fetal harm based on animal studies. Zonisamide is transferred into human milk during breast feeding. No reports have been made regarding harm to baby during lactation on zonisamide. Oligohidrosis has been associated with zonisamide in pediatric patients. Therefore, it is not approved for patients less than 16 years of age. Patients with renal impairment may require slower titration of Zonisade and more frequent monitoring while on therapy. Patients with renal failure, eGFR <50 mL/min should avoid use of Zonisade as it is cleared renally. Clinical studies of zonisamide did not have an accurate representation of patients 65 years of age and older. Therefore, it is unknown if older patients will respond differently to treatment. It is recommended to start older patients at lower doses and titrate the dose slowly.

Zonisamide is contraindicated in patients with a hypersensitivity to sulfonamides. Severe skin reactions such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported in post marketing studies. Patients experiencing an unexplainable rash should discontinue zonisamide. Antiepileptic drugs may increase the risk for suicidal ideation or behavior in patients. Patients taking zonisamide should be monitored for new or worsening symptoms of depression.

The most common adverse reactions reported for zonisamide include dizziness (13%), anorexia (13%), headache (10%), nausea (9%), and confusion or difficulty concentrating (6%).

The efficacy of Zonisade has been established in clinical trials of zonisamide oral capsules. The study included 3 multicentered, placebo-controlled, double blind, 3 month long clinical trials. This included 499 patients that had a baseline of at least 4 partial-onset seizures per month and were receiving one or two antiepileptic drugs at therapeutic doses. The mean age of participants was 35 years old. Patients were given zonisamide capsules or placebo in addition to their current antiepileptic regimen. The primary endpoint to determine effectiveness was the median percent decrease from baseline in partial seizure

frequency. The study reported that 27% of patients in the zonisamide group experienced a 75% or greater reduction in seizure from baseline, compared to 12% in the placebo group.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Zonisade is a pharmacy benefit and will not be added to the Geisinger Commercial/Exchange/CHIP formulary. The following prior authorization criteria should apply.

- Medical record documentation of a diagnosis of alpha-mannosidosis supported by:
- Medical record documentation of an age > 16 years **AND**
- Medical record documentation of Epilepsy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Zonisamide **OR**
- Medical record documentation of the inability to tolerate or swallow capsules
  **If requested dose exceeds 400 mg per day:**
- Medical record documentation of therapeutic failure of 400 mg dose **AND**
- Adequate medical and scientific evidence in the medical literature to support doses above 400 mg per day

**RPH SIGNOFF REQUIRED:** Yes

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

---

**APONVIE (aprepitant)**

**Review:** Aponvie (aprepitant) is a substance P/neurokinin-1 (NK1) receptor antagonist, indicated for the prevention of postoperative nausea and vomiting (PONV) in adults. Aponvie has not been studied for treatment of established nausea and vomiting. Aponvie is an injectable emulsion supplied as a 32mg/4.4ml (7.2mg/ml) single-dose vial. The recommended dose is 32mg administered as a 30 second intravenous injection prior to induction of anesthesia.

The term postoperative nausea and vomiting is used to describe nausea and/or vomiting or retching in the post-anesthesia care unit (PACU) or in the immediate 24 postoperative hours. Without prophylaxis, PONV occurs in approximately 30 percent of children and adults after anesthesia, with rates as high as 80% in high-risk patients. The incidence of PONV varies with patient factors, anesthetic choices, and possibly the type of surgery. The use of risk scores are recommended to help guide the need for prophylaxis. The Apfel, et al risk score using a simplified risk score to include the four highly predictive risk factors: female gender, nonsmoker, history of motion sickness of previous PONV, expected administration of postoperative opioids is commonly used. The 2020 Guidelines for the management of PONV recommend multimodal prophylaxis (more than one agent with different mechanisms of action) in patients with one or more risk factors. Patients with 1-2 risk factors should use 2 or more interventions and patients with greater than or equal to 3 risk factors should use 3 or more interventions.

The efficacy of Aponvie was based on adequate and well-controlled studies of a single dose of oral aprepitant in adults. In two multicenter, randomized, double-blind, active comparator-controlled, parallel-group clinical studies (Studies 1 and 2), oral aprepitant was compared with ondansetron for the prevention of postoperative nausea and vomiting in 1658 patients undergoing open abdominal surgery. In

the two studies, patients were randomized to receive 40 mg oral aprepitant, 125 mg oral aprepitant, or 4 mg intravenous ondansetron as a single dose. Aprepitant was given orally 1 to 3 hours before anesthesia. Ondansetron was given intravenously immediately before induction of anesthesia. A comparison between the oral aprepitant 125 mg dose did not demonstrate any additional clinical benefit over the oral 40 mg dose. The antiemetic activity of oral aprepitant was evaluated during the 0 to 48 hour period following the end of surgery. In study 1 oral aprepitant was found to be superior to IV ondansetron when comparing those patient's with: no emetic episodes within 24 hours (84.0% vs 71.4%), no emesis and no rescue therapy withing 24 hours (63.8% vs 55.0%), and no emetic episodes within 48 hours (81.5% vs 66.3%). In study 2 oral aprepitant was found to be superior to IV ondansetron when comparing patients with no emetic episodes within 48 hours (84.6 vs 66.9). In addition, Aponvie 32mg IV showed bioequivalence to oral aprepitant 40mg in a phase 1 clinical pharmacokinetic study. Therapeutic plasma concentrations associated with > 97% receptor occupancy in the brain are achieved within 5 minutes of Aponvie administration compared to 3 hours after administration of oral aprepitant. However, by 4 hours both plasma concentrations remained similar throughout the 48-hour mark.

The safety of Aponvie was evaluated in a study of healthy subjects given a single 32mg IV dose as well as prior oral aprepitant studies. In the Aponvie study of 51 patients adverse reactions reported in at least 3% of subjects were constipation (8%), fatigue (6%), and headache (4%). The most common adverse reactions of oral aprepitant in a pooled analysis of PONV studies were constipation (9%) and hypotension (6%). There are no black box warnings for Aponvie. Aponvie is contraindicated in patients with a history of hypersensitivity reactions to aprepitant or any component of the product as well as use in combination with pimozide (CYP3A4 substrate). Use in combination could result in life threatening QT prolongation. Warnings and precautions include hypersensitivity reactions to aprepitant, clinically significant CYP3A4 drug interactions (aprepitant acts as a CYP3A4 substrate, a weak to moderate (dose-dependent) inhibitor, and an inducer of CYP3A4. Decrease in INR with concomitant warfarin use and risk of reduced efficacy of Hormonal contraceptives for up to 28 days following Aponvie administration. There is insufficient data on use in pregnant women, but use of Aponvie should be avoided due to the alcohol content of the formulation. Safety and effectiveness of Aponvie have not been established in pediatric patients. Clinical studies of aprepitant did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects.

While the guidelines for the management of PONV recommend multimodal prophylaxis in patients with one or more risk factors, there is insufficient evidence to guide the clinician to select the most effective regimen that provides the optimal combination except to use agents from different pharmacological classes. Therefore, the choice of drugs should be determined by patient and surgical factors, side effect profiles, as well as cost. Aponvie does not appear to have any clinical advantages over generic aprepitant, other than faster onset of action.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Aponvie will be a medical benefit. It is recommended to add Aponvie to the medical benefit cost share list. 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 use for prevention of post-operative nausea and vomiting (PONV) **AND**
- Medical record documentation that the medication is prescribed by a surgeon or anesthesiologist

**GPI LEVEL:** GPI-14

**QUANTITY LIMIT:** One vial per 1 day supply with a Darwin RX count of 1 (32mg/4.4ml) and a Facets RX count of 32

**RPH SIGNOFF REQUIRED:** No

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

---

**LEUKOCYTE GROWTH FACTOR DRUG REVIEW**
**FYLNETRA (pegfilgrastim-pbbk)**
**STIMUFEND (pegfilgrastim-fpgk)**
**ROLVEDON (eflapegrastim-xnst)**

**Review:** Fylnetra and Stimufend are the fifth and sixth Neulasta biosimilar products. Like the previous biosimilars, they are indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. The dosage for each is 6 mg administered subcutaneously once per chemotherapy cycle. For pediatric patients weighing less than 45 kg, weight based dosing is used.

No new clinical trials were conducted for the approval of Fylnetra and Stimufend. Approval is based on biosimilar studies comparing Fylnetra and Stimufend to Neulasta which found that there are no clinically meaningful differences between the products and Neulasta in terms of safety, purity, and potency of the product.

No new safety signals were identified for the new products Fylnetra and Stimufend. Warnings, precautions, and adverse reactions are consistent with the known safety profile of pegfilgrastim.

Rolvedon is a recombinant human granulocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.

The recommended dosage of Rolvedon is a single subcutaneous injection of 13.2 mg administered once per chemotherapy cycle. Rolvedon is administered 24 hours after cytotoxic chemotherapy and is not administered within the period from 14 days before to 24 hours after administration of cytotoxic chemotherapy. Rolvedon is supplied as a single-dose prefilled syringe containing 13.2/0.6 mL of eflapegrastim-xnst.

Two randomized, open-label, active-controlled non-inferiority studies of similar design evaluated the efficacy of Rolvedon in decreasing the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs in 634 patients with early-stage breast cancer. Docetaxol and cyclophosphamide were administered intravenously every 21 days for up to 4 cycles. A fixed dose of Rolvedon or pegfilgrastim was administered subcutaneously on Day 2 of each cycle of TC chemotherapy. Efficacy was evaluated based on the duration of severe neutropenia in Cycle 1. In both studies, Rolvedon was non-inferior to pegfilgrastim.

Warnings and Precautions of Rolvedon are consistent with other leukocyte growth factors, including Neulasta and biosimilar products. During clinical trials of Rolvedon, the most common adverse reactions were fatigue, nausea, diarrhea, bone pain, headache, pyrexia, anemia, rash, myalgia, arthralgia, and back pain. The safety and efficacy of Rolvedon has not been established for use in pediatric patients. Of the 314 patients in clinical studies, 39% were 65 years and older and 6% were 75 years and older. No overall differences in safety and efficacy were observed between older and younger patients.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** Bret asked if it is time to review utilization of these products and variability based on prescribers. Would it be worth evaluating again to determine if it is now more standardized. Believe this is a class that should likely be looked at in a future class review. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Fylnetra and Stimufend are pharmacy or medical benefits and should be added to the Specialty tier or Brand Non-preferred tier for members with a three tier benefit of the Commercial, Marketplace, and GHP Kids formularies. Fylentra and Stimufend should be added to the medical benefit cost share list when processed on the medical benefit. They will require a prior authorization and will be added to the Commercial Policy 162.0 and Medical Benefit Policy 59.0.

Rolvedon is a pharmacy or medical benefit and should be added to the Specialty tier or Brand Non-preferred tier for members with a three tier benefit of the Commercial, Marketplace, and GHP Kids formularies. Rolvedon should be added to the medical benefit cost share list when processed on the medical benefit. It will require a prior authorization and will be added to the Commercial Policy 162.0 and Medical Benefit Policy 59.0.

**Commercial Policy 162.0**
**NEUPOGEN, NEULASTA, FULPHILA, LEUKINE, UDENYCA, ZIEXTENZO, ZARXIO, GRANIX, NIVESTYM, RELEUKO, NYVEPRIA, FYLNETRA, STIMUFEND, AND ROLVEDON**

- **Medical record documentation of a diagnosis of cancer, and when any of the following FDA labeled indications or uses supported by clinical guidelines are present:**

**Primary Prophylaxis** – For the prevention of febrile neutropenia (FN) when the risk of FN due to the myelosuppressive chemotherapy regimen is 20% or greater. Those regimens include but are not limited to:

- TC (paclitaxel/cisplatin, or cyclophosphamide/docetaxel or docetaxel/cisplatin or paclitaxel/carboplatin)
- MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
- AC (doxorubicin, cyclophosphamide, docetaxel)
- AT (doxorubicin, paclitaxel)
- TIC (paclitaxel, ifosfamide, mesna, cisplatin)
- VAPEC-B (vincristine, doxorubicin, prednisolone, etoposide, cyclophosphamide, bleomycin)
- DHAP (dexamethasone, cisplatin, cytarabine)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

**NOTE:** Regimens not specified in this document must be listed on a nationally recognized guideline stating risk of FN of greater than 20%.

**OR**

For the prevention of FN when the risk of developing FN is less than 20%, but **any** other risk factor listed below is present:

- Age 65 years or greater
- Poor performance status
- Previous history of FN
- Extensive prior radiation or chemotherapy treatment
- Poor nutritional status
- Recent surgery or open wounds or active infection
- Advanced cancer
- Persistent neutropenia
- Bone marrow involvement by tumor
- Liver dysfunction (bilirubin greater than 2.0)
- Renal dysfunction (CrCl less than 50)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

---

**NEUPOGEN, NEULASTA, FULPHILA, LEUKINE, UDENYCA, ZIEXTENZO, ZARXIO, NIVESTYM, RELEUKO, NYVEPRIA, FYLNETRA, STIMUFEND, AND ROLVEDON**

- **Medical record documentation of any of the following FDA labeled indications or uses supported by clinical guidelines:**

**Secondary Prophylaxis** – prevention of FN when a previous cycle of chemotherapy resulted in a neutropenic complication and for which primary prophylaxis was not received, and a dose reduction will compromise disease-free or overall survival or treatment outcome

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

**Treatment of Febrile Neutropenia** – as an adjunct to antibiotics in high-risk individuals with FN who are at high risk for infection related complications or when **any** of the following prognostic factors are documented:

- Age 65 years or greater
- Anticipated prolonged and profound neutropenia
- Uncontrolled primary disease
- Pneumonia
- Invasive fungal infection
- Hypotension
- Multi-organ dysfunction
- Hospitalized at the time of development of the fever

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

**Dose Dense Therapy** – specifically in the treatment of node positive breast cancer, small cell lung cancer, and diffuse aggressive non-Hodgkin's lymphoma

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

**Stem Cell Transplantation** – when one of the following is met:

- Bone marrow transplant (BMT) –
  - Documentation of a non-myeloid malignancy undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplant (G-CSF is given after BMT)

**OR**

- Peripheral Blood Progenitor Cell (Mobilization)Transplant (PBPC)
  - Used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. (G-CSF is given prior to and throughout leukapheresis)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

**NOTE: Neulasta, Udenyca, Ziextenzo, Nyvepria, Fylnetra, Stimufend, Rolvedon, and Fulphila are considered off-label for PBPC mobilization.**

**Leukemia or Myelodysplastic Syndromes** – insured individuals with:

- Acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy
- Acute lymphoblastic leukemia (ALL) after completion of the first few days of chemotherapy of the initial induction or the first post-remission course
- Myelodysplastic syndrome with less than 15% blasts in the bone marrow, or recurrent neutropenic infections are experienced

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

**Lymphoma** – Age 65 years or greater treated with curative chemotherapy, e.g., CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila

**Radiation therapy** –

- If prolonged delays secondary to neutropenia are anticipated
- As treatment for radiation injury secondary to doses of 3-10 Grays (Gy) or greater

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria **AND** Fulphila

**NOTE: Fulphila, Ziextenzo, Nyvepria, Fylnetra, Stimufend, and Udenyca are considered off-label for radiation injury syndrome; however, the biosimilars are considered medically accepted for this use by the NCCN guidelines.**

**Rolvedon is not indicated for radiation injury syndrome.**

---

**ROLVEDON**

- Medical record documentation of age greater than or equal to 18 years

**NEUPOGEN, ZARXIO, NIVESTYM, and RELEUKO**

- **Medical record documentation of any of the following FDA labeled indications or uses supported by clinical guidelines:**

**Severe Chronic Neutropenia** – when the following criteria are met:
- Diagnosis of congenital, cyclic, or idiopathic neutropenia **AND**
- Documentation of an absolute neutrophil count (ANC) <500 cells/mm3 on three separate occasions during a 6 month period (for congenital or idiopathic neutropenia) **OR** five consecutive days of ANC <500 cells/mm3 per cycle (for cyclic neutropenia) **AND**
- Documentation that the member experienced a clinically significant infection, fever, or oropharyngeal ulcer during the past 12 months
- prolonged delays secondary to neutropenia are anticipated

**LEUKINE**

- **Medical record documentation of any of the following FDA labeled indications or uses supported by clinical guidelines:**

**Delayed Neutrophil Recovery or Graft Failure**
- Medical record documentation that the member has had an allogeneic or autologous bone marrow transplant and neutrophil recovery* has not occurred

*Note to reviewer: Neutrophil engraftment is defined as the first day of three consecutive days where the neutrophil count (ANC) is 500 cells/$mm^3$ or greater.

**MEDISPAN AUTHORIZATION LEVEL:** GPI-10

**AUTHORIZATION DURATION:** 6 months

**NEULASTA/FULPHILA/ZIEXTENZO/UDENYCA/NYVEPRIA/FYLNETRA/STIMUFEND/ROLVEDON QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*
- QL FOR LETTER ONLY: 1 syringe per 14 days (0.043 mL per day)

If an exception is made, Neupogen, Neulasta, Fulphila, Leukine, Udenyca, Ziextenzo, Zarxio, Granix, Nivestym, Releuko, Fylnetra, Stimufend, Rolvedon or Nyvepria will be paid for under the member's prescription drug benefit.

**EXCLUSIONS:**
There is insufficient evidence in the published, peer reviewed medical literature to clearly establish that the use of colony stimulating factors (CSF) improves the health outcomes in any of the following indications. The use of CSF's for the following indications is considered not medically necessary and are **NOT COVERED:**
- Routine use as prophylaxis on most chemotherapy regimens; or
- Use as prophylaxis during chemotherapy regimens with a febrile neutropenia risk of less than 20% and no high risk for complications; or
- Use in insured members who are neutropenic but afebrile and not meeting any of the above criteria; or
- Use as an adjunct to antibiotics in uncomplicated febrile neutropenia; or use in relapsed or refractory myeloid leukemia; or
- Use in chemo-sensitization of myeloid leukemias; or
- Use prior to or concurrent with chemotherapy for acute myeloid leukemia; or

- Use prior to or concurrently with chemotherapy for “priming” effect; or
- Use to allow an increase in the dose-intensity of cytotoxic chemotherapy beyond the established dose ranges for these regimens; or
- Use during concomitant chemotherapy and radiation therapy; or
- Continued use if no response is seen within 45 days.

**Medical Benefit Policy 059.0**
**Neupogen, Neulasta, Nivestym, Fulphila, Udenyca, Ziextenzo, Zarxio, Leukine, Granix, Releuko, Nyvepria, Fylnetra, Stimufend, and Rolvedon:**

**1. Primary Prophylaxis** - the prevention of febrile neutropenia (FN) when the risk of FN due to the myelosuppressive chemotherapy regimen is 20% or greater. Those regimens include but are not limited to:

- TC (paclitaxel/cisplatin, or cyclophosphamide/docetaxel or docetaxel/cisplatin or paclitaxel/carboplatin)
- MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
- AC (doxorubicin, cyclophosphamide, docetaxel)
- AT (doxorubicin, paclitaxel)
- TIC (paclitaxel, ifosfamide, mesna, cisplatin)
- VAPEC-B (vincristine, doxorubicin, prednisolone, etoposide, cyclophosphamide, bleomycin)
- DHAP (dexamethasone, cisplatin, cytarabine)

***NOTE:*** *Regimens not specified in this document must be listed on a nationally recognized guideline stating risk of FN of greater than 20%.*

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila.

OR

For the prevention of FN when the risk of developing FN is less than 20%, but any other risk factor listed below is present:

- Age 65 years or greater
- Poor performance status
- Previous history of FN
- Extensive prior radiation or chemotherapy treatment
- Poor nutritional status
- Recent surgery or Open wounds or active infection
- Advanced cancer
- Persistent neutropenia
- Bone marrow involvement by tumor
- Liver dysfunction (bilirubin >2.0)
- Renal dysfunction (CrCl <50)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila.

**Neupogen, Neulasta, Nivestym, Fulphila, Udenyca, Releuko, Nyvepria, Fylnetra, Stimufend, Rolvedon, Ziextenzo, Zarxio, or Leukine:** May also be considered medically necessary for any of the following:

**2. Secondary Prophylaxis** – prevention of FN when a previous cycle of chemotherapy resulted in a neutropenic complication and for which primary prophylaxis was not received, and a dose reduction will compromise disease-free or overall survival or treatment outcome.

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila.

**3. Treatment of Febrile Neutropenia** - as an adjunct to antibiotics in high-risk individuals with FN who are at high risk for infection related complications or when **any** of the following prognostic factors are documented:

- Age 65 years or greater
- Anticipated prolonged and profound neutropenia
- Uncontrolled primary disease
- Pneumonia
- Invasive fungal infection
- Hypotension
- Multi-organ dysfunction
- Hospitalized at the time of development of the fever

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila.

**4. Dose Dense Therapy** – specifically in the treatment of node positive breast cancer, small cell lung cancer, and diffuse aggressive non-Hodgkin's lymphoma.

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila.

**5. Stem Cell Transplantation-** when one of the following is met:

- Bone Marrow Transplant (BMT)
  - Documentation of a non-myeloid malignancy undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplant (G-CSF is given after BMT)

OR

- Peripheral Blood Progenitor Cell (Mobilization)Transplant (PBPC)
  - Used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. (G-CSF is given prior to and throughout leukapheresis)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila.

Note: Neulasta, Udenyca, Ziextenzo, Nyvepria, Fylnetra, Stimufend, and Fulphila are considered off-label for PBPC mobilization

**6. Leukemia or Myelodysplastic Syndromes** – insured individuals with any of the following conditions:

- Acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy
- Acute lymphoblastic leukemia (ALL) after completion of the first few days of chemotherapy of the initial induction or the first post-remission course

- Myelodysplastic syndrome with less than 15% blasts in the bone marrow, or recurrent neutropenic infections are experienced.
  **AND**
- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila.

**7. Lymphoma –** Age 65 years or greater treated with curative chemotherapy, e.g., CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila.

**8. Radiation therapy –** with any of the following conditions

- If prolonged delays secondary to neutropenia are anticipated.
- As treatment for radiation injury secondary to doses of 3-10 Grays (Gy) or greater

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, Nyvepria, Fylnetra, Stimufend, **AND** Fulphila.

Note: Fulphila, Ziextenzo, Nyvepria, Fylnetra, Stimufend, and Udenyca are not indicated for radiation injury syndrome; however, the biosimilars are considered medically accepted for this indication by the NCCN guidelines.

Note: Rolvedon is not indicated for radiation injury syndrome.

**Neupogen, Nivestym, Releuko, and Zarxio:** May also be considered medically necessary for the following:

**9. Severe Chronic Neutropenia –** when the following criteria are met

- Diagnosis of Congenital, Cyclic, or Idiopathic Neutropenia AND
- Documentation of an Absolute Neutrophil Count (ANC) <500 cells/$mm^3$ on three separate occasions during a 6 month period (for Congenital or Idiopathic Neutropenia) OR five consecutive days of ANC <500 cells/$mm^3$ per cycle (for Cyclic Neutropenia) AND
- Documentation that the member experienced a clinically significant infection, fever, or oropharyngeal ulcer during the past 12 months.

**Leukine:** May also be considered medically necessary for the following:

**10. Delayed Neutrophil Recovery or Graft Failure**

- Medical record documentation that the member has had an allogeneic or autologous bone marrow transplant and neutrophil recovery* has not occurred.

  *Note to reviewer: Neutrophil engraftment is defined as the first day of three consecutive days where the neutrophil count (ANC) is 500 cells/$mm^3$ or greater.

**AUTHORIZATION:** When approved, the duration of the authorization will be for 6 months.

**QUANTITY LIMITS:**

- **Ziextenzo**: Facets RX Count: 144 (Q5120 Units), Darwin QL: 0.043mL per day (1 syringe per 14 days)

- **Udenyca**: Facets RX Count: 144 (Q5111 Units), Darwin QL: 0.043mL per day (1 syringe per 14 days)
- **Fulphila**: Facets RX Count: 144 (Q5108 Units), Darwin QL: 0.043mL per day (1 syringe per 14 days)
- **Nyvepria**: Facets RX Count: 144 (Q5122 Units), Darwin QL: 0.043 ML per day (1 syringe per 14 days)
- **Neulasta/Neulasta Onpro**: Facets RX Count: 144 (J2506 Units), Darwin QL: 0.043mL per day (1 syringe per 14 days)
- **Fylnetra:** Facets RX Count: 144 (Q5130 Units), Darwin QL: 0.043 ML per day (1 syringe per 14 days)
- **Stimufend:** Facets RX Count: 144 (Q5127 Units), Darwin QL: 0.043 ML per day (1 syringe per 14 days)
- **Rolvedon:** Facets RX Count: 144 (J1449 Units), Darwin QL: 0.043 ML per day (1 syringe per 14 days)

**EXCLUSIONS:** There is insufficient evidence in the published, peer reviewed medical literature to clearly establish that the use of colony stimulating factors (CSF) improves the health outcomes in any of the following indications. The use of CSF's for the following indications is considered not medically necessary and are **NOT COVERED:**

- Routine use as prophylaxis on most chemotherapy regimens; or
- Use as prophylaxis during chemotherapy regimens with a febrile neutropenia risk of less than 20% and no high risk for complications; or
- Use in insured members who are neutropenic but afebrile and not meeting any of the above criteria; or
- Use as an adjunct to antibiotics in uncomplicated febrile neutropenia; or use in relapsed or refractory myeloid leukemia; or
- Use in chemo-sensitization of myeloid leukemias; or
- Use prior to or concurrent with chemotherapy for acute myeloid leukemia; or
- Use prior to or concurrently with chemotherapy for "priming" effect; or
- Use to allow an increase in the dose-intensity of cytotoxic chemotherapy beyond the established dose ranges for these regimens; or
- Use during concomitant chemotherapy and radiation therapy; or
- Continued use if no response is seen within 45 days.

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

---

**AREXVY & 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.

**AREXVY**
The dosage of Arexvy is a single dose of (0.5 mL) of Arexvy as an intramuscular injection. Arexyv is supplied as a suspension for injection that is reconstituted with an accompanying vial of adjuvant suspension and contains a single dose of 0.5 mL after reconstitution.

The efficacy of Arexvy was evaluated in Study 1, an ongoing Phase 3, randomized, placebo-controlled, observer-blind clinical study in adult patients 60 years of age and older to prevent RSV-associated LRTD. The primary efficacy population, included 24,960 adult patients 60 years and older receiving 1 dose of Arexvy or placebo who did not report an RSV-confirmed acute respiratory illness (ARI) prior to Day 15

after vaccination. Patients were randomized 1:1 to received Arexvy (n=12,466) or placebo (n=12,494). At the time of primary analysis, participants had been followed for development of RSV-associated LRTD for up to 10 months.

The primary objective was to demonstrate the efficacy of Arexvy in the prevention of a first episode of confirmed RSV-A and/or B-associated LRTD during the first season. Confirmed RSV cases were determined by quantitative Reverse Transcription Polymerase Change Reaction (qRT-PCR) on a nasopharyngeal swab during all ARI episodes. Acute Respiratory illness (ARI) was defined by the presence of at least 2 respiratory symptoms/signs for at least 24 hours (nasal congestion, sore throat, lower respiratory symptoms/signs), or at least 1 respiratory symptom/sign and 1 systemic symptom/sign (fever or feverish, fatigue, body aches, headache, decreased appetite) for at least 24 hours. LRTD was defined as 2 lower respiratory signs/symptoms, included at least 1 lower respiratory sign for at least 24 hours, or at least 3 lower respiratory symptoms for at least 24 hours. Lower respiratory symptoms include new or increased sputum, new or increased cough, new or increased dyspnea. Lower respiratory signs include new or increased wheezing, crackles/rhonchi, respiratory rate ≥ 29 respirations/min, low or decreased oxygen saturation, or need for oxygen supplementation.

Compared to placebo, Arexvy significantly reduced the risk of developing RSV-associated LRTD by 82.6% in participants 60 years of age and older. The median duration of efficacy was 6.7 months. The vaccine efficacy against RSV A-associated LRTD cases and RSV B-associated LRTD cases was 84.6% and 80.9%, respectively. Table 6 shows vaccine efficacy by age subgroup.

Study 1 also evaluated the incidence of severe RSV-associated LRTD defined as RT-PCR confirmed RSV-associated LRTD with at least 2 lower respiratory signs, or as an RT-PCR confirmed RSV-associated LRTD episode preventing normal, everyday activities. One case of severe RSV-associated LRTD occurred in the Arexvy group compared to 17 cases in the placebo group. Compared with placebo, Arexvy significantly reduced the risk of developing severe RSV-associated LRTD by 94.1% in participants 60 years of age and older.

**Table 6. Efficacy Analysis: First Respiratory Syncytial Virus-associated Lower Respiratory Tract Disease Overall, by Age and Co-morbidity Subgroups in Study 1 a (Modified Exposed Set)**

| | AREXVY | | | Placebo | | | |
|---|---|---|---|---|---|---|---|
| Subgroup | N | n | Incidence Rate per 1,000 Person-Years | N | n | Incidence Rate per 1,000 Person-Years | % Efficacy (CI)[b] |
| Overall (≥60 years) | 12,466 | 7 | 1.0 | 12,494 | 40 | 5.8 | 82.6 (57.9, 94.1) |
| 60 to 69 years | 6,963 | 4 | 1.0 | 6,979 | 21 | 5.5 | 81.0 (43.6, 95.3) |
| 70 to 79 years | 4,487 | 1 | 0.4 | 4,487 | 16 | 6.5 | 93.8 (60.2, 99.9) |
| Participants with at least 1 comorbidity of interest | 4,937 | 1 | 0.4 | 4,861 | 18 | 6.6 | 94.6 (65.9, 99.9) |

Two-sided exact CI for vaccine efficacy is derived based on Poisson model adjusted by age categories and regions. N = Number of participants included in each group. n = Number of participants having first occurrence of RSV-confirmed LRTD occurring from Day 15 post-vaccination. a Study 1: NCT04886596. b CI = Confidence Interval (96.95% for the overall ≥60 years and 95% for all subgroup analyses).

Warnings and precautions for Arexvy include allergic reactions, syncope, and altered immunocompetence in immunocompromised patients. The most common adverse reactions reported with Arexvy were injection site pain including pain, erythema, and swelling, and systemic adverse reactions including

fatigue, myalgia, headache, arthralgia, and fever. Serious adverse reactions within 6 months following vaccination were reported at similar rates in participants who received Arexvy or placebo.

Evidence from animal models strongly suggests that Arexvy would be unsafe in individuals younger than 2 years of age because of increased risk of enhanced respiratory disease. Safety and efficacy of individuals 2 years through 17 years of age have been established.

Arexvy is approved for use in indviduals 60 years of age and older. Of the total number of participants in Study 1, 13,943 (55.8%) were 60 to 69 years of age, 8,978 (36%) were 70 to 79 years of age, and 2,045 (8.2%) were 80 years of age and older.

**ABRYSVO**
The dosage of Abrysvo is a single dose (0.5 mL) of Abrysvo intramuscularly. Abrysvo is supplied as a single dose solution for injection that after reconstituted is 0.5 mL.

The efficacy of Abrysvo in the prevention of RSV-associated lower respiratory tract disease in patients 60 years of age and older was evaluated in Study 3, a randomized, double-blind, placebo-controlled study. Patients were randomized 1:1 to receive Abrysvo (n=17,197) or placebo (n=17,186). Starting 14 days after study vaccination, all participants were actively monitored for onset of acute respiratory illness (ARI) symptoms. Patients with 1 or more ARI symptom, were tested by RT-PCR for RSV. RSV-LRTD was defined as an RT-PCR confirmed RSV illness with two or more or three or more of the following respiratory symptoms within 7 days of symptom onset and lasting more than 1 day during the same illness: new or increased cough, wheezing, sputum production, shortness of breath, or tachypnea. Severe RSV-LRTD was defined as meeting the RSV-LRTD criteria plus at least one of the following: hospitalization due to RSV-LRTD, new or increased oxygen supplementation, or mechanical ventilation including Continuous Positive Airway Pressure (CPAP).

The study results demonstrated efficacy for the primary objectives of prevention of RSV-LRTD with ≥ 2 symptoms and prevention of RSV-LRTD with ≥ 3 symptoms. The median duration of follow-up for efficacy was 7 months. Vaccine efficacy is shown in Table 7.

**Table 7. Vaccine Efficacy of Abrysvo Against RSV-LRTD in Individuals 60 Years of Age and Older (Study 3)**

| Efficacy Endpoint | ABRYSVO N=16,306[b] n | Placebo N=16,308[b] n | VE (%) (96.66% CI) |
|---|---|---|---|
| First episode of RSV-associated lower respiratory tract disease with ≥2 symptoms | 11 | 33 | 66.7 (28.8, 85.8) |
| First episode of RSV-associated lower respiratory tract disease with ≥3 symptoms | 2 | 14 | 85.7 (32.0, 98.7) |

CI – confidence interval; N – number of participants; n = number of cases; RSV – respiratory syncytial virus; VE – vaccine efficacy
(VE based on case count ratio is calculated as 1-(P/[1-P]), where P is the number of RSVpreF cases divided by the total number of cases)
[a] NCT05035212
[b] Evaluable efficacy population

The efficacy of Abrysvo in the prevention of RSV-associated lower respiratory tract disease (RSV-LRTD) in infants born to individuals vaccinated during pregnancy was evaluated in Study 1, a Phase 3, randomized, placebo-controlled trial. The trial randomized maternal participants 1:1 to receive Abyrsvo (n=3,695) or placebo (n=3,697). Vaccine efficacy was defined as relative risk reduction of the endpoints of severe LRTD caused by RSV and RSV-LRTD in infants born to individuals who received Abrysvo compared to infants born to individuals who received placebo. RSV-LRTD in infants was defined as a medically attended visit with an RT-PCR confirmed RSV illness with one or more of the following respiratory symptoms: tachypnea, SpO2 measured in room air < 95%, chest wall indrawing. RSV-

associated severe LRTD with a subset defined as meeting the LRTD RSV criteria plus at least one of the following: tachypnea, SpO2 measured in room air < 93%, high-flow nasal cannula or mechanical ventilation (invasive or noninvasive), ICU admission for > 4 hours and/or failure to respond/unconscious. Secondary efficacy endpoints included hospitalizations due to RSV.

Abrysvo met the statistical criterion for success for reducing severe LRTD due to RSV, at all timepoints to within 180 days. The VE results did not meet the statistical criterion for success for reduction LRTD due to RSV, however clinically meaningful efficacy was observed after 90 days through 180 days after birth. Table 8 through 12 shows additional vaccine information.

**Table 8. Vaccine Efficacy of ABRYSVO Against Severe LRTD Caused by RSV - Infants From Birth Through 6 Months of Age by Active Immunization of Pregnant Individuals (Study 1) [a]**

| Time Period | ABRYSVO Number of Cases N=3,495[b] | PLACEBO Number of Cases N=3,480[b] | VE (%) (CI)[c] |
|---|---|---|---|
| 90 days | 6 | 33 | 81.8 (40.6, 96.3) |
| 120 days | 12 | 46 | 73.9 (45.6, 88.8) |
| 150 days | 16 | 55 | 70.9 (44.5, 85.9) |
| 180 days | 19 | 62 | 69.4 (44.3, 84.1) |

CI - confidence interval; N – number of participants; RSV – respiratory syncytial virus; VE - vaccine efficacy a The prespecified success criterion was met for this endpoint evaluation b Evaluable efficacy population c 99.5% CI at 90 days; 97.58% CI at later intervals

**Table 9. Vaccine Efficacy of ABRYSVO Against LRTD Caused by RSV - Infants From Birth Through 6 Months of Age by Active Immunization of Pregnant Individuals (Study 1) [a]**

| Time Period | ABRYSVO Number of Cases N=3,495[b] | PLACEBO Number of Cases N=3,480[b] | VE (%) (CI)[c] |
|---|---|---|---|
| 90 days | 24 | 56 | 57.1 (14.7, 79.8) |
| 120 days | 35 | 81 | 56.8 (31.2, 73.5) |
| 150 days | 47 | 99 | 52.5 (28.7, 68.9) |
| 180 days | 57 | 117 | 51.3 (29.4, 66.8) |

CI - confidence interval; N – number of participants; RSV – respiratory syncytial virus; VE - vaccine efficacy a The prespecified success criterion (a CI lower bound >20%) was not met for this endpoint evaluation at 90 days b Evaluable efficacy population c 99.5% CI at 90 days; 97.58% CI at later intervals

**Table 10. Vaccine Efficacy of ABRYSVO Against Severe LRTD Caused by RSV - Infants From Birth Through 6 Months of Age by Active Immunization of Pregnant Individuals at 32 Through 36 Weeks Gestational Age (Study 1)[a]**

| Time Period | ABRYSVO Number of Cases N=1572[b] | PLACEBO Number of Cases N=1539[b] | VE (%) (CI)[c] |
|---|---|---|---|
| 90 days | 1 | 11 | 91.1 (38.8, 99.8) |
| 180 days | 6 | 25 | 76.5 (41.3, 92.1) |

CI - confidence interval; N – number of participants; n - number of cases; RSV – respiratory syncytial virus; VE - vaccine efficacy a This descriptive subgroup analysis was not controlled for multiple comparisons; results from 90 days and 180 days are presented. b Evaluable efficacy population c 95% CI

**Table 11. Vaccine Efficacy of ABRYSVO Against LRTD Caused by RSV - Infants From Birth Through 6 Months of Age by Active Immunization of Pregnant Individuals at 32 Through 36 Weeks Gestational Age (Study 1)[a]**

| Time Period | ABRYSVO Number of Cases N=1572[b] | PLACEBO Number of Cases N=1539[b] | VE (%) (CI)[c] |
|---|---|---|---|
| 90 days | 14 | 21 | 34.7 (-34.6, 69.3) |
| 180 days | 24 | 55 | 57.3 (29.8, 74.7) |

CI - confidence interval; N – number of participants; n - number of cases; RSV – respiratory syncytial virus; VE - vaccine efficacy a This descriptive subgroup analysis was not controlled for multiple comparisons; results from 90 days and 180 days are presented. b Evaluable efficacy population c 95% CI

**Table 12. Vaccine Efficacy of ABRYSVO Against Hospitalization Due to RSV – Infants From Birth Through 6 Months of Age by Active Immunization of Pregnant Individuals (Study 1)[a]**

| Time Period | ABRYSVO Number of Cases N=3,495[b] | PLACEBO Number of Cases N=3,480[b] | VE (%) (CI)[c] |
|---|---|---|---|
| 90 days | 10 | 31 | 67.7 (15.9, 89.5) |
| 120 days | 15 | 37 | 59.5 (8.3, 83.7) |
| 150 days | 17 | 39 | 56.4 (5.2, 81.5) |
| 180 days | 19 | 44 | 56.8 (10.1, 80.7) |

CI – confidence interval; N – number of participants; n – number of cases; RSV – respiratory syncytial virus; VE – vaccine efficacy a NCT04424316 b Evaluable efficacy population c 99.17% CI

Warnings and precautions were consistent with Arexvy including risk of allergic reactions, syncope, and altered immunocompetence in immunocompromised individuals. Abrysvo also includes warnings for potential risk of preterm birth based on a numerical imbalance in preterm births in Abrsyvo recipients compared to placebo recipients in two clinical studies. To avoid potential risk Absyvo is administered in pregnant individuals at 32 to 36 weeks gestational age. Pregnant individuals at increased risk of preterm birth were generally excluded from the study.

In clinical trials, the most commonly reported adverse reactions in pregnant individuals were pain at the injection site, headache, muscle pain, and nausea. Serious adverse reactions in maternal participants were reported by 16.2% of patients in the Abrysvo group and 15.2% in the placebo group. Most serious adverse events were related to pregnancy complications and occurred after the 1 month period following vaccination. Adverse reactions in infants from birth to 1 month of age were observed in 37.1 of patients in the Abrysvo group compared to 34.5% in the placebo group. Low birth weight was reported in 5.1% of participants in the Abrysvo group versus 4.4% in the placebo group. Neonatal jaundice was observed in 7.2% in the Abrysvo group versus 6.7% in the placebo group.

The most commonly reported adverse reactions in individuals 60 years of age and older were fatigue, headache, pain at injection site, and muscle pain. Serious adverse reactions were reported in 2.3% of patients. Three participants in the Abrysvo group had SAEs which were assessed as possibly related to study vaccination: Guillain-Barre Syndrome reported 7 days after vaccination, Miller Fisher Syndrome reported 8 days after vaccination, and hypersensitivity reported 8 days after vaccination.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**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. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Arexvy and Abrysvo will be medical or pharmacy benefits and should be added to the Commercial, Exchange, and GHP Kids formulary as preventive vaccines ($0 copay). 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 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

**GPI LEVEL:** GPI-12

**RPH SIGNOFF REQUIRED:** No

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.

For neonates and infants born during or entering the RSV season, Beyfortus should be administered starting from birth. For infants born outside the RSV season, Beyfortus should be administered once prior to the start of the RSV seasons considering duration of protection provided by Beyfortus. The recommended dosage of Beyfortus for neonates and infants born during or entering the first RSV season is based on body weight and is administered as a single intramuscular injection.

**Table 4. Recommended Dosage of Beyfortus in Neonates and Infants Born During or Entering Their First RSV Season**

| Body Weight at Time of Dosing | Recommended Dosage |
|---|---|
| Less than 5 kg | 50 mg by IM injection |
| 5 kg and greater | 100 mg by IM injection |

For children up to 24 months of age who remain at increased risk for severe RSV disease in their second RSV season, the recommended dosage of Beyfortus is a single 200 mg dose administered as two IM injections (2 x 100 mg). Children undergoing cardiac surgery with cardiopulmonary bypass, an additional dose of Beyfortus is recommended as soon as the child is stable after surgery to ensure adequate

Beyfortus serum levels. For the first RSV season, if surgery is within 90 days after receiving Beyfortus, the additional dose should be based on body weight. If more than 90 days have elapsed since receiving Beyfortus, the additional dose should be 50 mg regardless of body weight. For the second RSV season, if surgery is within 90 days after receiving Beyfortus, the additional dose should be 200 mg regardless of body weight. If more than 90 days have elapsed since receiving Beyfortus, the additional dose should be 100 mg regardless of body weight. Beyfortus must be administered by a healthcare professional.

The efficacy and safety of Beyfortus was evaluated in a Phase 2b trial and the Phase 3 MELODY trial which compared Beyfortus to placebo and the Phase 3 MEDLEY trial which compared Beyfortus to Synagis in patients at higher risk for severe RSV disease. In the Phase 2b trial and MELODY trial, efficacy is evaluated as incidence of medically attended RSV lower respiratory tract infection (MA RSV LRTI), characterized predominantly as bronchitis or pneumonia through 150 days after dosing. Results for the Phase 2b trial (Trial 03) and the MELODY trial are shown in Table 5 and 6.

**Table 5. Incidence of MA RSV LRTI in Infants Born at ≥29 Weeks to < 35 Weeks Through 150 Days Post Dose (Trial 03)**

| | N | Incidence % (n) | Efficacy* (95% CI) |
|---|---|---|---|
| BEYFORTUS | 969 | 2.6% (25) | 70.1% (52.3, 81.2)†‡ |
| Placebo | 484 | 9.5% (46) | |

* Efficacy for MA RSV LRTI based on relative risk reduction against placebo adjusted for age at randomization and hemisphere.

† p-value =<0.001.

‡ In a post-hoc analysis of all randomized infants in Trial 03 weighing <5 kg at baseline, and who received the recommended dose of BEYFORTUS, efficacy for MA RSV LRTI, based on relative risk reduction against placebo was 86.2% (95% CI 68.0, 94.0); efficacy for RSV LRTI with hospitalization based on relative risk reduction against placebo was 86.5% (95% CI 53.5, 96.1).

**Table 6. Incidence of MA RSV LRTI in Infants Born at ≥35 Weeks Through 150 Days Post Dose for the MELODY trial (Trial 04)***

| | N | Incidence % (n) | Efficacy† (95% CI) |
|---|---|---|---|
| BEYFORTUS | 994 | 1.2% (12) | 74.9% (50.6, 87.3)‡ |
| Placebo | 496 | 5.0% (25) | |

* The primary efficacy analysis for Trial 04 is based on subjects from the Primary Cohort.

† Efficacy for MA RSV LRTI based on relative risk reduction against placebo adjusted for age at randomization.

‡ p-value =<0.001.

The MEDLEY trial which compared Beyfortus to Synagis was not powered for efficacy but efficacy was assessed as a secondary endpoint. Patients were randomized 2:1 to receive Beyfortus or Synagis. In the first RSV season of the MEDLEY trial, the incidence of MA RSV LRTI through 150 days post dose was 0.6% in the Beyfortus group and 1.0% in the Synagis group. In the second RSV season, there were no cases of MA RSV LRTI through Day 150 post-dose in subjects who received either Beyfortus or Synagis.

Warnings and Precautions for Beyfortus include risk of hypersensitivity reactions, including anaphylaxis which have been observed with other IgG1 monoclonal antibodies. As with any other IM injections, Beyfortus should be used with caution in infants and children with thrombocytopenia, any coagulation disorder, or to individuals on anticoagulation therapy. In the pooled safety data from the Phase 2b trial and the MELODY trial, adverse reactions were mild to moderate in intensity and included rash and injection site reaction. The safety data from the MEDLEY trial was consistent with previous adverse reactions reported to the pooled safety data from previous trials.

Advisory Committee on Immunization Practices (ACIP) recommends 1 dose of Beyfortus for all infants aged < 8 months born during or entering their first RSV season. ACIP recommends 1 dose for infants and children aged 8 -19 months who are at increased risk of severe RSV disease and entering their second RSV season. The recommends for Beyfortus apply to infants and children recommended to receive Synagis by AAP.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** How soon in relation to the RSV season did the patients in the clinical trial get the vaccine? If the season starts on November 1st should this be administered prior to the season starting? Will need to request provider input and investigate further. Dr. Gotham stated there is no use for co-adminsiterd Synagis and Beyfortus. It's okay to switch agents from one season to the next. Believe that over time Beyfortus will replace Synagis, but with the drug release so close to the season starting it's likely Synagis will still be used more often this year. She mentioned that the AAP added Native American children are now considered high risk. Will investigate to determine if this should be added. No additional comments or questions. The committee unanimously voted to accept the recommendations as amended. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Beyfortus is a medical benefit 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. Beyfortus should be added to the medical benefit cost share list. When processed at a specialty pharmacy, Beyfortus should process on the Specialty tier, or the Brand Non Preferred tier for members with a three tier benefit. The following prior authorization criteria will apply:

The indication criteria is based on the American Academy of Pediatrics policy statement. 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), listed indications may also be met on dates deemed appropriate by Geisinger Health Plan in conjunction with guidance from the American Academy of Pediatrics (AAP) and other applicable clinical resources.

- Infants ≤ 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:
- 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.

## CLASS REVIEWS

## WEIGHT LOSS CLASS REVIEW

| Agents for Weight Loss[1-5] | | | |
|---|---|---|---|
| **Brand Name** | **Generic** | **Generic Available?** | **Manufacturer** |
| **Glucagon-Like Peptide-1 Receptor Agonists (GLP-1)** | | | |
| Saxenda | Liraglutide | No | Novo Nordisk A/S |
| Wegovy | Semaglutide | No | Novo Nordisk A/S |
| **Lipase Inhibitor** | | | |
| Xenical | Orlistat | Yes | Cheplapharm |
| **Combination Medications** | | | |
| **Pure Opioid Antagonist/Dopamine and Norepinephrine Reuptake Inhibitor** | | | |
| Contrave | Naltrexone/bupropion | No | Currax Pharmaceuticals |
| **Sympathomimetic Amine Anorectic/Carbonic Anhydrase Inhibitor Anticonvulsant** | | | |
| Qsymia | Phentermine/topiramate | No | Vivus LLC |

**Review:** According to the Centers for Disease Control and Prevention (CDC), obesity prevalence in adults in the United States (US) have increased from 30.5% in 1999-2000 to 41.9% in 2017-2020 making this a country-wide crisis. Obesity is defined as having a body mass index (BMI) of ≥30 kg/m$^2$. A BMI of 25-29.9 kg/m$^2$ is considered overweight. Obesity can be further classified into class I or BMI 30-34.9 kg/m2, class II or BMI 35-39.9 kg/m$^2$, and class III or BMI ≥40 kg/m$^2$. There are many factors that can play a role in the development of obesity including genetics, social determinants of health as well as certain medical conditions and medications. Adults with obesity are at an increased risk for several disease states such as type 2 diabetes, hypertension, cardiovascular disease, stroke, cancer, and mental health conditions. Therefore, it is prevalent to prevent or treat patients with obesity using lifestyle modifications in diet and physical activity with or without pharmacotherapy or bariatric surgery.

**2013 American Heart Association Task Force/American College of Cardiology**

- Weight loss treatment is indicated in patients with a BMI ≥30 kg/m$^2$ or BMI 25-29.9 kg/m$^2$ with cardiovascular risk factors including diabetes, prediabetes, hypertension, dyslipidemia, and/or elevated waist circumference or other weight related risk factors.
- Goal weight loss within 6 months is 5-10% of baseline weight.
- Comprehensive lifestyle intervention including reduced-calorie diet, increased physical activity, and behavior therapy is recommended in all overweight or obese individuals with or without professional guidance or weight loss program enrollment.
- Pharmacotherapy can be added to lifestyle interventions in individuals with BMI ≥30 kg/m$^2$ or BMI ≥27 kg/m$^2$ with ≥1 obesity-related comorbidity.
- Bariatric surgery is an invasive weight loss option for motivated adults with BMI ≥40 kg/m$^2$ or BMI ≥35 kg/m$^2$ with obesity-related comorbidities who have failed therapy with behavioral lifestyle interventions with or without pharmacotherapy.

**2016 American Association of Clinical Endocrinologists/American College of Endocrinology**

- Comprehensive lifestyle modifications including reduced-calorie diet, physical activity, and behavioral health is recommended in all overweight or obese patients.
- Pharmacotherapy should be used for individuals considered overweight with BMI ≥27 kg/m$^2$ and ≥1 obesity-related condition or obese with BMI ≥30 kg/m$^2$ as an adjunct to lifestyle modifications if unsuccessful attempts made with only comprehensive lifestyle modifications.
    - Pharmacotherapy in addition to lifestyle changes results in greater success in weight loss than lifestyle changes alone.
    - Long term use of medications is recommended over short-term use.
- Pharmacotherapy selection should be individualized.
    - One medication is not preferred over another in current guidelines as there are no head-to-head trials of the current FDA approved medications.

- Contrave and Saxenda preferred in patients at risk or with history of nephrolithiasis.
- Orlistat, Qsymia, and Saxenda are preferred for patients with hypertension.
- Orlistat preferred in established atherosclerotic cardiovascular disease (ASCVD).
- Saxenda and orlistat are preferred in patients with a history of or at risk of glaucoma.
- Qsymia, Saxenda, and Orlistat are preferred in patients with a history of or at risk for seizure/epilepsy.
- Qsymia, Saxenda, and Orlistat are preferred in patients requiring chronic use of opioids.

- Bariatric surgery may be considered in patients with BMI ≥40 kg/m$^2$, BMI of ≥35 kg/m2 and ≥1 severe obesity-related factor.

**2021 FDA**

- Wegovy can be used as an adjunct to lifestyle interventions in patients with obesity or BMI ≥27 kg/m$^2$ with at least 1 weight-related comorbidity.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:**

| Medication | Recommendations |
|---|---|
| **Saxenda (liraglutide)** | **Recommend prior authorization for new starts only with the following criteria:**<br><br>**Saxenda Policy**<br>• Medical record documentation has participated in comprehensive lifestyle modifications including reduced-calorie diet, physical activity, and behavioral health for at least 3 months prior to beginning Saxenda **AND**<br>• Medical record documentation of use as adjunct therapy to reduced calorie diet and increased physical activity for chronic weight management **AND**<br>• Medical record documentation of age greater than or equal to 18 years with one of the following:<br>o Medical record documentation of body mass index (BMI) greater than or equal to 30 kg/m2 **OR**<br>o Medical record documentation of body mass index (BMI) greater than or equal to 27 kg/m2 and at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)<br>**AND**<br>• Medical documentation of therapeutic failure to Wegovy.<br><br>**OR**<br>• Medical documentation of age greater than or equal to 12 years and less than 18 years with body weight above 60 kg and an initial body mass index (BMI) corresponding to 30 kg/m2 for adults by international cut-offs (Cole Criteria)<br>**AND**<br>• Medical documentation of therapeutic failure to Wegovy.<br><br>**AUTHORIZATION DURATION:** Initial approval will be for **6 months**. Subsequent approvals will be for an additional **6 months** and will require: |

| | |
|---|---|
| | - Medical record documentation that the member continues to experience clinical benefit from the Obesity Treatment Agent based on the prescriber's assessment **AND**<br>- Medical record documentation that member has experienced at least a 4% reduction in weight from baseline.<br><br>**NOTE:** Saxenda is not indicated for treatment of chronic weight management:<br>• In combination with liraglutide containing products or any other GLP-1 receptor agonist<br>• In combination with other products for weight loss, as safety and efficacy or coadministration has not been established<br>• In pediatric patients with type 2 diabetes<br>•In patients with acute pancreatitis. Caution in patients with history of pancreatitis.<br>• In patients with personal or family history of medullary thyroid C-cell carcinoma or Multiple Endocrine Neoplasia syndrome type 2<br>• In known hypersensitivity to liraglutide or any of the excipients<br>• In pregnancy |
| **Wegovy (semaglutide)** | **Wegovy Policy 686.0**<br>• Medical record documentation has participated in comprehensive lifestyle modifications including reduced-calorie diet, physical activity, and behavioral health for at least 3 months prior to beginning Wegovy **AND**<br>• Medical record documentation of use as adjunct therapy to reduced calorie diet and increased physical activity for chronic weight management **AND**<br>• Medical record documentation of age greater than or equal to 18 years with one of the following:<br>o Medical record documentation of body mass index (BMI) greater than or equal to 30 kg/m2 **OR**<br>o Medical record documentation of body mass index (BMI) greater than or equal to 27 kg/m2 and at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)<br>**OR**<br>• Medical record documentation of age greater than or equal to 12 years and less than 18 years with an initial body mass index (BMI) in the 95th percentile or higher for age and sex<br><br>**AUTHORIZATION DURATION:** Initial approval will be for **6 months**. Subsequent approvals will be for an additional **6 months** and will require:<br>- Medical record documentation that the member continues to experience clinical benefit from the Obesity Treatment Agent based on the prescriber's assessment **AND**<br>- Medical record documentation that member has experienced at least a 5% reduction in weight from baseline.<br><br>**NOTE:** Wegovy is not indicated for treatment of chronic weight management:<br>• In combination with semaglutide containing products or any other GLP-1 receptor agonist<br>• In combination with other products for weight loss, as safety and efficacy or coadministration has not been established<br>• In patients with acute ~~history of~~ pancreatitis. Use in caution in patients with history of pancreatitis. |

| | |
|---|---|
| | • In patients with personal or family history of medullary thyroid C-cell carcinoma or Multiple Endocrine Neoplasia syndrome type 2<br>• In known hypersensitivity to semaglutide or any of the excipients<br>• In pregnancy |
| **Xenical (orlistat)** | **Recommend prior authorization for new starts only with the following criteria:**<br><br>**Xenical Policy**<br>• Medical record documentation has participated in comprehensive lifestyle modifications including reduced-calorie diet, physical activity, and behavioral health for at least 3 months prior to beginning Xenical **AND**<br>• Medical documentation of use in conjunction with reduced calorie diet for chronic weight management **AND**<br>• Medical record documentation of age greater than or equal to 18 years with one of the following:<br>o Medical record documentation of body mass index (BMI) greater than or equal to 30 kg/m2 **OR**<br>o Medical record documentation of body mass index (BMI) greater than or equal to 27 kg/m2 and at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)<br>**AND**<br>• Medical documentation of therapeutic failure to Wegovy.<br>**OR**<br>• Medical documentation of use for reduced risk of weight regain after prior established weight loss<br><br>**AUTHORIZATION DURATION:** Initial approval will be for **6 months**. Subsequent approvals will be for an additional **6 months** and will require:<br>- Medical record documentation that the member continues to experience clinical benefit from the Obesity Treatment Agent based on the prescriber's assessment **AND**<br>- Medical record documentation that member has experienced at least a 4% reduction in weight from baseline.<br><br>**NOTE:** Xenical is not indicated for treatment of chronic weight management:<br>• In patients with chronic malabsorption syndrome<br>• In patients with cholestasis<br>• In known hypersensitivity to orlistat or any of the excipients<br>• In pregnancy |
| **Contrave (naltrexone/bupropion)** | **Recommend prior authorization for new starts only with the following criteria:**<br><br>**Contrave Policy**<br>• Medical record documentation has participated in comprehensive lifestyle modifications including reduced-calorie diet, physical activity, and behavioral health for at least 3 months prior to beginning Contrave **AND**<br>• Medical record documentation of use as adjunct therapy to reduced calorie diet and increased physical activity for chronic weight management **AND**<br>• Medical record documentation of age greater than or equal to 18 years with one of the following:<br>o Medical record documentation of body mass index (BMI) greater than or equal to 30 kg/m2 **OR** |

| | |
|---|---|
| | o Medical record documentation of body mass index (BMI) greater than or equal to 27 kg/m2 and at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)<br>**AND**<br>• Medical documentation of therapeutic failure to Wegovy.<br><br>**AUTHORIZATION DURATION:** Initial approval will be for **6 months**. Subsequent approvals will be for an additional **6 months** and will require:<br>- Medical record documentation that the member continues to experience clinical benefit from the Obesity Treatment Agent based on the prescriber's assessment **AND**<br>- Medical record documentation that member has experienced at least a 4% reduction in weight from baseline.<br><br>**NOTE:** Contrave is not indicated for treatment of chronic weight management:<br>• In patients with major depressive disorder or other psychiatric disorders due to increased risk of suicidal thinking and behavior.<br>• In combination with bupropion containing products<br>• In combination with other products for weight loss, as safety and efficacy or coadministration has not been established<br>• In uncontrolled hypertension<br>• In patients with seizure disorders, anorexia nervosa or bulimia, or undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs<br>• In combination with chronic opioid use<br>• In concomitant use or within 14 days of taking monoamine oxidase inhibitors (MAOI)<br>• In known hypersensitivity to any ingredients of naltrexone/bupropion<br>• In pregnancy<br>• In pediatric patients |
| **Qsymia (phentermine/topiramate)** | **Recommend prior authorization for new starts only with the following criteria:**<br><br>**Qsymia Policy**<br>• Medical record documentation has participated in comprehensive lifestyle modifications including reduced-calorie diet, physical activity, and behavioral health for at least 3 months prior to beginning Qsymia **AND**<br>• Medical record documentation of use as adjunct therapy to reduced calorie diet and increased physical activity for chronic weight management **AND**<br>• Medical record documentation of age greater than or equal to 18 years with one of the following:<br>o Medical record documentation of body mass index (BMI) greater than or equal to 30 kg/m2 **OR**<br>o Medical record documentation of body mass index (BMI) greater than or equal to 27 kg/m2 and at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)<br>**AND**<br>• Medical documentation of therapeutic failure to Wegovy.<br><br>**OR**<br>• Medical record documentation of age greater than or equal to 12 years and less than 18 years with an initial body mass index (BMI) in the 95th percentile or higher for age and sex<br>**AND** |

| | |
|---|---|
| | • Medical documentation of therapeutic failure to Wegovy.<br><br>**AUTHORIZATION DURATION:** Initial approval will be for **6 months**. Subsequent approvals will be for an additional **6 months** and will require:<br>- Medical record documentation that the member continues to experience clinical benefit from the Obesity Treatment Agent based on the prescriber's assessment **AND**<br>- Medical record documentation that member has experienced at least a 3% reduction in weight from baseline.<br><br>**NOTE:** Qsymia is not indicated for treatment of chronic weight management:<br>• In pregnancy<br>• In combination with other products for weight loss, as safety and efficacy or coadministration has not been established<br>• In patients with glaucoma<br>• In patients with hyperthyroidism<br>• In concomitant use or within 14 days of taking monoamine oxidase inhibitors (MAOI)<br>• In known hypersensitivity to any component of Qsymia or idiosyncrasy to sympathomimetic amines |

No additional recommendations based on cost analysis.

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

**INSULIN DELIVERY SYSTEMS CLASS REVIEW**

| Agents for Insulin Delivery Systems | | | |
|---|---|---|---|
| **Brand Name** | **Generic** | **Generic Available?** | **Manufacturer** |
| **V-Go** | | | |
| V-Go 20 | N/A | No | Valeritas, Inc. |
| V-Go 30 | N/A | No | Valeritas, Inc. |
| V-Go 40 | N/A | No | Valeritas, Inc. |
| **Omnipod** | | | |
| Omnipod 5 | N/A | No | Insulet Corporation |
| Omnipod DASH | N/A | No | Insulet Corporation |
| **Cequr** | | | |
| Cequr Simplicity Patch | N/A | No | Cequr Corporation |

**Review:** Over 37 million people in the United States have been diagnosed with diabetes, and 96 million adults have prediabetes. Of this, about 5-10% of cases account for type 1 diabetes, which is due to cell-mediated autoimmune destruction of pancreatic beta cells. Type 2 diabetes accounts for 90-95% of diabetes cases and results from relative insulin deficiency and peripheral insulin resistance. When uncontrolled blood sugar is left untreated, it can increase the risk of macrovascular and microvascular complications. Macrovascular complications include ischemic heart disease, cerebrovascular disease, and peripheral artery disease while microvascular complications include retinopathy, neuropathy, and nephropathy. For patients with type 1 diabetes, insulin treatment is essential due to absent or near-absent beta cell function. Insulin should be considered if there is evidence of catabolism, symptoms of hyperglycemia are present, or when A1c (> 10%) or blood glucose levels (≥ 300 mg/dL) are very high in patients with type 2 diabetes.

Rigorous trials for medical devices, such as continuous glucose monitors and insulin delivery systems, are lacking compared to pharmaceutical drugs. Also, with evolving technology, studies can become outdated as soon as they are published because the features of the device become updated.

- American Association of Clinical Endocrinology Clinical Practice Guideline, Diabetes Technology: Standards of Medical Care in Diabetes 2023, Diabetes Technology – Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults
    - Recommendations for use of insulin delivery technologies
        - AIS should be offered to insulin dependent individuals who are capable of safely using the device themselves or with a caregiver
        - The type and selection of device should be individualized to each patient based on needs, preferences, and skill level
        - In patients with type 1 diabetes who have no achieved their A1c goal, continuous subcutaneous insulin infusions are recommended over basal-bolus multiple daily injections
        - All patients with type 1 diabetes would benefit from the use of more advanced insulin pump technologies to reduce the severity and duration of hypoglycemia
        - Anyone with frequent hypoglycemia, impaired hypoglycemia awareness, or those who fear hypoglycemia that leads to hyperglycemia

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** Philip Krebs, asked if any of these devices sync to a CGM. Morgan Casciole, Pharm.D., responded that the Omnipod 5 is compatible with the Dexcom G6. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:**

| Medication | Recommendations |
|---|---|
| **V-Go 20** | **Recommend adding V-Go to formulary with quantity limits of 30 per 30 days** |
| **V-Go 30** | |
| **V-Go 40** | |
| **Omnipod 5** | **Recommend adding Omnipod to formulary with a prior authorization requiring the following:**<br>- **Medical record documentation of a diagnosis of type 1 diabetes mellitus AND Medical record documentation that member is 2 years of age or older.** |
| **Omnipod DASH** | **No changes recommended** |
| **Cequr Simplicity Patch** | **Recommend adding an age edit to Cequr patch – Member must be 21 years of age or older. Claims for members less than 21 years of age will require prior authorization. Also recommend adding a quantity limit of 10 each per 30 days.** |

No additional recommendations based on cost analysis.

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

## FAST FACTS

### LEQEMBI (lecanemab-irmb)

**Clinical Summary:** Previously, Leqembi was approved under accelerated approval for the treatment of Alzheimer's disease (AD). The prescribing information states "Leqembi should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication was approved under accelerated approval based on the reduction in amyloid beta plaques observed [and] continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial."

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.

The efficacy of Leqembi was evaluated in a Phase 3, double-blind, placebo-controlled, parallel-group, randomized study (NCT03887455, CLARITY AD). CLARITY AD evaluated Leqembi in 1,795 patients with Alzheimer's disease, defined as patients with confirmed presence of amyloid pathology plus mild cognitive impairment (62%) or mild dementia (38%). Of the total patients enrolled, 69% were ApoE e4 carriers and 31% were ApoE e4 non-carriers. Overall median age was 72 (range 50 to 90 years) and 77% of patients were White, 17% Asian, and 3% Black. Patients were enrolled with a Clinical Dementia Rating (CDR) global score of 0.5 or 1.0, a CDR Memory Box score of 0.5 or greater, a Mini-Mental State Examination (MMSE) score of ≥22 and ≤30, and objective impairment in episodic memory as indicated by at least 1 standard deviation below age-adjusted mean in the Wechsler-Memory Scale IV-Logical Memory II (subscale) (WMS-IV LM-II). Key exclusion criteria was any neurological condition other than AD contributing to cognitive impairment, history of TIA, stroke or seizures, contraindications to MRI, significant pathological findings on MRI, and a bleeding disorder not adequately controlled. Patients could either be taking or not be taking other approved therapies for Alzheimer's Disease, including cholinesterase inhibitors and the N-methyl-D-aspartate antagonist, memantine. Patients who were on anticoagulants at screening were required to have their status optimized and stable for at least 4 weeks before receiving therapy.

Patients were randomized 1:1 to receive Leqembi 10 mg/kg or placebo once every 2 weeks. Randomization was stratified according to MCI or mild dementia, taking other approved therapies for Alzheimer's Disease, ApoE e4 carrier status and geographical region.

The primary efficacy outcome was change from baseline in CDR-SB at 18 months, while secondary endpoints included change from baseline at 18 months for the following measures: amyloid Positron Emission Tomography (PET), ADAS-Cog14, and Alzheimer's Disease Cooperative Study-Activities of Daily Living Scale for Mild Cognitive Impairment (ADCS MCI-ADL). Leqembi met the primary efficacy endpoint of reduced clinical decline on the CDR-SB compared to placebo at 18 months (-0.45 [-27%], $p<0.0001$). A statistically significant difference ($p<0.01$) was also seen in the results for ADAS-Cog14 and ADCS MCI-ADL between Leqembi and placebo at 18 months. An exploratory subgroup analysis observed that for ApoE e4 homozygotes (15% of the trial population), Leqembi did not exhibit a treatment effect for the primary efficacy endpoint compared to placebo. Leqembi did have a treatment effect in regard to secondary clinical endpoints and disease-relevant biomarkers in the ApoE e4 homozygous group. Results are summarized in Table 1 and Figure 1, note statistically significant changes in primary and all key secondary endpoints were seen between Leqembi and placebo starting at 6 months. Per the New England Journal of Medicine published research summary, it was concluded Leqembi was associated with moderately less decline on measures of cognition and function.

**Current Formulary Status:** Medical benefit, excluded, per MBP 288.0 Leqembi (lecanemab-irmb)

**Recommendation:** It is recommended Leqembi be covered as a medical benefit requiring prior authorization. The following criteria will apply to the Commercial/Marketplace/CHIP lines of business specifically:

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 [Aβ42] levels OR reduced amyloid beta 42 amyloid beta 40 ratio [Aβ42/Aβ40 ratio] in CSF OR elevated total tau amyloid beta 1-42 ratio [t-tau/Aβ1-42]) **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.

**Discussion:** No comments or questions.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

## UPDATES

## PAXLOVID

**Background:** Paxlovid, a COVID 19 treatment previously approved through and EUA, has now received full FDA approval for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. Paxlovid is not approved for use as pre-exposure or post-exposure prophylaxis for prevention of COVID-19. Paxlovid must be initiated as soon as possible after COVID-19 diagnosis and within 5 days of symptoms onset. The dosage is two 150 mg nirmatrelvir tablets taken with one 100 mg ritonavir tablet twice daily for 5 days. The dose is reduced to one 150 mg tablet and one 100 mg tablet twice daily for 5 days in patients with moderate renal impairment.

Paxlovid will work regardless of COVID-19 strain and is currently the only fully approved oral COVID-19 treatment.

**Recommendations:** It is recommended that Paxlovid be added to the Brand Non Preferred tier for the Commercial, Marketplace, and GHP Kids 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
-

**Discussion:** Phil Krebs asked if you receive the COVID vaccine and then contract Covid, are you not eligible for Paxlovid? Do not believe that is the case. If you are at high risk for progression, regardless of vaccination status, you can receive Paxlovid. No additional comments or questions.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

## SOVALDI QUANTITY LIMIT UPDATE

**Background:** Sofosbuvir dosing is based on patient weight.
Children ≥ 3 years of age and up:

- < 17 kg (pellets): 150mg once daily
- 17 to <35 kg (pellets/tablets): 200mg once daily
- ≥35kg (pellets/tablets): 400mg once daily

**Recommendation:** It is recommended that the quantity limit be updated as follows:

QL FOR LETTER ONLY:

- 200 mg and 400 mg tablets: 1 tablet per day, 28 day supply per fill
- 200 mg pellets: 2 packets per day, 28 day supply per fill
- 400 mg pellets: 1 packet per day, 28 day supply per fill
- 150mg pellets: 1 packet per day, 28 day supply per fill
- 200mg pellets: 2 packets per day, 28 day supply per fill

**Discussion:** No comments or questions.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

---

**STIMULANTS FOR ADHD**

**Background:** There are several medications that are classified as stimulants that are non-formulary for Commercial members. Only some of these medications are listed in the Stimulants for ADHD Commercial Policy 94.0. All of the medications listed in the policy are non-formulary, this has created some confusion regarding if any stimulant not listed in the Stimulants for ADHD Policy should be reviewed under that policy or if it should be reviewed under the Commercial Administrative Policy. Additionally, Cotempla XR-ODT and Mydayis have their own policies (Commercial Policy 490.0 Cotempla XR-ODT and Commercial Policy 491.0 Mydayis) which are identical in criteria to the Stimulants for ADHD Policy, except they also have an age requirement. Many of the stimulants listed in the Stimulants for ADHD Policy can only be used in patients of a certain age and older, but we do not require members to be of a certain age to use these medications, therefore, it may be beneficial to add Cotempla XR-ODT and Mydayis to this policy and abolish their current policies. In order to standardize how these medications should be reviewed and lessen any confusion, it is recommended to update the Stimulants for ADHD Commercial policy to include the previously unlisted medications and incorporate Cotempla XR-ODT and Mydayis.

**Recommendation:** It is recommended that the following medications be added to Commercial Policy 94.0 to reflect this change.

An exception for coverage of Adhansia XR, Adzenys XR-ODT, methylphenidate XR (generic Aptensio XR), Azstarys, Cotempla XR-ODT, methylphenidate transdermal patch (generic Daytrana), dexmethylphenidate HCl ER, dextroamphetamine solution, Dyanavel XR, Jornay PM, Mydayis, QuilliChew ER, Quillivant XR, methylphenidate HCl ER [OSM] 45mg, 63 mg (generic Relexxii), ~~or~~ Xelstrym, or Zenzedi 2.5 mg, 7.5 mg tablets may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Metadate CD$^{\Omega}$ **AND** amphetamine/dextroamphetamine SR combination

$^{\Omega}$ = **From the Metadate CD package insert, "Metadate CD may be swallowed whole with the aid of liquids, or alternately, the capsule may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of applesauce and given immediately, and not stored for future use. Drinking some fluids e.g. water, should follow the intake of the sprinkles with applesauce. The capsules and the capsule contents must not be crushed or chewed."**

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12, if request is for dextroamphetamine solution, methylphenidate XR (generic Aptensio XR), methylphenidate transdermal patch (generic Daytrana), methylphenidate HCl ER [OSM] 45 mg or 63 mg tablets (generic Relexxii), or dexmethylphenidate HCl ER include generic only.

**QUANTITY LIMIT:** *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY:
  - **Adhansia XR:** 1 capsule per day
  - **Adzenys XR-ODT:** 1 tablet per day
  - **Azstarys:** 1 capsule per day
  - **Cotempla XR-ODT 8.6 and 17.3 mg Tablets:** 1 tablet per day
  - **Cotempla XR-ODT 25.9 mg Tablets:** 2 tablets per day
  - **Dextroamphetamine 5 mg/5 mL Solution:** 60 mL per day
  - **Dyanavel XR Tablets:** 1 tablet per day

- **Jornay PM:** 1 capsule per day
- **Methylphenidate HCl ER [OSM] 45 mg and 63 mg Tablets:** 1 tablet per day
- **Mydayis:** 1 tablet per day
- **Xelstrym:** 1 patch per day
- **Zenzedi 2.5 mg and 7.5 mg Tablets:** 1 tablet per day

If an exception is made, Adhansia XR, Adzenys XR-ODT, methylphenidate XR (generic Aptensio XR), Azstarys, Cotempla XR-ODT, methylphenidate transdermal patch (generic Daytrana), dexmethylphenidate HCl ER, dextroamphetamine solution, Dyanavel XR, Jornay PM, Mydayis, QuilliChew ER, Quillivant XR, methylphenidate HCl ER [OSM] 45mg, 63 mg (generic Relexxii), ~~or~~ Xelstrym, or Zenzedi 2.5 mg, 7.5 mg tablets will be paid for under the member's prescription drug benefit.

**Discussion:** No comments or questions.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

---

**MEDICAL BENEFIT POLICY UPDATES**

**Background:** The following policies were updated at the direction of DHS during PARP submission.

**Recommendation:**

**Policies updated at the direction of DHS during PARP submission process:**

**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~~

**Discussion:** No comments or questions.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

---

**QUARTERLY CASE AUDIT**

The Quarterly Case Audit for 2nd quarter 2023 was held on August 31st, 2023. There were no formulary changes proposed at this meeting. We will continue to look for opportunities to create more drug specific policies at future quarterly case audit meetings.

**Discussion:** No comments or questions.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

---

**COMMERCIAL/MARKETPLACE FORMULARY REMOVALS**

**Recommendation:** The following changes are recommended for the 2024 Commercial & Marketplace formularies. Unless otherwise specified, members will not be grandfathered.

| Drug Name & Dosage Form | Drug Identifier | Drug ID Value | Coverage Tier | PA Required (Y/N) | Quantity Limit (Y/N) | Quantity Limit Details | Rationale | Line of Business |
|---|---|---|---|---|---|---|---|---|
| ClomiPHENE Citrate 50 MG TAB | NDC | 33261096201 | 98 | N | N | | Obsolete | Both |
| Temixys 300-300 MG TAB | NDC | 72606000201 | 98 | N | N | | Obsolete | Both |
| Avandia TAB | GPI-12 | 276070601003 | 98 | N | N | | Obsolete. | Both |
| Dexilant CAP DR | GPI-12 | 492700200065 | 99 | N/A | Y | QL by ratio: 1/1 | Brand name product with generic available. | Both |
| Viibryd Oral Tablet | GPI-12 | 581200881003 | 99 | N | Y | 1 tablet/1 day | Brand name product with generic available. | Both |
| Latuda Oral Tablet | GPI-12 | 594000231003 | 99 | N | N | | Brand name product with generic available. | Both |
| Vyvanse | GPI-12 | 611000251001 | 99 | N | Y | 1/1 day | Brand name product with generic available. | Commercial only |
| Daytrana | GPI-12 | 614000200059 | 99 | N | N | | Brand name product with generic available. | Both |
| Cefaclor 125 MG/5ML RECON SUSP | GPI-14 | 022000400019 05 | 99 | N | N | | High cost generic. Alternative cephalosporins available. | Both |
| Cefaclor 250 MG/5ML RECON SUSP | GPI-14 | 022000400019 10 | 99 | N | N | | High cost generic. Alternative cephalosporins available. | Both |
| Cefaclor 375 MG/5ML RECON SUSP | GPI-14 | 022000400019 15 | 99 | N | N | | High cost generic. Alternative cephalosporins available. | Both |
| Cefditoren Pivoxil 200 MG TAB | GPI-14 | 023000452003 20 | 98 | N | N | | Obsolete | Both |
| Cefditoren Pivoxil 400 MG TAB | GPI-14 | 023000452003 40 | 98 | N | N | | Obsolete | Both |
| Fortaz 1 GM RECON SOLN | GPI-14 | 023000800021 10 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Fortaz 2 GM RECON SOLN | GPI-14 | 023000800021 17 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Doxycycline Monohydrate 75 MG CAP | GPI-14 | 04000020000107 | 99 | N | N | | High cost generic. Alternative tetracyclines available. | Both |
| Doxycycline Monohydrate 150 MG CAP | GPI-14 | 04000020000115 | 99 | N | N | | High cost generic. Alternative tetracyclines available. | Both |
| Doxycycline Hyclate 50 MG TAB | GPI-14 | 04000020100305 | 99 | N | N | | High cost generic. Alternative tetracyclines available. | Both |
| Doxycycline Hyclate 75 MG TAB | GPI-14 | 04000020100307 | 99 | N | N | | High cost generic. Alternative tetracyclines available. | Both |
| Doxycycline Hyclate 150 MG TAB | GPI-14 | 04000020100315 | 99 | N | N | | High cost generic. Alternative tetracyclines available. | Both |
| Doxycycline Hyclate 50 MG TAB DR | GPI-14 | 04000020100610 | 99 | N | N | | High cost generic. Alternative tetracyclines available. | Both |
| Doxycycline Hyclate 75 MG TAB DR | GPI-14 | 04000020100620 | 99 | N | N | | High cost generic. Alternative tetracyclines available. | Both |
| Doryx 80 MG TAB DR | GPI-14 | 04000020100624 | 99 | N | N | | High cost generic. Alternative tetracyclines available. | Both |
| Doxycycline Hyclate 100 MG TAB DR | GPI-14 | 04000020100630 | 99 | N | N | | High cost generic. Alternative tetracyclines available. | Both |
| Doxycycline Hyclate 150 MG TAB DR | GPI-14 | 04000020100640 | 99 | N | N | | High cost generic. Alternative tetracyclines available. | Both |
| Doxycycline Hyclate 200 MG TAB DR | GPI-14 | 04000020100650 | 99 | N | N | | High cost generic. Alternative tetracyclines available. | Both |
| Vibramycin 50 MG/5ML SYRUP | GPI-14 | 04000020201205 | 98 | N | N | | Obsolete. | Both |
| Tygacil 50 MG RECON SOLN | GPI-14 | 04350070002120 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Paser 4 GM PACKET | GPI-14 | 09000010003020 | 98 | N | N | | Obsolete. | Both |
| Rifamate 150-300 MG CAP | GPI-14 | 09990002100110 | 98 | N | N | | Obsolete. | Both |
| Rifater 50-120-300 MG TAB | GPI-14 | 09990003200310 | 98 | N | N | | Obsolete. | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AmBisome 50 MG RECON SUSP | GPI-14 | 11000010401920 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Prezista Oral Tablet 600 MG | GPI-14 | 12104520000325 | 99 | N | Y | 2 tablets/1 day | Brand name product with generic available. | Commercial only |
| Prezista Oral Tablet 800 MG | GPI-14 | 12104520000350 | 99 | N | Y | 1 tablet/1 day | Brand name product with generic available. | Both |
| Crixivan 200 MG CAP | GPI-14 | 12104530200120 | 98 | N | N | | Obsolete. | Both |
| Crixivan 400 MG CAP | GPI-14 | 12104530200140 | 98 | N | N | | Obsolete. | Both |
| Invirase 500 MG TAB | GPI-14 | 12104580200320 | 98 | N | N | | Obsolete. | Both |
| Aptivus 100 MG/ML SOLUTION | GPI-14 | 12104585002020 | 98 | N | N | | Obsolete. | Both |
| Videx 2 GM RECON SOLN | GPI-14 | 12105015002120 | 98 | N | N | | Obsolete. | Both |
| Didanosine 200 MG CAP DR | GPI-14 | 12105015006528 | 98 | N | N | | Obsolete | Both |
| Didanosine 250 MG CAP DR | GPI-14 | 12105015006535 | 98 | N | N | | Obsolete | Both |
| Didanosine 400 MG CAP DR | GPI-14 | 12105015006550 | 98 | N | N | | Obsolete | Both |
| Rescriptor 200 MG TAB | GPI-14 | 12109020200330 | 98 | N | N | | Obsolete. | Both |
| Trizivir Oral Tablet 300-150-300 MG | GPI-14 | 12109903200320 | 99 | N | Y | 2 tablets/1 day | Brand name product with generic available. | Commercial only |
| PegIntron 50 MCG/0.5ML KIT | GPI-14 | 12353060106410 | 98 | N | N | | Obsolete. | Both |
| Primsol 50 MG/5ML SOLUTION | GPI-14 | 16000055102020 | 98 | N | N | | Obsolete. | Both |
| Merrem 500 MG RECON SOLN | GPI-14 | 16150050002120 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Vancomycin HCl 250 MG RECON SOLN | GPI-14 | 16280080102105 | 98 | N | N | | Obsolete | Both |
| AstraZeneca COVID-19 Vaccine 0.5 ML SUSPENSION | GPI-14 | 17100002101820 | 98 | N | N | | FDA Approval Withdrawn | Both |
| Tetanus-Diphtheria Toxoids Td 2-2 LF/0.5ML SUSPENSION | GPI-14 | 18990002201805 | 0 | N | N | | Update age limit to 7-999 | Both |
| Carimune NF 6 GM RECON SOLN | GPI-14 | 19100020102125 | 98 | N | N | | Obsolete. | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Carimune NF 12 GM RECON SOLN | GPI-14 | 1910002010 2135 | 98 | N | N | | Obsolete. | Both |
| Treanda Intravenous Solution Reconstituted 25 MG | GPI-14 | 2110000910 2110 | 99 | N | N | | Brand name product with generic available. | Both |
| Treanda Intravenous Solution Reconstituted 100 MG | GPI-14 | 2110000910 2120 | 99 | N | N | | Brand name product with generic available. | Both |
| Pepaxto 20 MG RECON SOLN | GPI-14 | 2110104210 2120 | 98 | N | N | | Obsolete. | Both |
| Erwinaze 10000 UNIT RECON SOLN | GPI-14 | 2125001040 2125 | 98 | N | N | | Obsolete. | Both |
| Arranon Intravenous Solution 5 MG/ML | GPI-14 | 2130005200 2020 | 99 | N | N | | Brand name product with generic available. | Both |
| Alimta Intravenous Solution Reconstituted 100 MG | GPI-14 | 2130005310 2110 | 99 | N | N | | Brand name product with generic available. | Both |
| Alimta Intravenous Solution Reconstituted 500 MG | GPI-14 | 2130005310 2120 | 99 | N | N | | Brand name product with generic available. | Both |
| Iressa Oral Tablet 250 MG | GPI-14 | 2136003000 0320 | 99 | N | Y | 30 tablets/30 days | Brand name product with generic available. | Commercial only |
| Depo-Provera 400 MG/ML SUSPENSION | GPI-14 | 2140401010 1840 | 98 | N | N | | Obsolete. | Both |
| Farydak 10 MG CAP | GPI-14 | 2153155010 0120 | 98 | N | N | | FDA Approval Withdrawn | Both |
| Farydak 15 MG CAP | GPI-14 | 2153155010 0130 | 98 | N | N | | FDA Approval Withdrawn | Both |
| Farydak 20 MG CAP | GPI-14 | 2153155010 0140 | 98 | N | N | | FDA Approval Withdrawn | Both |
| Istodax (Overfill) Intravenous Solution Reconstituted 10 MG | GPI-14 | 2153156000 2120 | 99 | N | N | | Brand name product with generic available. | Both |
| NexAVAR Oral Tablet 200 MG | GPI-14 | 2153306040 0320 | 99 | N | Y | 120 tablets/30 days | Brand name product with generic available. | Commercial only |
| Ukoniq 200 MG TAB | GPI-14 | 2153308040 0320 | 98 | N | N | | FDA Approval Withdrawn | Both |
| Velcade Injection Solution Reconstituted 3.5 MG | GPI-14 | 2153601500 2120 | 99 | N | N | | Brand name product with generic available. | Both |
| Intron A 6000000 UNIT/ML SOLUTION | GPI-14 | 2170006020 2022 | 98 | N | N | | Obsolete. | Both |
| Intron A 10000000 | GPI-14 | 2170006020 2030 | 98 | N | N | | Obsolete. | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| UNIT/ML SOLUTION | | | | | | | | |
| SOLU-medrol 1000 MG RECON SOLN | GPI-14 | 22100030202120 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Striant 30 MG MISC | GPI-14 | 23100030006320 | 98 | N | N | | Obsolete. | Both |
| Androderm 2 MG/24HR PATCH 24HR | GPI-14 | 23100030008503 | 99 | N | N | | Brand name testosterone replacement. Generic testosterone formulations available. | Both |
| Androderm 4 MG/24HR PATCH 24HR | GPI-14 | 23100030008510 | 99 | N | N | | Brand name testosterone replacement. Generic testosterone formulations available. | Both |
| Anadrol-50 50 MG TAB | GPI-14 | 23200050000320 | 98 | N | N | | Obsolete. | Both |
| Ogestrel 0.5-50 MG-MCG TAB | GPI-14 | 25990002900320 | 98 | N | N | | Obsolete | Both |
| TOLBUTamide 500 MG TAB | GPI-14 | 27200060000310 | 98 | N | N | | Obsolete | Both |
| Onglyza Oral Tablet 2.5 MG | GPI-14 | 27550065100320 | 99 | N | Y | 1 tablet/1 day | Brand name product with generic available. | Commercial only |
| Onglyza Oral Tablet 5 MG | GPI-14 | 27550065100330 | 99 | N | Y | 1 tablet/1 day | Brand name product with generic available. | Commercial only |
| Kombiglyze XR Oral Tablet Extended Release 24 Hour 2.5-1000 MG | GPI-14 | 27992502607520 | 99 | N | Y | 2 tablets/1 day | Brand name product with generic available. | Commercial only |
| Kombiglyze XR Oral Tablet Extended Release 24 Hour 5-500 MG | GPI-14 | 27992502607530 | 99 | N | Y | 1 tablet/1 day | Brand name product with generic available. | Commercial only |
| Kombiglyze XR Oral Tablet Extended Release 24 Hour 5-1000 MG | GPI-14 | 27992502607540 | 99 | N | Y | 1 tablet/1 day | Brand name product with generic available. | Commercial only |
| Nature-Throid 16.25 MG TAB | GPI-14 | 28100050000308 | 98 | N | N | | Obsolete/Unapproved Drug | Both |
| Adthyza 16.25 MG TAB | GPI-14 | 28100050000308 | 98 | N | N | | Obsolete/Unapproved Drug | Both |
| Nature-Throid 32.5 MG TAB | GPI-14 | 28100050000313 | 98 | N | N | | Obsolete/Unapproved Drug | Both |
| Nature-Throid 48.75 MG TAB | GPI-14 | 28100050000314 | 98 | N | N | | Obsolete/Unapproved Drug | Both |
| Nature-Throid 65 MG TAB | GPI-14 | 28100050000318 | 98 | N | N | | Obsolete/Unapproved Drug | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Nature-Throid 81.25 MG TAB | GPI-14 | 28100050000319 | 98 | N | N | | Obsolete/Unapproved Drug | Both |
| Nature-Throid 97.5 MG TAB | GPI-14 | 28100050000322 | 98 | N | N | | Obsolete/Unapproved Drug | Both |
| Nature-Throid 113.75 MG TAB | GPI-14 | 28100050000324 | 98 | N | N | | Obsolete/Unapproved Drug | Both |
| Nature-Throid 130 MG TAB | GPI-14 | 28100050000328 | 98 | N | N | | Obsolete/Unapproved Drug | Both |
| Nature-Throid 162.5 MG TAB | GPI-14 | 28100050000329 | 98 | N | N | | Obsolete/Unapproved Drug | Both |
| Nature-Throid 195 MG TAB | GPI-14 | 28100050000333 | 98 | N | N | | Obsolete/Unapproved Drug | Both |
| Nature-Throid 260 MG TAB | GPI-14 | 28100050000337 | 98 | N | N | | Obsolete/Unapproved Drug | Both |
| Nature-Throid 325 MG TAB | GPI-14 | 28100050000345 | 98 | N | N | | Obsolete/Unapproved Drug | Both |
| Nature-Throid 146.25 MG TAB | GPI-14 | 28100050000370 | 98 | N | N | | Obsolete/Unapproved Drug | Both |
| ClomiPHENE Citrate 50 MG TAB | GPI-14 | 30066030100305 | 98 | N | N | | Obsolete/Unapproved Drug | Both |
| ClomiPHENE Citrate 50 MG TAB | GPI-14 | 30066030100305 | 98 | N | N | | Obsolete/Unapproved Drug | Both |
| Lupaneta Pack 3.75 & 5 MG KIT | GPI-14 | 30089902506420 | 98 | N | N | | Obsolete. | Both |
| Lupaneta Pack 11.25 & 5 MG KIT | GPI-14 | 30089902506440 | 98 | N | N | | Obsolete. | Both |
| Humatrope 5 MG RECON SOLN | GPI-14 | 30100020002120 | 98 | N | N | | Obsolete. | Both |
| Octreotide Acetate 200 MCG/ML SOLUTION | GPI-14 | 30170070102015 | 98 | N | N | | Obsolete. | Both |
| Cystadane POWDER | GPI-14 | 30904520002920 | 99 | N | N | | Brand name product with generic available. | Both |
| Cystadane POWDER | GPI-14 | 30904520002920 | 99 | N | N | | Brand name product with generic available. | Both |
| Dilatrate-SR 40 MG CAP ER | GPI-14 | 32100020000205 | 98 | N | N | | Obsolete. | Both |
| Cardizem LA 120 MG TAB ER 24H | GPI-14 | 34000010107525 | 99 | N | N | | Brand name product with generic available. | Both |
| Nymalize 60 MG/20ML SOLUTION | GPI-14 | 34000022002050 | 98 | N | N | | Obsolete. | Both |
| Nisoldipine ER 8.5 MG TAB ER 24H | GPI-14 | 34000024007508 | 99 | N | N | | High cost generic. Alternative calcium channel blockers available. | Both |
| Nisoldipine ER 17 MG TAB ER 24H | GPI-14 | 34000024007517 | 99 | N | N | | High cost generic. Alternative | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | calcium channel blockers available. | |
| Nisoldipine ER 20 MG TAB ER 24H | GPI-14 | 34000024007520 | 99 | N | N | | High cost generic. Alternative calcium channel blockers available. | Both |
| Nisoldipine ER 25.5 MG TAB ER 24H | GPI-14 | 34000024007526 | 99 | N | N | | High cost generic. Alternative calcium channel blockers available. | Both |
| Nisoldipine ER 30 MG TAB ER 24H | GPI-14 | 34000024007530 | 99 | N | N | | High cost generic. Alternative calcium channel blockers available. | Both |
| Nisoldipine ER 34 MG TAB ER 24H | GPI-14 | 34000024007535 | 99 | N | N | | High cost generic. Alternative calcium channel blockers available. | Both |
| Nisoldipine ER 40 MG TAB ER 24H | GPI-14 | 34000024007540 | 99 | N | N | | High cost generic. Alternative calcium channel blockers available. | Both |
| Eprosartan Mesylate 600 MG TAB | GPI-14 | 36150024200330 | 98 | N | N | | Obsolete | Both |
| Propranolol-HCTZ 40-25 MG TAB | GPI-14 | 36992002400310 | 98 | N | N | | Obsolete | Both |
| Propranolol-HCTZ 80-25 MG TAB | GPI-14 | 36992002400320 | 98 | N | N | | Obsolete | Both |
| Methyldopa-Hydrochlorothiazide 250-15 MG TAB | GPI-14 | 36995002700310 | 98 | N | N | | Obsolete | Both |
| Methyldopa-Hydrochlorothiazide 250-25 MG TAB | GPI-14 | 36995002700320 | 98 | N | N | | Obsolete | Both |
| Adrenalin 1 MG/ML SOLUTION | GPI-14 | 38900040002030 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Fenofibric Acid 35 MG TAB | GPI-14 | 39200024000320 | 99 | N | N | | High cost generic. Alternative fenofibrates available. | Both |
| Fenofibric Acid 105 MG TAB | GPI-14 | 39200024000340 | 99 | N | N | | High cost generic. Alternative fenofibrates available. | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Fenofibrate 50 MG CAP | GPI-14 | 39200025000110 | 99 | N | N | | High cost generic. Alternative fenofibrates available. | Both |
| Fenofibrate 150 MG CAP | GPI-14 | 39200025000124 | 99 | N | N | | High cost generic. Alternative fenofibrates available. | Both |
| Fenofibrate 40 MG TAB | GPI-14 | 39200025000308 | 99 | N | N | | High cost generic. Alternative fenofibrates available. | Both |
| Fenofibrate 120 MG TAB | GPI-14 | 39200025000322 | 99 | N | N | | High cost generic. Alternative fenofibrates available. | Both |
| Zypitamag 1 MG TAB | GPI-14 | 39400058300320 | 98 | N | N | | Obsolete. | Both |
| Juxtapid 40 MG CAP | GPI-14 | 39480050200160 | 98 | N | N | | Obsolete. | Both |
| Juxtapid 60 MG CAP | GPI-14 | 39480050200170 | 98 | N | N | | Obsolete. | Both |
| Desloratadine 5 MG TAB | GPI-14 | 41550021000320 | 99 | N | N | | Available over-the-counter. | Both |
| Levocetirizine Dihydrochloride 5 MG TAB | GPI-14 | 41550027100320 | 99 | N | N | | Available over-the-counter. | Both |
| Levocetirizine Dihydrochloride 2.5 MG/5ML SOLUTION | GPI-14 | 41550027102020 | 99 | N | N | | Available over-the-counter. | Both |
| Triamcinolone Acetonide 55 MCG/ACT AEROSOL | GPI-14 | 42200060103210 | 99 | N | N | | Available over-the-counter. | Both |
| Clarinex-D 12 Hour 2.5-120 MG TAB ER 12H | GPI-14 | 43993002627420 | 98 | N | N | | Obsolete. | Both |
| Clarinex-D 12 Hour 2.5-120 MG TAB ER 12H | GPI-14 | 43993002627420 | 99 | N | N | | Over-the-counter antihistamine combinations available. | Both |
| Glenmax PEB DM 5-2-10 MG/5ML LIQUID | GPI-14 | 43995803080920 | 99 | N | N | | Available over-the-counter. | Both |
| LoHist-DM 5-2-10 MG/5ML SYRUP | GPI-14 | 43995803081220 | 99 | N | N | | Available over-the-counter. | Both |
| Albuterol Sulfate ER 4 MG TAB ER 12H | GPI-14 | 44201010107410 | 98 | N | N | | Obsolete | Both |
| Albuterol Sulfate ER 8 MG TAB ER 12H | GPI-14 | 44201010107420 | 98 | N | N | | Obsolete | Both |
| ProAir RespiClick 108 (90 Base) MCG/ACT AER POW BA | GPI-14 | 44201010108020 | 99 | N | N | | Brand name albuterol inhaler. Generic albuterol inhalers available. | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| ProAir Digihaler 108 (90 Base) MCG/ACT AER POW BA | GPI-14 | 44201010128020 | 99 | N | N | | Brand name albuterol inhaler. Generic albuterol inhalers available. | Both |
| Isuprel 0.2 MG/ML SOLUTION | GPI-14 | 44201040102005 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Arcapta Neohaler 75 MCG CAP | GPI-14 | 44201042200120 | 98 | N | N | | Obsolete. | Both |
| Metaproterenol Sulfate 10 MG/5ML SYRUP | GPI-14 | 44201050201205 | 98 | N | N | | Obsolete | Both |
| Daliresp Oral Tablet 250 MCG | GPI-14 | 44450065000310 | 99 | N | N | | Brand name product with generic available. | Both |
| Daliresp Oral Tablet 500 MCG | GPI-14 | 44450065000320 | 99 | N | N | | Brand name product with generic available. | Both |
| Prepopik 10-3.5-12 MG-GM-GM PACKET | GPI-14 | 46992003453020 | 98 | N | N | | Obsolete. | Both |
| Suprep Bowel Prep Kit Oral Solution 17.5-3.13-1.6 GM/177ML | GPI-14 | 46992003602020 | 99 | N | N | | Brand name product with generic available. | Both |
| Motofen 1-0.025 MG TAB | GPI-14 | 47100015100310 | 99 | N | N | | Brand name antidiarrheal. Diphenoxylate/atropine available. | Both |
| Propantheline Bromide 15 MG TAB | GPI-14 | 49102070100310 | 98 | N | N | | Obsolete | Both |
| RaNITidine HCl 150 MG CAP | GPI-14 | 49200020100105 | 98 | N | N | | Obsolete | Both |
| RaNITidine HCl 300 MG CAP | GPI-14 | 49200020100110 | 98 | N | N | | Obsolete | Both |
| RaNITidine HCl 150 MG TAB | GPI-14 | 49200020100305 | 98 | N | N | | Obsolete | Both |
| RaNITidine HCl 300 MG TAB | GPI-14 | 49200020100310 | 98 | N | N | | Obsolete | Both |
| RaNITidine HCl 75 MG/5ML SYRUP | GPI-14 | 49200020101210 | 98 | N | N | | Obsolete | Both |
| Zantac 50 MG/2ML SOLUTION | GPI-14 | 49200020102006 | 98 | N | N | | Obsolete. | Both |
| AcipHex Sprinkle 5 MG CAP SPRINK | GPI-14 | 49270076106805 | 98 | N | N | | Obsolete. | Both |
| Zuplenz 4 MG FILM | GPI-14 | 50250065008220 | 98 | N | N | | Obsolete. | Both |
| Zuplenz 8 MG FILM | GPI-14 | 50250065008240 | 98 | N | N | | Obsolete. | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Emend 150 MG RECON SOLN | GPI-14 | 50280035102130 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Metoclopramide HCl 10 MG TAB DISP | GPI-14 | 52300020107220 | 98 | N | N | | Obsolete | Both |
| Pentasa Oral Capsule Extended Release 500 MG | GPI-14 | 52500030000220 | 99 | N | N | | Brand name product with generic available. | Both |
| Toviaz Oral Tablet Extended Release 24 Hour 4 MG | GPI-14 | 54100020207520 | 99 | N | N | | Brand name product with generic available. | Both |
| Toviaz Oral Tablet Extended Release 24 Hour 8 MG | GPI-14 | 54100020207530 | 99 | N | N | | Brand name product with generic available. | Both |
| AVC Vaginal 15 % CREAM | GPI-14 | 55100070003705 | 98 | N | N | | Obsolete. | Both |
| Viibryd Starter Pack 10 & 20 MG KIT | GPI-14 | 58120088106410 | 99 | N | N | | Generic vilazodone available. | Both |
| Maprotiline HCl 25 MG TAB | GPI-14 | 58300010100305 | 98 | N | N | | Obsolete | Both |
| Maprotiline HCl 50 MG TAB | GPI-14 | 58300010100310 | 98 | N | N | | Obsolete | Both |
| Maprotiline HCl 75 MG TAB | GPI-14 | 58300010100315 | 98 | N | N | | Obsolete | Both |
| Lithium 8 MEQ/5ML SOLUTION | GPI-14 | 59500010002010 | 98 | N | N | | Obsolete | Both |
| Aubagio 7 MG TAB | GPI-14 | 62404070000320 | 99 | N | Y | 30 tablets/30 days | Brand name product with generic available. | Both |
| Aubagio 14 MG TAB | GPI-14 | 62404070000330 | 99 | N | Y | 30 tablets/30 days | Brand name product with generic available. | Both |
| Gilenya Oral Capsule 0.5 MG | GPI-14 | 62407025100120 | 99 | N | N | | Brand name product with generic available. | Both |
| Gralise 450 MG TAB | GPI-14 | 62540030000325 | 99 | N | N | | Generic gabapentin available. | Both |
| Gralise 750 MG TAB | GPI-14 | 62540030000345 | 99 | N | N | | Generic gabapentin available. | Both |
| Gralise 900 MG TAB | GPI-14 | 62540030000360 | 99 | N | N | | Generic gabapentin available. | Both |
| Abstral 400 MCG SL TAB | GPI-14 | 65100025100730 | 98 | N | N | | Obsolete. | Both |
| Abstral 600 MCG SL TAB | GPI-14 | 65100025100740 | 98 | N | N | | Obsolete. | Both |
| Abstral 800 MCG SL TAB | GPI-14 | 65100025100750 | 98 | N | N | | Obsolete. | Both |
| TraMADol HCl ER 150 MG CAP ER 24H | GPI-14 | 65100095107075 | 98 | N | N | | Obsolete | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| TraMADol HCl ER 150 MG CAP ER 24H | GPI-14 | 65100095107075 | 98 | N | N | | Obsolete | Both |
| Probuphine Implant Kit 74.2 MG IMPLANT | GPI-14 | 65200010102320 | 98 | N | N | | Obsolete. | Both |
| Oxycodone-Aspirin 4.8355-325 MG TAB | GPI-14 | 65990002220340 | 98 | N | N | | Obsolete | Both |
| Oxycodone-Ibuprofen 5-400 MG TAB | GPI-14 | 65990002260320 | 98 | N | N | | Obsolete | Both |
| Flurbiprofen 50 MG TAB | GPI-14 | 66100012000310 | 98 | N | N | | Obsolete | Both |
| Flurbiprofen 50 MG TAB | GPI-14 | 66100012000310 | 99 | N | N | | High cost generic. Alternative NSAIDs available. | Both |
| Ketoprofen 25 MG CAP | GPI-14 | 66100035000103 | 99 | N | N | | High cost generic. Alternative NSAIDs available. | Both |
| Ketoprofen 25 MG CAP | GPI-14 | 66100035000103 | 98 | N | N | | Obsolete | Both |
| Ketoprofen 50 MG CAP | GPI-14 | 66100035000105 | 99 | N | N | | High cost generic. Alternative NSAIDs available. | Both |
| Ketoprofen 75 MG CAP | GPI-14 | 66100035000110 | 98 | N | N | | Obsolete | Both |
| Ketoprofen ER 200 MG CAP ER 24H | GPI-14 | 66100035007030 | 99 | N | N | | High cost generic. Alternative NSAIDs available. | Both |
| Tolmetin Sodium 400 MG CAP | GPI-14 | 66100090100105 | 99 | N | N | | High cost generic. Alternative NSAIDs available. | Both |
| Tolmetin Sodium 600 MG TAB | GPI-14 | 66100090100320 | 99 | N | N | | High cost generic. Alternative NSAIDs available. | Both |
| Colchicine 0.6 MG CAP | GPI-14 | 68000020000120 | 99 | N | N | | High cost generic. Colchicine tablets available. | Both |
| Xylocaine-MPF 2 % SOLUTION | GPI-14 | 69100040102021 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Gabapentin 25 MG TAB | GPI-14 | 72600030000303 | 99 | N | N | | High cost generic. Gabapentin capsules available. | Both |
| Gabapentin 50 MG TAB | GPI-14 | 72600030000305 | 99 | N | N | | High cost generic. Gabapentin capsules available. | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Vimpat Oral Solution 10 MG/ML | GPI-14 | 72600036002060 | 99 | N | N | | Brand name product with generic available. | Both |
| LamoTRIgine 25 & 50 & 100 MG KIT | GPI-14 | 72600040006460 | 99 | N | N | | High cost generic. Lamotrigine tablets available. | Both |
| LaMICtal XR 21 x 25 MG & 7 x 50 MG KIT | GPI-14 | 72600040006470 | 99 | N | N | | Generic lamotrigine XR available. | Both |
| LaMICtal XR 25 & 50 & 100 MG KIT | GPI-14 | 72600040006475 | 99 | N | N | | Generic lamotrigine XR available. | Both |
| LaMICtal XR 50 & 100 & 200 MG KIT | GPI-14 | 72600040006480 | 99 | N | N | | Generic lamotrigine XR available. | Both |
| Trokendi XR Oral Capsule Extended Release 24 Hour | GPI-14 | 72600075007020 | 99 | N | N | | Brand name product with generic available. | Commercial only |
| Lioresal 40 MG/20ML SOLUTION | GPI-14 | 75100010002050 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Metaxalone 400 MG TAB | GPI-14 | 75100060000310 | 99 | N | N | | High cost generic. Alternative skeletal muscle relaxants available. | Both |
| Carisoprodol-Aspirin 200-325 MG TAB | GPI-14 | 75990002100310 | 98 | N | N | | Obsolete | Both |
| Carisoprodol-Aspirin 200-325 MG TAB | GPI-14 | 75990002100310 | 98 | N | N | | Obsolete | Both |
| Tizanidine Comfort Pac 4 MG MISC | GPI-14 | 75997502706320 | 98 | N | N | | Obsolete. | Both |
| Guanidine HCl 125 MG TAB | GPI-14 | 76000030100310 | 98 | N | N | | Obsolete | Both |
| Vitamin D3 250 MCG (10000 UT) CAP | GPI-14 | 77202032000160 | 98 | N | N | | OTC product. | Both |
| Prenatabs Rx 29-1 MG TAB | GPI-14 | 78512010000330 | 98 | N | N | | Remove OTC products only. | Both |
| Prenatabs FA 29-1 MG TAB | GPI-14 | 78512015000332 | 98 | N | N | | Remove OTC products only. | Both |
| Vinate Care 40-1 MG CHEW TAB | GPI-14 | 78512050000540 | 98 | N | N | | Remove OTC products only. | Both |
| Obtrex DHA 29-1 & 387 MG MISC | GPI-14 | 78512093006330 | 98 | N | N | | Remove OTC products only. | Both |
| Obstetrix DHA 29-1 & 350 MG MISC | GPI-14 | 78516015006320 | 98 | N | N | | Remove OTC products only. | Both |
| Cadeau DHA 29-0.4-0.8-375 MG CAP | GPI-14 | 78516022000135 | 98 | N | N | | Remove OTC products only. | Both |
| Sodium Acetate 2 MEQ/ML SOLUTION | GPI-14 | 79050010002005 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Calcium Gluconate 10 % SOLUTION | GPI-14 | 79100030002010 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Ionosol-MB in D5W SOLUTION | GPI-14 | 79993002782010 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| levOCARNitine 250 MG CAP | GPI-14 | 80303093100120 | 98 | N | N | | OTC product. | Both |
| levOCARNitine L-Tartrate 250 MG CAP | GPI-14 | 80303093600115 | 98 | N | N | | OTC product. | Both |
| Angiomax 250 MG RECON SOLN | GPI-14 | 83334020202120 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Bevyxxa 40 MG CAP | GPI-14 | 83370018200120 | 98 | N | N | | Obsolete. | Both |
| Bevyxxa 80 MG CAP | GPI-14 | 83370018200140 | 98 | N | N | | Obsolete. | Both |
| Ultomiris 300 MG/30ML SOLUTION | GPI-14 | 85805080202020 | 98 | N | N | | Obsolete. | Both |
| LevoFLOXacin 0.5 % SOLUTION | GPI-14 | 86101036002020 | 98 | N | N | | Obsolete. | Both |
| FML 0.1 % OINTMENT | GPI-14 | 86300020004205 | 98 | N | N | | Obsolete. | Both |
| Pred-G S.O.P. 0.3-0.6 % OINTMENT | GPI-14 | 86309902154210 | 98 | N | N | | Obsolete. | Both |
| Zioptan Ophthalmic Solution 0.0015 % | GPI-14 | 86330065002025 | 99 | N | N | | Brand name product with generic available. | Both |
| Atropine Sulfate 0.01 % SOLUTION | GPI-14 | 86350010102003 | 98 | N | N | | Non-FDA approved product from compounding facility. | Both |
| Restasis Ophthalmic Emulsion 0.05 % | GPI-14 | 86720020001620 | 99 | N | N | | Brand name product with generic available. | Both |
| Lastacaft 0.25 % SOLUTION | GPI-14 | 86802004002020 | 98 | N | N | | OTC product. | Both |
| BP Wash 2.5 % LIQUID | GPI-14 | 90050010000903 | 98 | N | N | | OTC product. | Both |
| Benzoyl Peroxide Cleanser 6 % LIQUID | GPI-14 | 90050010000906 | 98 | N | N | | Obsolete | Both |
| Tretinoin Microsphere 0.04 % GEL | GPI-14 | 90050030204015 | 99 | N | N | | High cost generic. Alternative tretinoin formulations available. | Both |
| Tretinoin Microsphere 0.1 % GEL | GPI-14 | 90050030204030 | 99 | N | N | | High cost generic. Alternative tretinoin | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | formulations available. | |
| Clindamycin Phosphate 1 % FOAM | GPI-14 | 90051010103905 | 99 | N | N | | High cost generic. Alternative clindamycin formulations available. | Both |
| Brimonidine Tartrate External Gel 0.33 % | GPI-14 | 90060020104020 | 3 | Y | Y | 30 grams/fill | Add QL to generic product. | Both |
| Mirvaso External Gel 0.33 % | GPI-14 | 90060020104020 | 99 | N | N | | Brand name product with generic available. | Both |
| Penciclovir External Cream 1 % | GPI-14 | 90060020104020 | 3 | Y | Y | 5 grams/fill | Add QL to generic product. | Both |
| Naftifine HCl 1 % GEL | GPI-14 | 90150078004010 | 98 | N | N | | Obsolete. | Both |
| Naftin 2 % GEL | GPI-14 | 90150078004030 | 99 | N | N | | Brand name product with generic available. | Both |
| Exoderm 25-1 % LOTION | GPI-14 | 90159902304120 | 99 | N | N | | Brand name antifungal. Generic antifungal formulations available. | Both |
| Tazorac 0.05 % CREAM | GPI-14 | 90250070003720 | 99 | N | N | | Tazarotene 0.05% gel available as well as alternate strengths of generic tazarotene. | Both |
| Tazorac External Gel 0.05 % | GPI-14 | 90250070004020 | 99 | N | N | | Brand name product with generic available. | Both |
| Tazorac External Gel 0.1 % | GPI-14 | 90250070004030 | 99 | N | N | | Brand name product with generic available. | Both |
| Denavir External Cream 1 % | GPI-14 | 90350060003720 | 99 | N | N | | Brand name product with generic available. | Both |
| Fluoroplex 1 % CREAM | GPI-14 | 90372030003710 | 98 | N | N | | Obsolete. | Both |
| Picato 0.015 % GEL | GPI-14 | 90378035204020 | 98 | N | N | | Obsolete. | Both |
| Picato 0.05 % GEL | GPI-14 | 90378035204040 | 98 | N | N | | Obsolete. | Both |
| Silver Nitrate 10 % SOLUTION | GPI-14 | 90500040002010 | 98 | N | N | | Obsolete. | Both |
| Silver Nitrate 25 % SOLUTION | GPI-14 | 90500040002025 | 98 | N | N | | Obsolete. | Both |
| Silver Nitrate 50 % SOLUTION | GPI-14 | 90500040002050 | 98 | N | N | | Obsolete. | Both |
| Clocortolone Pivalate 0.1 % CREAM | GPI-14 | 90550030103705 | 99 | N | N | | Formulary removal | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | approved at July 2022 P&T. | |
| Diflorasone Diacetate 0.05 % CREAM | GPI-14 | 90550050103705 | 99 | N | N | | High cost generic. Alternative topical steroids available. | Both |
| Halog 0.1 % Ointment | GPI-14 | 90550070004205 | 99 | N | N | | High cost topical steroid. Alternative topical steroids available. | Both |
| Hydrocortisone 1 % LOTION | GPI-14 | 90550075004115 | 98 | N | N | | OTC product. | Both |
| Advanced Allergy Collection 2.5 % KIT | GPI-14 | 90550075006430 | 99 | N | N | | High cost hydrocortisone kit. Alternative topical steroids available. | Both |
| Prednicarbate 0.1 % CREAM | GPI-14 | 90550083003710 | 98 | N | N | | Obsolete. | Both |
| Salicylic Acid-Cleanser 6 % (Lotion) KIT | GPI-14 | 90750030406430 | 98 | N | N | | Obsolete. | Both |
| Ulesfia 5 % LOTION | GPI-14 | 90900004004120 | 98 | N | N | | Obsolete. | Both |
| Regenecare 2 % GEL | GPI-14 | 90949903654020 | 98 | N | N | | Wound care products excluded from prescription drug formulary. | Both |
| Narcan 4 MG/0.1ML LIQUID | GPI-14 | 93400020100920 | 99 | N | N | | Brand name product with generic available. | Both |
| Cellulose POWDER | GPI-14 | 96465064642900 | 98 | N | N | | Compounding excipient. | Both |
| Cellulose CRYSTALS | GPI-14 | 96465064643800 | 98 | N | N | | Compounding excipient. | Both |
| HYDROXYprogesterone Caproate POWDER | GPI-14 | 96568812502900 | 98 | N | N | | Bulk compounding ingredient. | Both |
| Nystatin POWDER | GPI-14 | 96688858002900 | 98 | N | N | | Bulk compounding ingredient. | Both |
| Autoject 2 MISC/Inject-Ease MISC/NovoPen Echo DEVICE | GPI-14 | 97051050106300 | 99 | N | N | | Non-preferred insulin delivery device. | Both |
| InPen/CeQur Simplicity 2U DEVICE | GPI-14 | 97051050126220 | 99 | N | N | | Non-preferred insulin delivery device. | Both |
| OneTouch Solutions Starter Kit w/ Well Device KIT | GPI-14 | 97202010006420 | 95 | N | N | | Pending P&T Review | Both |
| Amielle Restore Vag Exercisers MISC | GPI-14 | 97700000000000 | 98 | N | N | | Durable medical equipment. | Both |
| Pegasys ProClick 180 MCG/0.5ML SOLN A-INJ | GPI-14 | 1235306005D540 | 98 | N | N | | Obsolete. | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Afluria/Fluzone Quadrivalent 0.25 ML SUSP PRSYR | GPI-14 | 1710002025 E610 | 98 | N | N | | Obsolete 0.25 ML prefilled syringes discontinued by manufacturer | Both |
| Fluad 0.5 ML SUSP PRSYR | GPI-14 | 1710002046 E620 | 98 | N | N | | Obsolete | Both |
| Xpovio (40 MG Once Weekly) 20 MG TAB THPK | GPI-14 | 2156006000 B712 | 98 | N | N | | Obsolete | Both |
| Xpovio (40 MG Twice Weekly) 20 MG TAB THPK | GPI-14 | 2156006000 B715 | 98 | N | N | | Obsolete | Both |
| Xpovio (100 MG Once Weekly) 20 MG TAB THPK | GPI-14 | 2156006000 B730 | 98 | N | N | | Obsolete | Both |
| Xpovio (80 MG Once Weekly) 20 MG TAB THPK | GPI-14 | 2156006000 B740 | 98 | N | N | | Obsolete | Both |
| Xpovio (60 MG Once Weekly) 20 MG TAB THPK | GPI-14 | 2156006000 B750 | 98 | N | N | | Obsolete | Both |
| Dexamethasone 1.5 MG (21) TAB THPK | GPI-14 | 2210002000 B720 | 99 | N | N | | High cost dexamethasone therapy pack. Dexamethasone tablets available. | Both |
| TaperDex 7-Day 1.5 MG (27) TAB THPK | GPI-14 | 2210002000 B722 | 99 | N | N | | High cost dexamethasone therapy pack. Dexamethasone tablets available. | Both |
| Dexamethasone 1.5 MG (35) TAB THPK | GPI-14 | 2210002000 B725 | 99 | N | N | | High cost dexamethasone therapy pack. Dexamethasone tablets available. | Both |
| Dexamethasone 1.5 MG (51) TAB THPK | GPI-14 | 2210002000 B730 | 99 | N | N | | High cost dexamethasone therapy pack. Dexamethasone tablets available. | Both |
| Millipred DP 5 MG (21) TAB THPK | GPI-14 | 2210004000 B720 | 98 | N | N | | Obsolete. | Both |
| Millipred DP 12-Day 5 MG (48) TAB THPK | GPI-14 | 2210004000 B730 | 98 | N | N | | Obsolete. | Both |
| Atropine Sulfate 1 MG/10ML SOLN PRSYR | GPI-14 | 4910101010 E510 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Humira 20 MG/0.4ML PREF SY KT | GPI-14 | 6627001500 F810 | 98 | N | N | | Obsolete. | Both |
| SUMAtriptan Succinate 6 MG/0.5ML SOLN PRSYR | GPI-14 | 6740607010 E520 | 98 | N | N | | Obsolete. | Both |
| Lidocaine HCl 0.5 MG J-INJ | GPI-14 | 6910004010 D720 | 98 | N | N | | Obsolete. | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Xcopri (250 MG Daily Dose) 50 & 200 MG TAB THPK | GPI-14 | 7212001000 B735 | 98 | N | N | | Obsolete. | Both |
| Vitafol FE+ 90-1-200 & 50 MG CAP THPK | GPI-14 | 7851608000 B260 | 98 | N | N | | Obsolete. | Both |
| Dotarem 5 MMOL/10ML SOLN PRSYR | GPI-14 | 9450003710 E510 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Dotarem 7.5 MMOL/15ML SOLN PRSYR | GPI-14 | 9450003710 E515 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Dotarem 10 MMOL/20ML SOLN PRSYR | GPI-14 | 9450003710 E520 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| RomiDEPsin 10 MG RECON SOLN | GPI-14 | 2153156000 2120 | 98 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Noxafil Oral Suspension 40 MG/ML | GPI-14 | 1140706000 1820 | 99 | N | Y | 20 mL/1 day | Brand name product with generic available. Medical benefit. | Both |
| Divigel 0.25 MG/0.25GM GEL | GPI-14 | 2400003500 4035 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Divigel 0.5 MG/0.5GM GEL | GPI-14 | 2400003500 4040 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Divigel 0.75 MG/0.75GM GEL | GPI-14 | 2400003500 4042 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Divigel 1 MG/GM GEL | GPI-14 | 2400003500 4045 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Divigel 1.25 MG/1.25GM GEL | GPI-14 | 2400003500 4050 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Esbriet 267 MG TAB | GPI-14 | 4555006000 0325 | 99 | N | Y | 270 capsules /30 days | Brand name product with generic available. Medical benefit. | Both |
| Esbriet 801 MG TAB | GPI-14 | 4555006000 0345 | 99 | N | Y | 270 capsules /30 days | Brand name product with generic available. Medical benefit. | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Sucralfate 1 GM/10ML SUSPENSION | GPI-14 | 49300010001820 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| LaMICtal 25 MG TAB | GPI-14 | 72600040000310 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| LaMICtal 100 MG TAB | GPI-14 | 72600040000330 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| LaMICtal 150 MG TAB | GPI-14 | 72600040000335 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| LaMICtal 200 MG TAB | GPI-14 | 72600040000340 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| LaMICtal 5 MG CHEW TAB | GPI-14 | 72600040000510 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| LaMICtal 25 MG CHEW TAB | GPI-14 | 72600040000520 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| LaMICtal Starter 35 x 25 MG KIT | GPI-14 | 72600040006420 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| LaMICtal XR 25 MG TAB ER 24H | GPI-14 | 72600040007510 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| LaMICtal XR 50 MG TAB ER 24H | GPI-14 | 72600040007520 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| LaMICtal XR 100 MG TAB ER 24H | GPI-14 | 72600040007530 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| LaMICtal XR 200 MG TAB ER 24H | GPI-14 | 72600040007540 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| LaMICtal XR 250 MG TAB ER 24H | GPI-14 | 72600040007545 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| LaMICtal XR 300 MG TAB ER 24H | GPI-14 | 72600040007550 | 99 | N | N | | Brand name product with generic | Both |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | available. Medical benefit. | |
| Targretin 1 % GEL | GPI-14 | 90376220004020 | 99 | N | N | | Brand name product with generic available. Medical benefit. | Both |
| Ivermectin 0.5 % LOTION | GPI-14 | 90900017004120 | 99 | N | N | | Over-the-counter products available. | Both |

**Discussion:** No comments or questions.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

---

**SEPTEMBER 2023 P&T DUR/ADHERENCE UPDATE**

**Discussion:**
**Commercial/Exchange/TPAs (COMM, D6)**
**Drug Use Evaluations (DUEs)**

- Overutilization of albuterol and levalbuterol
  - This is our 2022 3rd quarter Geisinger Health Plan DUE for Commercial, Exchange, Medicaid, Chip
  - For this report, we identified members who had greater than a 180-day cumulative day supply of Albuterol and/or levalbuterol (based on pharmacy claims from 1/1/2022-12/23/22) with a diagnosis of Asthma (based on medical claims from 4/1/2021 through 12/23/22)
    - See below for the number of members identified:
      - For COMM: **61**
      - For D6: **66**
    - Letters were sent to the MI attributed PCP of each member with their medication fill history of both their controller and rescue inhalers to help providers identify members that may be overutilizing their rescue inhalers and to identify potential compliance concerns with their controller inhaler.
    - Adam K. re-ran this data on 8/4/23 to analyze the effectiveness of the letter. Of the original 150 Commercial/Exchange members 114 members were still active and only 28 of those members still have 180+ days with a rescue inhaler. This is 24.6% of members and included data from 1/1/23 to 7/27/23.
- Use of Opioids at High Dosage
  - This is our 2022 2nd quarter Geisinger Health Plan DUE for Commercial, Exchange, TPA, Medicaid, Medicare
  - From this report, we identified members 18 years and older with 15+ opioid covered days and had an MME of 90 or greater per day based on claims from 1/1/2022 through 7/27/2022
    - See below for the number of members that were identified with an MME of 90 or greater per day:

        - For COMM: **13**
        - For D6: **19**
        - For TP45: **2**
        - For TPE0: **1**
        - For SASN: **1**
        - For TG48/TG51: **18**
    - Letters were sent to the MI attributed PCP of each member with the respective medication fill history for providers to evaluate their patients current pain regimen and ensure lowest effective doses are utilized.
    - Letters were mailed out on 9/15/2023
    - Adam K. re-ran this data on 5/5/2023 to analyze the effectiveness of the letter. The following number of members had not filled an opioid within the past 60 days, had an MME less than 90, and/or had an average MME decrease:
        - For COMM: Of the 13 members originally identified, 7 were still active. Of those members, **2 members** did not fill an opioid in the past 60 days, **4 members** had an average MME decrease
        - For D6: Of the 19 members originally identified, 15 were still active. Of those members, **1 member** did not fill an opioid in the past 60 days, **1 member** had an average MME less than 90, **8 members** had an average MME decrease
        - For TG48: Of the 18 members originally identified, 15 were still active. Of those members, **1 member** did not fill an opioid in the past 60 days, **1 member** had an average MME less than 90, **8 members** had an average MME decrease
        - For TG45: Of the 2 members originally identified, 2 were still active. Of those members, **1 member** had an average MME decrease
        - For TPE0: Of the 1 member originally identified, 1 was still active. Of those members, **1 member** had an average MME decrease
        - For SASN: Of the 1 member originally identified, 1 was still active. Of those members, **1 member** had an average MME decrease

- <u>Asthma Medication Ratio</u>
    - This is our 2022 1st quarter Geisinger Health Plan DUE for Commercial, Exchange, Medicaid, CHIP
    - From this report, we used proactive HEDIS data and identified members aged 5-64 with an AMR<0.5. Pharmacy claims from the prior 6 months (9/2021-3/2022) were pulled into the report.
        - See below for the number of members that were identified with an AMR<0.5
            - For **COMM:** 6
            - For **D6: 6**
        - Letters were sent to the MI attributed PCP of each member with the respective medication fill history to encourage conversation around the importance of controller medications.
    - Letters were mailed out on 4/20/2022
    - Adam K. re-ran this data on 8/29/2022 to analyze the effectiveness of the letter. Of the 12 members initially identified, 9 members were still active. Of those members, **4 members** showed an AMR increase compared to 4/2022.

**In Progress**

- Pharmacotherapy for Opioid Use Disorder (POD) HEDIS measure report

**Ongoing**

- DPP-4/GLP-1 Diabetes Duplicate Therapy Report
    - We receive this report monthly for all LOBs (Star team addresses Medicare) from Adam Kelchner. This report identifies members who potentially have duplicate therapy on a DPP-4/GLP-1 combination. Calls are made to the prescribers to discuss the lack of clinical evidence of this combination and/or duplicate therapy. Recommendations are made to discontinue one agent (ex. the DPP-4 if member on both a GLP-1 and DPP-4).
        - For 2023 we have resolved the following number of **c**ases of therapeutic duplication:
        - **COMM: 15 cases** of therapeutic duplication resulting in a projected savings of **$8,254.84 per script** (this is savings to both member and the health plan)
        - **D6: 4 cases** of therapeutic duplication resulting in a projected savings of **$2,215.19 per script** (this is savings to both member and the health plan)
        - **TG48: 5 cases** of therapeutic duplication resulting in a projected savings of **$3,196.40 per script** (this is savings to both member and the health plan)
        - **EMYD: 4 cases** of therapeutic duplication resulting in a projected savings of **$2,849.14 per script** (this is savings to both member and the health plan)
        - **TPN2: 1 case** of therapeutic duplication resulting in a projected savings of **$529.60 per script** (this is savings to both member and the health plan)
        - **TPM2: 1 case** of therapeutic duplication resulting in a projected savings of **$488.33 per script** (this is savings to both member and the health plan)
- TNF and Oral Oncology Agent Report
    - We get this report monthly for the Commercial/Exchange, TPA, and CHIP LOBs from Adam Kelchner.
    - This report was generated in response to removing the renewal prior authorization requirement for these agents.
    - This report identifies members who are on a TNF or Oral Oncology agent and may not have been seen by their applicable specialist in the last 15 months.
    - We research these members and reach out to the offices/members as necessary to ensure the member has been seen within the last 15 months, an appointment has been scheduled or will be scheduled with the member to ensure the member continues to be able to receive their medication.
    - For 2023:
        - For COMM
            - Members Reviewed: **34**
            - Outreaches Made: **5**
            - Letters Sent: **2**
            - Negative Overrides Entered: **0**
        - For D6
            - Members Reviewed: **47**
            - Outreaches Made: **7**
            - Letters Sent: **5**
            - Negative Overrides Entered: **2**
        - For TG48
            - Members Reviewed: **34**
            - Outreaches Made: **9**

        - Letters Sent: **4**
        - Negative Overrides Entered: **0**
- For TG51
    - Members Reviewed: **10**
    - Outreaches Made: **1**
    - Letters Sent: **1**
    - Negative Overrides Entered: **0**
- For TGW2
    - Members Reviewed: **5**
    - Outreaches Made: **0**
    - Letters Sent: **0**
    - Negative Overrides Entered: **0**
- For TP23
    - Members Reviewed: **2**
    - Outreaches Made: **0**
    - Letters Sent: **0**
    - Negative Overrides Entered: **0**
- For TP45
    - Members Reviewed: **1**
    - Outreaches Made: **0**
    - Letters Sent: **0**
    - Negative Overrides Entered: **0**
- For TP50
    - Members Reviewed: **1**
    - Outreaches Made: **0**
    - Letters Sent: **0**
    - Negative Overrides Entered: **0**
- For TPH0
    - Members Reviewed: **4**
    - Outreaches Made: **1**
    - Letters Sent: **0**
    - Negative Overrides Entered: **0**
- For TPT2
    - Members Reviewed: **1**
    - Outreaches Made: **0**
    - Letters Sent: **0**
    - Negative Overrides Entered: **0**
- For WF89
    - Members Reviewed: **1**
    - Outreaches Made: **0**
    - Letters Sent: **0**
    - Negative Overrides Entered: **0**
- For SASE
    - Members Reviewed: **1**
    - Outreaches Made: **0**
    - Letters Sent: **0**
    - Negative Overrides Entered: **0**
- For SASN

        - Members Reviewed: **1**
        - Outreaches Made: **0**
        - Letters Sent: **0**
        - Negative Overrides Entered: **0**
    - For SASX
        - Members Reviewed: **1**
        - Outreaches Made: **0**
        - Letters Sent: **0**
        - Negative Overrides Entered: **0**
- Cystic Fibrosis Adherence Report
    - We get this report monthly for all LOBs from Adam Kelchner. The report identifies patients who have a specific diagnosis of Cystic Fibrosis & outpatient/office visits within the past 2 years. Further the report calls out medication fill history for specific CF medications and the corresponding PDC.
        - For those members who are seen by a GHS provider we send their information to the CF coordinators to discuss their medication adherence
        - We send letters to non-GHS providers with the CF medication fill history for those members with a PDC less than 80%
        - And for all members we send a letter discussing the importance of medication adherence
        - For 2023, please see below for the number of **members** an adherence letter was sent to:
            - Letters are only sent to members every 6 months
                - For COMM: **3**
                - For D6: **3**
                - For TG48: **2**
                - For WF89: **2**
        - Please see below for the number of letters sent to non-GHS pulmonologists
            - For D6: **0**
        - Please see below for the number of members referred to the CF coordinators:
            - For COMM: **12**
            - For D6: **12**
            - For TG48: **11**
            - For WF89: **5**

- Duplicate Anticoagulant Report
    - We get this report **weekly** for **all LOBs** flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/members of the flagged members to confirm proper medication therapy.
    - For 2023:
        - For COMM (Commercial): **5 members** reviewed and **0 interventions** made
        - For D6 (Exchange): **7 members** reviewed and **0 interventions** made
        - For TG48/GH51: **5 members** reviewed and **1 intervention** made
        - For TP23: **0 members** reviewed and **0 interventions** made
        - For TP45: **0 members** reviewed and **0 interventions** made
        - For TP56: **0 members** reviewed and **0 interventions** made
        - For EMYD: **2 members** reviewed and **0 interventions** made
        - For MT38: **0 members** reviewed and **0 interventions** made

        - For TP74: **0 members** reviewed and **0 interventions** made
        - For SASN: 0 **member** reviewed and **0 interventions** made
        - For SASF: 0 **member** reviewed and **0 interventions** made
        - For TPH3: **2 memberd** reviewed and **0 interventions** made
- Duplicate Specialty Therapy
    - We run an in-house retrospective report **quarterly** for **all LOBs** with help from Adam Kelchner and Aubrielle Smith. These members are identified and written up and sent to a medical director if follow up is needed.
        - For Commercial/Exchange/TPA for, **0 members** were referred to Dr. Yarczower for additional follow-up.
- Duplicate Buprenorphine Therapy
    - We get this report **quarterly** with help from Adam Kelchner. The report works to identify members who have at least a 7 day overlap period of generic Buprenorphine and generic Buprenorphine/naloxone products. Members identified as being on both products are being forwarded to Dr. Meadows and Dr. Hossler for further outreach.
        - For Commercial/Exchange, TPAs for 2023, we have reviewed **0 members** and **0 members** were referred to Dr. Meadows
- Suboxone with an Opioid Report
    - We get this report **weekly** for **all LOBs** from Adam Kelchner and we are writing up each new member that flags on the report. These members are being discussed at our weekly meeting with Dr. Meadows and Dr. Hossler. Both medical directors look into whether it is appropriate to end the opioid authorizations still in place or if further intervention is required.
    - For Commercial/Exchange/TPA for 2023, see below for the new members reviewed and those referred to the MDs:
        - For COMM: we have reviewed **0 new members** and **0 members** were referred to MDs
        - For D6: we have reviewed **2 new members** and **0 members** were referred to MDs
        - For EMYD: we have reviewed **0 new members** and **0 members** were referred to MDs
        - For TG48: we have reviewed **3 new members** and **0 members** was referred to MDs
        - For SASE: we have reviewed **0 new members** and **0 members** was referred to MDs
        - For SASN: we have reviewed **0 new members** and **0 members** was referred to MDs
        - For TPI2: we have reviewed **0 new members** and **0 members** was referred to MDs
- Ending Opioid Authorizations
    - We are working on identifying members who have active opioid authorizations in place but have since started Buprenorphine therapy. The letter is sent to the members notifying them the opioid authorization has been ended due to the start of buprenorphine therapy.
    - For Commercial/Exchange/TPA for 2023, see below for the number of letters we sent to members notifying them that we are ending their opioid authorization(s):
        - For D6: **0**
        - For COMM: **0**

        - For TG48/TG51: **0**
        - For SASN: **0**
- Opioid Overutilization Report
    - We get this report **monthly** from PerformRx and we write up each member that flags on the report. We have been monitoring the members that are continuously showing up on the report by any change in their MED. For those members we deem appropriate we will send a letter to their PCP.
    - For Commercial/Exchange/TPA for 2023, see below for the number of reviewed cases.
        - For COMM: we have reviewed **0 members** and sent **0 cases** to MDs for review
        - For EMYD: we have reviewed **0 members** and sent **0 cases** to MDs for review
        - For TG48: we have reviewed **0 members** and sent **0 cases** to MDs for review
- FWA Reports
    - We get this report **weekly** for **all LOBs** from Jeremy Baker. We prepare this report by determining which claims need to be verified, and our GHP technician makes calls to pharmacies to correct/verify claims.
    - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers
        - For COMM for 2023, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $6,579.84**
        - For D6 for 2023, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $4,740.82**
        - For TPJ0 for 2023, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $51.77**
        - For TPH2 for 2023, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $430.83**
        - For TPE0 for 2023, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $17.19**
        - For TPN2 for 2023, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $453.76**
        - For EMYD for 2023, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $3,795.86**
        - For TG48, TG51 for 2023, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $10,730.59**
        - For SASE for 2023, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $170.57**
        - For SASN for 2023, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $1,615.75**
        - For SASK for 2023, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $7.81**
        - For TP23 for 2023, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $64.69**
        - For TP45 for 2023, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $190.87**
        - For WF89 for 2023, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $312.96**
        - For TPD2 for 2023, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $286.50**
        - For TP49 for 2023, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $27.91**

        - For TGW2 for 2023, we reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $0**
- Duplicate Antipsychotics
    - We get this report **quarterly**, and we send letters to the PCPs to address potential duplicate therapy issues.
        - We have sent the following provider letters in 2023
            - For COMM: **20**
            - FOR D6: **23**
            - FOR TG48, TG51: **19**
            - For TP45: **2**
            - For TP56: **0**
            - For EMYD: **0**
            - For MT38: **0**
            - For TP74: **0**
            - For SASN: **0**
            - For SASF: **0**
            - For TGW2: **2**

- Severity Report
    - We get this report **monthly** for **all LOBs** on members who have filled a medication that has a level one interaction with another medication they have a claim for
        - For Commercial/Exchange/TPA for 2023 see below for the number of members identified and had sent letters to their MI attributed PCP:
            - For COMM: **41**
            - For D6: **38**
            - For EMYD: **0**
            - For SASF: **0**
            - For SASN: **4**
            - For SASE: **1**
            - For TG48: **31**
            - For TG51: **4**
            - For TGW2: **4**
            - For TPB3: **0**
            - For TPE0: **0**
            - For TPH2: **0**
            - For TPH3: **1**
            - For TPJ3: **1**
            - For TPM2: **0**
            - For TP23: **0**
            - For TP41: **1**
            - For TP45: **2**
            - For TP46: **1**
            - For TP50: **0**
            - For TP56: **0**
            - For TP88: **0**
            - For TPU1: **1**
            - For TPA6: **0**
            - For WF89: **0**

- Tobacco Cessation Program
    - We get this report **monthly** to identify members on prolonged tobacco cessation treatment. We send a letter and resource pamphlet to provide additional behavioral health support through Geisinger Health and Wellness.
    - For Commercial/Exchange/TPA for 2023, we sent letters to the below number of members:
        - For COMM: **12**
        - For D6: **5**
        - For EMYD: **9**
        - For SASN: **2**
        - For SASE: **1**
        - For TG48, TG51: **6**
        - For TPB3: **0**
        - For TP23: **0**
        - For TP33: **0**
        - For TP41: **1**
        - For TP45: **2**
        - For TP46: **0**
        - For TP50: **0**
        - For TP56: **0**
        - For TP64: **0**
        - For TP88: **1**
        - For TPA6: **0**
        - For TPM2: **1**
        - For TPT2: **0**
        - For WF89: **0**
- STENT Adherence Report
    - We get this report **monthly** to identify members on an antiplatelet medication and then flag for betablocker and statin medication claims.
    - In 2023, we have sent letters encouraging adherence to the below number of members:
        - **Members for Antiplatelet:**
            - COMM: **55**
            - D6: **42**
            - EMYD: **8**
            - SASN: **8**
            - TG48, TG51: **16**
            - TP41: **0**
            - TP23: **0**
            - TP33: **0**
            - TP45: **1**
            - TP46: **0**
            - TP50: **0**
            - TP56: **1**
            - TP64: **0**
            - TP74: **0**
            - PM71: **0**
            - TP88: **0**
            - TPA6: **0**
            - WF89: **3**
            - TPD2: **0**
            - SASE: **2**
            - SASF: **0**
            - SASK: **0**
            - SASX: **2**
            - TPB3: **0**
            - TPF2: **0**
            - TPH2: **1**
            - TPI0: **0**
            - TPL0: **0**
            - TPM2: **0**
            - TPT2: **1**
            - TPU2: **1**
            - **P**M70: **0**
            - PM71: **0**

- **Members for Beta-Blocker:**
  - COMM: **62**
  - D6: **51**
  - EMYD: **7**
  - SASN: **9**
  - TG48, TG51: **18**
  - TP23: **0**
  - TP41: **2**
  - TP45: **2**
  - TP46: **1**
  - TP50: **0**
  - TP56: **1**
  - TP88: **1**
  - TPA6: **0**
  - WF89: **1**
  - TPI0: **0**
  - SASK: **1**
  - TPB3: **0**
  - TPR1: **0**
  - TPT2: **0**
  - TPU1: **2**
  - TGW2: **2**
  - SASE: **3**
- **Members for Statin:**
  - COMM: **66**
  - D6: **46**
  - EMYD: **10**
  - SASN: **5**
  - SASF: **0**
  - TG48, TG51: **31**
  - TP23: **0**
  - TP41: **1**
  - TP45: **0**
  - TP46: **2**
  - TP56: **0**
  - PM71: **0**
  - SASK: **0**
  - SAQ2: **0**
  - TPI0: **0**
  - TPM2: **0**
  - TPR1: **0**
  - TP88: **0**
  - TPA6: **0**
  - TPA7: **1**
  - TPU1: **0**
  - WF89: **4**
  - TP33: **1**
  - TP50: **0**
  - TP64: **0**
  - PM70: **0**
  - TP74: **0**
  - SASE: **1**
  - SASX: **1**
  - TPB3: **0**
  - TPH2: **1**
  - TPT2: **0**
  - TP41: **0**
- *member may flag for more than one measure and are included in the count for each measure

- In 2023, we have attempted telephonic outreach to the below number of members non-adherent in all 3 measures and reached the below members to encourage adherence.
  - COMM:
    - Attempted: **1**
    - Reached: **0**
  - D6:
    - Attempted: **0**
    - Reached:**0**
  - SASN:
    - Attempted: **0**
    - Reached: **0**

- **<u>HEDIS Initiatives: *Using proactive HEDIS data*</u>**
- <u>Asthma Medication Ratio (AMR)</u>
  - Jesse Barsh runs this report **<u>monthly,</u>** and we send letters to the flagged members who have a ratio of controller to total asthma medications of < 0.5.

        - For Commercial/Exchange for 2023, see below for the number of letters sent to members:
            - COMM: **21**
            - D6: **17**
- Asthma Medication Ratio (AMR) Member Calls
    - Adam Kelchner runs this report **weekly** based off of proactive HEDIS reporting. The RPHs call Commercial/Exchange members who have had a controller or reliever medication filled in the past 3 months AND are past due for their controller medication.
    - For Commercial/Exchange for 2023, see below for the number of members we have outreached to and the number of members that have been reached:
        - COMM:
            - Outreached to: **36**
            - Reached: **22**
        - D6:
            - Outreached to: **50**
            - Reached: **38**
- Antidepressant Medication Management (AMM)
    - Jesse Barsh runs this report **monthly,** and we send letters to the flagged members who appear non-adherent to their antidepressant medications.
        - For Commercial/Exchange for 2023, see below for the number of letters sent to members:
            - Effective Acute Phase:
                - COMM: **0**
                - D6: **1**
            - Effective Continuation Phase:
                - COMM: **28**
                - D6: **13**
- Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - Jesse Barsh runs this report **monthly,** and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
        - For Commercial/Exchange for 2023, see below for the number of letters sent to members:
            - COMM: **2**
            - D6: **0**
- Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - We get this report **monthly** to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For Commercial/Exchange in 2023, see below for the number of letters sent to **providers** to encourage statin therapy initiation**:**
            - COMM: **21**
            - D6: **15**
        - For Commercial/Exchange in 2023, see below for the number of letters sent to **members** to promote statin adherence:
            - COMM: **14**
            - D6: **5**
- Statin Therapy for Patients with Diabetes (SPD)
    - We get this report **monthly** to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy

        - For Commercial/Exchange for 2023, see below for the number of letters sent to **providers** to encourage statin therapy initiation**:**
            - COMM: **390**
            - D6: **181**
        - For Commercial/Exchange for 2023, see below for the number of letters sent to **members** to promote statin adherence:
            - COMM: **23**
            - D6: **8**
- Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
    - We get this report **monthly** to identify members with a diagnosis of AMI who received beta-blocker treatment for 6 months after discharge and who are non-adherent to beta-blocker therapy
        - For Commercial/Exchange for 2023, see below for the number of letters sent to **members:**
            - COMM: **0**
            - D6: **0**
- Use of Opioids from Multiple Providers (UOP)
    - We get this report quarterly to identify members 18 years of age and older with a total day supply of all opioid claims to be 15 days or greater
        - See below for the number of members that were identified who were seeing 4 or more providers from different offices for their opioid prescriptions for 2023
            - **COMM: 13**
            - **D6: 12**
        - See below for the number of members that were identified who were seeing 4 or more providers within the same office for their opioid prescriptions for 2023
            - **COMM: 0**
            - **D6: 2**
        - We sent letters to the MI attributed PCP of each member with the respective medication fill history to encourage medication evaluation of the opioid medications
- **HEDIS PQA Initiatives:**
- HEDIS PQA- INR Report
    - We get this report **weekly** for the Exchange population from Adam Kelchner
    - This report looks at the percentage of members 18 years of age and older who had at least one 56-day interval of warfarin therapy and who received at least one international normalized ratio (INR) monitoring test during each 56-day interval with active warfarin therapy.
        - For Exchange for 2023, we have performed telephonic outreach to providers for **5 members** that had not had an INR level drawn.
- HEDIS PQA-AMO Report
    - We get this report **monthly** for the Exchange population from Adam Kelchner
    - This report looks at the percentage of members 18 years of age and older who are prescribed long-term opioid therapy and have not received a drug test at least once during the measurement year.
        - For Exchange for 2023, we have reviewed **35 members** that had not had a drug test completed and completed outreach to those without a drug test.
- HEDIS PQA-PDC Letters

- We get this report **monthly** for the Exchange population from Adam Kelchner
- This report looks at the percentage of members 18 years of age and older who have a PDC of less than 80% during the measurement year for the below medication classes who are past due for a medication refill:
    - Renin Angiotensin System Antagonists (PDC-RASA)
    - Diabetes All Class (PDC-DR)
    - Statins (PDC-STA)
    - For Exchange for 2023, we have identified the following number of members and sent letters:
        - Renin Angiotensin System Antagonists (PDC-RASA): **527**
        - Diabetes All Class (PDC-DR): **261**
        - Statins (PDC-STA): **518**

**Fliers/Letters**

- Commercial/Exchange DUR/FWA Program internal Fliers
    - Last updated 6/2023 next update 11/2023
- Current Provider Letters
    - Cystic Fibrosis Adherence Letter
    - TNF/Oral Oncology Letter
    - Statin Use in Persons with Diabetes DUE
    - Opioid Overutilization
    - Duplicate Antipsychotic medication
    - Severity Report
    - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - SUPD/SPD Provider Letter
    - HEDIS: Asthma Medication Ratio (AMR)
    - HEDIS: Use of Opioids from multiple providers (UOP)
    - HEDIS: Use of Opioids at High Dosage (HDO)
- Current Member Letters
    - Exchange PQA Adherence Letters
    - Cystic Fibrosis Adherence Letter
    - TNF/Oral Oncology Letter
    - Ending Opioid Authorizations
    - Tobacco Cessation Letter
    - STENT Adherence Report
    - HEDIS: Asthma Medication Ratio (AMR)
    - HEDIS: Antidepressant Medication Management (AMM)
    - HEDIS: Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - HEDIS: Statin Therapy for Patients with Diabetes (SPD)
    - HEDIS: Persistence of eta-Blocker Treatment After a Heart Attack (PBH)

**CHIP** (CHBQ)

- All of our Medicaid adherence/DUR reports include logic to identify the CHIP population

**Drug Use Evaluations (DUEs)**

- Overutilization of albuterol and levalbuterol
    - This is our 2022 3rd quarter Geisinger Health Plan DUE for Commercial, Exchange, Medicaid, Chip
    - For this report, we identified members who had greater than a 180-day cumulative day supply of Albuterol and/or levalbuterol (based on pharmacy claims from 1/1/2022-12/23/22) with a diagnosis of Asthma (based on medical claims from 4/1/2021 through 12/23/22)
        - **5 members** were identified with overutilization of their inhalers
        - Letters were sent to the MI attributed PCP of each member with their medication fill history of both their controller and rescue inhalers to help providers identify members that may be overutilizing their rescue inhalers and to identify potential compliance concerns with their controller inhaler.
        - Adam K. re-ran this data on 8/4/23 to analyze the effectiveness of the letter. Of the original 5 CHIP members 5 members were still active and only 1 of those members still have 180+ days with a rescue inhaler. This is 20% of members and included data from 1/1/23 to 7/27/23.
- Asthma Medication Ratio
    - This is our 2022 1st quarter Geisinger Health Plan DUE for Commercial, Exchange, Medicaid, CHIP
    - From this report, we used proactive HEDIS data and identified members aged 5-64 with an AMR<0.5. Pharmacy claims from the prior 6 months (9/2021-3/2022) were pulled into the report.
        - **0 members** were identified with an AMR<0.5
        - Letters were sent to the MI attributed PCP of each member with the respective medication fill history to encourage conversation around the importance of controller medications.

**In Progress**

- Pharmacotherapy for Opioid Use Disorder (POD) HEDIS measure report

**Ongoing**

- DPP-4/GLP-1 Diabetes Duplicate Therapy Report
    - We receive this report monthly for all LOBs (Star team addresses Medicare) from Adam Kelchner. This report identifies members who potentially have duplicate therapy on a DPP-4/GLP-1 combination. Calls are made to the prescribers to discuss the lack of clinical evidence of this combination and/or duplicate therapy. Recommendations are made to discontinue one agent (ex. the DPP-4 if member on both a GLP-1 and DPP-4).
        - For 2023 we have resolved **0 cases** of therapeutic duplication.
- Cystic Fibrosis Adherence Report
    - We get this report **monthly** for **all LOBs** from Adam Kelchner. The report identifies patients who have a specific diagnosis of Cystic Fibrosis & outpatient/office visits within the past 2 years. Further the report calls out medication fill history for specific CF medications and the corresponding PDC.
        - For those members who are seen by a GHS provider we send their information to the CF coordinators to discuss their medication adherence with the member

        - We send letters to non-GHS providers with the CF medication fill history for those members with a PDC less than 80%
        - And for all members we send a letter discussing the importance of medication adherence
        - For CHBQ for 2023, we sent **0 members** an adherence letter
            - Letters are only sent to members every 6 months
            - There were **0 members** who saw a non-GHS pulmonologist and a letter was sent to that pulmonologist
            - There were **0 members** who saw GHS pulmonologists and were sent to the CF coordinators for follow up
- Duplicate Anticoagulant Report
    - We get this report **weekly** for **all LOBs** flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/members of the flagged members to confirm proper medication therapy.
        - For CHBQ in 2023, we have reviewed **0 members** and have made interventions for **0 members**
- Duplicate Specialty Therapy
    - We run an in-house retrospective report **quarterly** for **all LOBs** with help from Adam Kelchner and Aubrielle Smith. These members are identified and written up and sent to a medical director if follow up is needed.
        - For CHBQ for 2023, **0 members** were referred to Dr. Yarczower for additional follow-up.
- Duplicate Buprenorphine Therapy
    - We get this report **quarterly** with help from Adam Kelchner. The report works to identify members who have at least a 7 day overlap period of generic Buprenorphine and generic Buprenorphine/naloxone products. Members identified as being on both products are being forwarded to Dr. Meadows and Dr. Hossler for further outreach.
        - For CHBQ for 2023, we have reviewed **0 members** and **0 members** were referred to MDs
- Suboxone with an Opioid Report
    - We get this report **weekly** for **all LOBs** from Adam Kelchner and we are writing up each member that flags on the report. These members are being discussed at our weekly meeting with Dr. Meadows and Dr. Hossler. Both MDs look into whether it is appropriate to end the opioid authorizations still in place or if further intervention is required.
        - For CHBQ for 2023, we have reviewed **0 new members**, and **0 members** were referred to MDs
- Ending Opioid Authorizations
    - We are working on identifying members who have active opioid authorizations in place but have since started Buprenorphine therapy. The letter is sent to the members notifying them the opioid authorization has been ended due to the start of buprenorphine therapy.
        - For CHBQ for 2023, we sent **0 members** a letter notifying them of the end of their opioid authorization(s).
- Severity Report
    - This is a **monthly** report for **all LOBs** on members who have filled a medication that has a level one interaction with another medication they have a claim for

        - For CHBQ for 2023, letters have been sent to MI attributed providers of **3 CHIP members**
- FWA Reports
    - We get this report **weekly** for **all LOBs** from Jeremy Baker. We prepare this report by determining which claims need to be verified, and our GHP technician makes calls to pharmacies to correct/verify claims.
    - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers
        - For CHBQ for 2023, we have reviewed cases and corrected claims, resulting in a potential **cost savings/avoidance of $2,492.73**
- Tobacco Cessation Program
    - We get this report **monthly** to identify members on prolonged tobacco cessation treatment. We send a letter and resource pamphlet to provide additional behavioral health support through Geisinger Health and Wellness.
        - For CHBQ for 2023, we have not sent any letters
- STENT Adherence Report
    - We get this report **monthly** to identify members on an antiplatelet medication and then flag for betablocker and statin medication claims.
    - For CHBQ for 2023, we have sent letters encouraging adherence to:
        - Members for Antiplatelet:
            - CHBQ: **0**
        - Members for Beta-blocker:
            - CHBQ: **0**
        - Members for Statin:
            - CHBQ: **0**
        - *member may flag for more than one measure and are included in the count for each measure
- Antipsychotic with Opioid Report
    - We get this report **quarterly** to identify **CHIP** members with an overlap of 8 or more days between an opioid and antipsychotic medication.
    - We send a letter with claims data to both the opioid prescriber and the antipsychotic prescriber to encourage collaboration in medication management.
        - For CHBQ for 2023, we sent **0 letters** to **opioid and antipsychotic prescribers**
- Duplicate Antipsychotics
    - We get this report **quarterly**, and we send letters to the PCPs to address potential duplicate therapy issues.
        - For CHBQ in 2023, we have sent letters to **4 providers**
- **HEDIS Initiatives: *Using proactive HEDIS data***
- Asthma Medication Ratio (AMR)
    - Jesse Barsh runs this proactive HEDIS report **monthly,** and we send letters to the flagged members who have a ratio of controller to total asthma medications of < 0.5.
        - For CHBQ for 2023, we sent **3 letters** to members
- Asthma Medication Ratio (AMR) Member Calls
    - Adam Kelchner runs this report **weekly** based off of proactive HEDIS reporting. we send CHIP members who have had a controller or reliever medication filled in the past 3 months AND are past due for their controller medication to the Respiratory Therapists for direct telephonic outreach.

        - For CHBQ for 2023, we have referred **10 members** to the Respiratory Therapists for outreach.
        - For CHBQ for 2023, our pharmacy technician and the STAR reps have outreached to **8 members** and reached **7 members**
- Antidepressant Medication Management (AMM)
    - Jesse Barsh runs this proactive HEDIS report **monthly,** and we send letters to the flagged members who appear non-adherent to their antidepressant medications.
        - For CHBQ for 2023, we sent **0 letters** to members in the **Effective Acute Phase**, and **1 letter** to members in the **Effective Continuation Phase**
- Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - Jesse Barsh runs this report **monthly,** and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
        - For CHBQ for 2023, we have sent **0 letters** to members
- Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - This is a **monthly** report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For CHBQ for 2023, we have sent **0 letters** to providers
        - For CHBQ for 2023, we have sent **0 letters** to members
- Statin Therapy for Patients with Diabetes (SPD)
    - This is a **monthly** report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
        - For CHBQ for 2023, we have sent **0 letters** to providers
        - For CHBQ for 2023, we have sent **0 letters** to members
- Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
    - This is a **monthly** report to identify members with a diagnosis of AMI who received beta-blocker treatment for 6 months after discharge and who are non-adherent to beta-blocker therapy
        - For CHBQ for 2023, we have sent **0 letters** to members

**Fliers/Letters**

- Chip DUR/FWA Program internal Fliers
    - Last updated 6/2023 next update 11/2023
- Current Provider Letters
        - Cystic Fibrosis Adherence Letter
        - TNF/Oral Oncology Letter
        - Duplicate Antipsychotic medication
        - Severity Report
        - HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
        - SUPD/SPD Provider Letter
        - HEDIS: Asthma Medication Ratio (AMR)
- Current Member Letters
        - Cystic Fibrosis Adherence Letter
        - TNF/Oral Oncology Letter
        - Ending Opioid Authorizations
        - Tobacco Cessation Letter
        - STENT Adherence Report
        - HEDIS: Asthma Medication Ratio (AMR)
        - HEDIS: Antidepressant Medication Management (AMM)

- HEDIS: Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
- HEDIS: Statin Therapy for Patients with Cardiovascular Disease (SPC)
- HEDIS: Statin Therapy for Patients with Diabetes (SPD)

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.

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

Meeting will be held virtually via phone/Microsoft Teams.