P&T Committee Meeting Minutes
Medicaid
January 14, 2025

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Alyssa Cilia, RPh
Amir Antonius, Pharm.D.	Michael Evans, RPh
Leslie Astleford, PharmD.	Jason Howay, Pharm.D.
Emily Bednarz, Pharm.D.	Nichole Hossler, MD
Kristen Bender, Pharm.D.	Jamie Miller, RPh
Jeremy Bennett, MD	Jonas Pearson, RPh
Kim Castelnovo, RPh	Michael Shepherd, MD
Kimberly Clark, Pharm.D.	
Bhargavi Degapudi, MD	
Keri Jon Donaldson	
Michael Dubartell, MD	
Kelly Faust, Pharm.D.	
Tricia Heitzman, Pharm.D.	
Keith Hunsicker, Pharm.D.	
Kelli Hunsicker, Pharm.D.	
Emily Jacobson, Pharm.D.	
Dennis Janosczyk, Pharm.D.	
Alexandra Kempf-Malys	
Kerry Ann Kilkenny, MD	
Philip Krebs, R.EEG T	
Briana LeBeau, Pharm.D.	
Ted Marines, Pharm.D.	
Lisa Mazonkey, RPh	
Tyreese McCrea, Pharm.D.	
Perry Meadows, MD	
Mark Mowery, Pharm.D.	
Austin Paisley, Pharm.D.	
Lauren Pheasant, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Sartori, Pharm.D.	
Kristen Scheib, Pharm.D.	
Kirsten Smith, Pharm.D.	
Aubrielle Smith-Masri, Pharm.D.	
Michael Spishock, RPh	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
Luke Sullivan, DO	
Kevin Szczecina, RPh	
Amanda Taylor, MD	
Ariana Wendoloski, Pharm.D.	
Brandon Whiteash, Pharm.D.	
Margaret Whiteash, Pharm.D.	
Dr. Abigail L Chua, DO (non-voting participant)	
Dr. Scott Friedenberg, MD (non-voting participant)	

Jeremy Garris, Pharm.D. (non-voting participant) Abigail Perriello, PharmD. (pharmacy resident) Dr. Jonathan Spahr, MD (non-voting participant)	

Call to Order: Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday January 14, 2025.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the November 19, 2024 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Vyloy (zolbetuximab-clzb)

Review: Vyloy is indicated in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction adenocarcinoma whose tumors are claudin (CLDN) 18.2 positive as determined by an FDA approved test. Vyloy is a claudin 18.2 (CLDN18.2)-directed cytolytic antibody that depletes CLDN18.2-positive cells via antibody-dependent cellular cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC). Vyloy combined with chemotherapy had increased antitumor activity in CLDN18.2-expressing mouse tumor models compared to Vyloy or chemotherapy alone. Vyloy is the first and only approved CLDN18.2-directed therapy. CLDN18.2 is overexpressed in various digestive malignancies, such as GC, GEJ cancer, esophageal cancer, and pancreatic cancer to varying degrees. Approximately 30 to 40% of patients with gastric or gastroesophageal junction adenocarcinoma have CLDN18.2 positive tumors

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

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

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

- Medical record documentation that Vyloy is prescribed by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction adenocarcinoma AND
- Medical record documentation that Vyloy will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy for first-line treatment AND
- Medical record documentation of Claudin (CLDN) 18.2 positive tumors (defined as ≥75% of tumor cells demonstrating moderate to strong membranous CLDN18 immunohistochemical staining) as determined by an FDA approved test*

*NOTE: The FDA approved test for detection of Claudin (CLDN) 18.2 protein expression is VENTANA CLDN18 (43-14A) RxDx Assay

Authorization Duration: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals 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 the member experiences unacceptable toxicity or worsening of disease.

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

Tryvio (aprocitentan)

Review: Tryvio is an endothelin receptor antagonist (ERA) indicated for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs. Tryvio is the first oral antihypertensive medication to be approved in more than 30 years and works on a new pathway that inhibits the binding of endothelin (ET)-1 to ET_A and ET_B receptors, in turn inhibiting ET-1 hypertensive effects such as endothelial dysfunction, vascular hypertrophy and remodeling, sympathetic activation, and increased aldosterone synthesis. Tryvio is available as a 12.5 mg oral tablet with a recommended dose of 12.5 mg once daily, with or without food.

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

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

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

- Medical record documentation of age 18 years or older **AND**
- Medical record documentation of diagnosis of resistant hypertension **AND**
- Medical record documentation of continued concurrent use of a medication from **ALL** the following antihypertensive classes at maximally tolerated doses:
    - Renin-angiotensin system [angiotensin-converting enzyme (ACE) inhibitor **OR** angiotensin II receptor blocker (ARB)]
    - Calcium channel blocker
    - Diuretic

AND

- Medical record documentation of therapeutic failure on intolerance to, or contraindication to at least two (2) additional formulary alternatives of different classes (i.e. beta blockers, aldosterone receptor antagonists, alpha-blockers, vasodilators, etc.).

GPI Level: GPI-12

Authorization Duration: Initial authorization will be for 3 months. Subsequent approvals will be for an additional 12 months and will require:

- Medical record documentation of clinical improvement or lack of worsening in blood pressure shown through office visit blood pressure readings**.**

Formulary alternatives:
ANGIOTENSIN MODULATOR COMBINATIONS: amlodipine-Benazepril, amlodipine-olmesartan, amlodipine-valsartan, amlodipine-valsartan-HCTZ, olmesartan-amlodipine-HCTZ, telmisartan-amlodipine, trandolapril-verapamil ER
ANGIOTENSIN MODULATORS: benazepril, benazepril-HCTZ, captopril, enalapril, enalapril-HCTZ, fosinopril, fosinopril-HCTZ, irbesartan, irbesartan-HCTZ, lisinopril, lisinopril-HCTZ, losartan, losartan-HCTZ, olmesartan,

olmesartan-HCTZ, quinapril, quinapril-HCTZ, ramipril, telmisartan, trandolapril, valsartan, valsartan-HCTZ, aliskiren**
ANTIHYPERTENSIVES, SYMPATHOLYTIC: clonidine, guanfacine, methyldopa, prazosin
BETA BLOCKERS: acebutolol, atenolol, atenolol-chlorthalidone, betaxolol, bisoprolol, carvedilol, labetalol, metoprolol succinate ER, metoprolol tartrate, nadolol, nebivolol, pindolol, propranolol, propranolol ER, sorine, sotalol
CALCIUM CHANNEL BLOCKERS: amlodipine, Cartia XT, Dilt-XR, diltiazem, diltiazem ER, felodipine ER, nifedipine, nifedipine ER, nimodipine, Taztia XT, Tiadylt ER verapamil, verapamil ER, verapamil SR
Diuretics: amiloride, bumetanide, chlorthalidone, eplerenone, furosemide, hydrochlorothiazide (HCTZ), indapamide, metolazone, spironolactone, spironolactone-HCTZ, triamterene, torsemide
Miscellaneous Vasodilators: hydralazine, minoxidil

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

Yorvipath (palopegteriparatide)

Review: Yorvipath (palopegteriparatide) is a parathyroid hormone analog (PTH(1-34)) indicated for the treatment of hypoparathyroidism in adults. Yorvipath is a prodrug that contains an inert carrier of teriparatide and mimics endogenous parathyroid hormone (PTH). PTH is one of three key hormones that regulates serum calcium and phosphate homeostasis by increasing serum calcium and decreasing serum phosphate. PTH is excreted by the parathyroid glands in response to low serum calcium levels. PTH exerts its effects primarily on the bones, kidneys, and intestines

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

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

Outcome: Yorvipath is a pharmacy benefit and should not be added to the GHP Family formulary. The following prior authorization criteria will apply:

- Medical record documentation of a diagnosis of hypoparathyroidism **AND**
- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation that Yorvipath is being prescribed by an endocrinologist **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 no increased baseline risk for osteosarcoma **AND**
- Medical record documentation of serum 25(OH) vitamin D within normal range within 2 weeks prior to the first dose **AND**
- Medical record documentation of albumin-corrected serum calcium ≥ 7.8 mg/dL within 2 weeks prior to the first dose **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to calcitriol **OR**
    - Medical record documentation that member will use Yorvipath in addition to calcitriol and/or elemental calcium.

Note to reviewer:

- The safety and effectiveness of Yorvipath was not studied in patients diagnosed with postsurgical acute hypoparathyroidism.
- Increased risks of osteosarcoma:
    - Open epiphyses
    - Metabolic bone diseases other than hypoparathyroidism, including Paget's disease of bone
    - Unexplained elevations of alkaline phosphatase
    - Bone metastases or a history of skeletal malignancies
    - History of external beam or implant radiation therapy involving the skeleton
    - Hereditary disorders predisposing to osteosarcoma
- The normal range for albumin-corrected serum calcium is 8.3 to 10.6 mg/dL.
- The normal range for serum 25(OH) vitamin D is ≥ 20 ng/mL

Formulary Alternatives: calcitriol
GPI Level:

- Medicaid: GPI-12

Authorization Duration: 1 year

Reauthorization info: Subsequent approvals will be for an additional 12 months and will require:

- Medical record documentation of albumin-corrected serum calcium within the lower-half of the normal reference range **AND**
- Medical record documentation of prescriber attestation that member is responding to Yorvipath therapy

Require RPH Sign off: Yes

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

Vafseo (vadadustat)

Review: Vafseo is indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months. Vafseo has limitations of use that it has not been shown to improve quality of life, fatigue, or patient well-being, is not indicated for use as a substitute for transfusion in patients requiring immediate correction of anemia, and not indicated in patients with anemia due to CKD not on dialysis. Vafseo is the second oral HIF-PH inhibitor approved for the treatment of anemia due to CKD in adult patients on dialysis. Jesduvroq was approved for the same indication in patients who have been on dialysis for at least four months.

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

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

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

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of anemia due to chronic kidney disease AND

- Medical record documentation that member has been receiving dialysis for at least three months AND
- Medical record documentation of a Hemoglobin less than or equal to 11 g/dL AND
- Medical record documentation of ferritin greater than or equal to 100 ng/mL or transferrin saturation level greater than or equal to 20% or history of chelation therapy for iron

NOTES:

- For continuation of therapy, a repeat Hgb should be submitted after 12 months of therapy.
- In individuals whose Hgb is greater than or equal to 11 g/dL or rises by 1g/dL in any two-week period, additional doses should be withheld.
- For initiation or continuation of therapy, a ferritin level no greater than 3 months old and/ or transferrin saturation level no greater than 6 months old should be submitted.
- The member should receive supplemental iron if serum ferritin is less than 100ng/ml and transferrin saturation is less than 20 percent.

GPI Level: GPI-12

Authorization Duration: Approval of Vafseo will be given for an initial duration of 12 months. Subsequent authorization will be considered based on the stated criteria.

Require RPH Sign off: Yes, RPh Signoff will be required to ensure appropriate utilization.

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

Ervebo (Ebola Zaire Vaccine, Live)

Review: Ervebo, approved in the United States in 2019, is the first vaccine indicated for the prevention of disease caused by *Zaire ebolavirus* in individuals 12 months of age and older. The duration of protection conferred by Ervebo is unknown. Ervebo does not protect against other species of *Ebolavirus* or *Marburgvirus*. Effectiveness of the vaccine when administered concurrently with antiviral medication, IVIG, and/or blood or plasma transfusions is unknown. Ervebo is a replication-competent, live, attenuated recombinant vesicular stomatitis virus vaccine. Ervebo is made by taking a small piece of the Ebola virus and adding it to the vesicular stomatitis virus, forming what is referred to as the "vaccine virus". Immunization with Ervebo results in an immune response and protection from disease caused by *Zaire ebolavirus.* The relative contributions of innate, humoral, and cell-mediated immunity to protection from *Zaire ebolavirus* are unknown. Ervebo is not currently available to purchase in the United States. It is approved by the FDA, but the only supply is in the Federal Government stock for an emergency outbreak. Ervebo was used during a 2018 outbreak in Zaire and has since been used during other outbreaks with over 90,000 people vaccinated. The ACIP recommends pre-exposure vaccination with Ervebo for adults 18 years of age and older who are at potential risk of exposure because they are responding to an outbreak of *Zaire ebolavirus*, work as healthcare personnel at a federally-designated Ebola Treatment Center, or work in a laboratory or are staff at biosafety-level 4 facilities.

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

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

Outcome: Ervebo is not currently available to purchase in the United States and will only be distributed by the Federal Government if needed for an outbreak. If Ervebo becomes commercially available, it will be a medical benefit managed by GHP. No prior authorization criteria will apply.

If Made Commercially Available:
Authorization Limitations: Approval is for a one-time injection
Quantity Limit: 1 ml per 999 days
Age Limit: 12 months of age and older

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

Aucatzyl (obecabtagene autoleucel)

Review: Aucatzyl is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). Anti-CD19 CAR-positive T cells engage with CD19-expressing target cells (cancer and normal B cells), which leads to activation of the anti-CD19 CAR-positive T cells, resulting in anti-tumor activity and killing of CD19-expressing target cells. Aucatzyl is the second CAR-T to be approved for the treatment of ALL in all adults, and it will directly compete with already approved Tecartus. Aucatzyl does not require a Risk Evaluation and Mitigation Strategy (REMS) program, which is unlike other CAR-T therapies. It is designed to reduce the excessive activation of the programmed T cells, which can potentially improve safety, including what appears to be lower rates of CRS and ICANS compared to Tecartus.

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

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

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

- Medical record documentation that Aucatzyl is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years old **AND**
- Medical record documentation of a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy.

Authorization Duration: One-time six (6) month authorization for split dose administration of Aucatzyl.
Quantity Limit: Maximum of two (2) lifetime doses, given on day 1 and day 10 (± 2 days).
Require RPH Sign off: Yes
Formulary Alternatives: Tecartus

Other Recommendations for Tecartus
It is recommended to update the Tecartus criteria to align with other CAR-T policies. The following additional prior authorization criteria should apply:

Mantle Cell Lymphoma (MCL)

- Medical record documentation that Tecartus is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of relapsed or refractory mantle cell lymphoma (MCL) **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy.

Acute Lymphoblastic Leukemia (ALL)

- Medical record documentation that Tecartus is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) **AND**

Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapyAdditional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

FAST FACTS

UPDATES

December ELECTRONIC VOTE

An electronic vote was held from December 13, 2024, to December 1, 2024. Responses were received from 33 members (out of 49 members) and all voted to approve. Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Kisunla (donanemab-azbt)

Eli Lilly's Kisunla (donanemab) was approved on July 2, 2024, for the treatment of early symptomatic AD. Kisunla is a humanized immunoglobulin G1 mAB directed against insoluble Aβ present in brain amyloid plaques. Donanemab binds to the N-terminal truncated form of Aβ and aids plaque removal through microglial-mediated phagocytosis. Donanemab specifically targets deposited amyloid plaque and has been shown to lead to plaque clearance in treated patients.

Recommendation: Kisunla will be a medical benefit managed by GHP. The following prior authorization criteria will apply:

- Medical record documentation that Kisunla 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 at appropriate intervals (prescribing information states MRI is to be obtained at baseline and prior to the 2nd, 3rd, 4th, and 7th infusion) 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, G 30.1, G30.8, G 30.9, 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 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]) OR blood based biomarker testing positive for beta-amyloid plaques (as indicated by reduced amyloid beta 42 amyloid beta 40 ratio [Aβ42/Aβ40 ratio] in plasma OR assays for tau phosphorylated at amino acid 181 (p-tau 181), 217 (p-tau217), or 231 (p-tau231) OR high NfL concentrations OR plasma GFAP) AND
- Medical record documentation of at least two (2) of the following:
    - Mini-Mental State Examination (MMSE) score of ≥20 to ≤28
    - 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 or other similar neuropsychology testing demonstrating minor neurocognitive disorder or mild stage dementia level major neurocognitive disorder, and/or
    - Quick Dementia Rating System (QDRS) score less than or equal to 12 AND
- Medical record documentation that the member does not have history of stroke, transient ischemic attack (TIA), or seizures in the past year AND
- Medical record documentation that the member does not have a bleeding disorder that is not under adequate control (e.g. a platelet count <50,000 or international normalized ratio [INR] > 1.5) AND
- Medical record documentation that the member does not have a presence of ARIA-E (and/or ARIA-H) on the most recent MRI scan (brain edema or sulcal effusions) AND
- Do not see significant pathological findings on a pre-treatment MRI:
    - 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: 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 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:

- Provider attestation that Kisunla is still medically necessary to continue AND
- Medical record documentation that the member is tolerating Kisunla AND
- Medical record documentation Kisunla 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 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 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) OR other similar neuropsychology testing and/or,
    - Quick Dementia Rating System (QDRS)

AND

- One of the following:
    - Medical record documentation that the member does not have history of stroke, transient ischemic attack (TIA), or seizures in the past year OR
    - Medical record documentation of rationale for use in members that have a history of stroke, transient ischemic attack (TIA), or seizures in the past year AND
- Medical record documentation that the member does not have a bleeding disorder that is not under adequate control (e.g. a platelet count <50,000 or international normalized ratio [INR] > 1.5) AND
- Medical record documentation that the member does not have a presence of ARIA-E (and/or ARIA-H) on the most recent MRI scan (brain edema or sulcal effusions) AND
- Do not see significant pathological findings on a recent MRI:
    - 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

Require RPh Sign Off: Yes

Leqembi Updates

Based on the feedback we received from Dr. Glen Finney, we are making updates to the Leqembi policy to match Kisunla. The rationales for the following are listed in the Kisunla review above.

- 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]) OR blood based biomarker testing positive for beta-amyloid plaques (as indicated by reduced amyloid beta 42 amyloid beta 40 ratio [Aβ42/Aβ40 ratio] in plasma OR assays for tau phosphorylated at amino acid 181 (p-tau 181), 217 (p-tau217), or 231 (p-tau231) OR high NfL concentrations OR plasma GFAP) **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 OR other similar neuropsychology testing demonstrating minor neurocognitive disorder or mild stage dementia level major neurocognitive disorder 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~~
- Provider attestation that Leqembi is still medically necessary to continue AND
- Medical record documentation that the member is tolerating Leqembi 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) OR other similar neuropsychology testing 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:
    - One of the following:
        - Medical record documentation of a history of stroke, transient ischemic attack (TIA), or seizures in the past year OR
        - Medical record documentation of rationale for use in members that have 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 recent brain MRI 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.

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

Rytelo (imetelstat)

Rytelo is an oligonucleotide telomerase inhibitor indicated for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA). The recommended dose of Rytelo is 7.1mg/kg every 4 weeks, to be administered over 2 hours. Rytelo is supplied in either a 47mg single dose vial (82959-112-01) or a 188mg single dose vial (82959-111-01). The prescribing information recommends to discontinue therapy if the patient does not experience a decrease in red blood cell (RBC) transfusion burden after 24 weeks of therapy (6 doses). Premedication to be given at least 30 minutes prior to Rytelo includes diphenhydramine and hydrocortisone, intravenous or oral for both. The dose may be delayed, reduced or entirely discontinued for Grade 3 or Grade 4 hematologic adverse reactions and for Grade 2 through 4 non-hematologic adverse reactions.

Recommendation: Rytelo is a medical benefit requiring prior authorization that is GHP managed. No additional prior authorization criteria will apply:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of myelodysplastic syndromes (MDS) **AND**
- Medical record documentation of low to intermediate-1 risk disease per the Revised International Prognostic Scoring System (IPSS-R)* **AND**
- Medical record documentation that patient requires an average of at least four (4) red blood cell units per 8 weeks **AND**
- Medical record documentation of baseline number of transfusions and red blood cell (RBC) units required for the previous six (6) months **AND**
- Medical record documentation of therapeutic failure, intolerance to, contraindication to, or ineligibility for an erythropoiesis stimulating agent (ESA) OR medical record documentation that an ESA is not indicated per FDA labeling and NCCN guidelines **AND**
- Medical record recommendation that Rytelo is being dosed consistent with FDA-approved labeling** **AND**
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to Reblozyl (luspatercept-aamt) OR medical record documentation that Reblozyl is not indicated per FDA labeling and NCCN guidelines

Authorization Duration: Approval will be given for an initial duration of six (6) months or less if the reviewing provider feels it is medically appropriate. After the initial six (6) month approval, subsequent approvals will be for a duration of six (6) months or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- A decrease in red blood cell (RBC) transfusion burden from baseline **AND**
- Rytelo being dosed consistent with the FDA-approved labeling**

Ongoing subsequent approvals will be for a duration of six (6) months or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- A sustained reduction of red blood cell (RBC) transfusion burden from baseline **AND**
- Rytelo being dosed consistent with the FDA-approved labeling**

LIMITATIONS: Rytelo will no longer be covered if the patient does not experience a decrease in transfusion burden after twenty four (24) weeks of treatment (administration of 6 doses) or if unacceptable toxicity occurs at any time.

*Note: Per NCCN guidelines, Intermediate-Risk MDS may be managed as lower risk if the IPSS-R score is less than or equal to 3.5 (versus higher risk if the score is >3.5).

**Note: Per FDA labeling, the dose of Rytelo is 7.1mg/kg every 4 weeks, with dose reductions allowed for Grade 3 or Grade 4 adverse reactions.

***Note: Per NCCN guidelines, ESA and Reblozyl are not recommended prior to Rytelo when member has: ring sideroblasts (RS) <15% (or RS <5% with a SF3B1 mutation) AND serum EPO >200 mU/mL AND a poor probability to respond to immunosuppressive therapy (IST). Patients with poor probability to respond generally have any of the following: >60 years old, >5% marrow blasts, No hypocellular marrows, No paroxysmal nocturnal hemoglobinuria (PNH) clone positivity, No STAT3-mutant cytotoxic T-cell clones.

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

Brineura

Updated Indication: The age was recently updated from age 3 and older to include the pediatric population from birth up.

Recommendation: It is recommended to update policy MBP 157.0 by removing the age bullet since the FDA approved age is now from birth and up instead of 3 years of age and up.

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

Fabhalta

Updated Indication: Fabhalta is now approved for the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio ≥ 1.5g/g. Previously, this medication was approved for the treatment of paroxysmal nocturnal hemoglobinuria in adult patients.

Recommendation: No formulary placement changes recommend. It is recommended to update the PA criteria.

Primary Immunoglobulin A Nephropathy

- Medical record documentation of a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by biopsy **AND**
- Medical record documentation that Fabhalta will be used for reduction of proteinuria in members at risk of rapid disease progression defined as a urine protein-to-creatinine ratio (UPCR) of ≥1.5 g/g or proteinuria ≥ 1g/day **AND**
- Medical record documentation that Fabhalta is prescribed by a nephrologist **AND**

- Medical record documentation that member has received vaccinations against encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B **AND**
- Medical record documentation of eGFR ≥ 30 mL/min/1.73 m2 AND
- Medical record documentation that member has received a stable dose of a RAS inhibitor (ACE inhibitor or ARB) at a maximally tolerated dose for ≥ 90 days AND
- Medical record documentation that patient has received ≥ 90 days of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification 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.

Auth Duration for PNH: Initial approval will be for 6 months. Subsequent authorizations will be for 6 months and will require:

- Medical record documentation of:
    - Hemolysis control measured by lactic acid dehydrogenase (LDH) level less than 1.5 times the upper limit of normal (ULN) AND
    - Reduced need or elimination of transfusion requirements OR
    - Stabilization of hemoglobin levels

Auth Duration for IgAN: Initial approval will be for 9 months. Subsequent authorizations will be for 12 months and will require:

- Medical record documentation of continued diseases improvement or lack of disease progression according to prescriber (i.e., decreased levels of proteinuria from baseline or decreased urine protein-to-creatinine ratio (UPCR) from baseline).

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

Livmarli

Updated Indication: Livmarli is now indicated for the treatment of cholestatic pruritus in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Livmarli is not recommended in a subgroup of PFIC type 2 patients with specific ABCB11 variants resulting in non-functional or complete absence of bile salt export pump (BSEP) protein. Previously, Livmarli was indicated for the treatment of Alagille syndrome (ALGS) in patients 3 months of age and older. Livmarli is the second drug indicated for PFIC after Bylvay which is also indicated in the treatment of ALGS and PFIC.

Recommendation: Livmarli 19.0 mg/mL is a pharmacy benefit that will be managed by GHP and should not be added to the GHP Family formulary. The following prior authorization criteria should be added to GHP Family Policy 1552.0F to incorporate the new indication

ALGS:

- Prescription written by or in consultation with a hepatologist or gastroenterologist AND
- Medical record documentation of diagnosis of Alagille Syndrome (ALGS) AND
- Medical record documentation of the presence of moderate to severe pruritus AND

- Medical record documentation that the member is receiving an appropriate dose* based on the patient's weight AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ursodiol and one of the following: cholestyramine, rifampin, naltrexone, sertraline

*** Note to reviewing pharmacist:** The recommended dose of Livmarli for ALGS is shown in the table below

Patient Weight (kg)	Days 1-7 (190 mcg/kg once daily)	Beginning Day 8 (380 mcg/kg once daily)
	9.5 mg/mL Solution (for ALGS) Volume per Dose (mL)	
5 to 6	0.1	0.2
7 to 9	0.15	0.3
10 to 12	0.2	0.45
13 to 15	0.3	0.6
16 to 19	0.35	0.7
20 to 24	0.45	0.9
25 to 29	0.5	1
30 to 34	0.6	1.25
35 to 39	0.7	1.5
40 to 49	0.9	1.75
50 to 59	1	2.25
60 to 69	1.25	2.5
70 or higher	1.5	3

PFIC:

- Prescription written by or consultation with a hepatologist or gastroenterologist AND
- Medical record documentation of diagnosis of progressive familial intrahepatic cholestasis (PFIC) confirmed by genetic testing AND
- Medical record documentation of the presence of moderate to severe pruritus AND
- Medical record documentation of age greater than or equal to 12 months AND
- Medical record documentation that the member is receiving an appropriate dose* based on the patient's weight AND
- Medical record documentation of concurrent use or therapeutic failure on, intolerance to, or contraindication to ursodiol.

*** Note to reviewing pharmacist:** The recommended dose of Livmarli for PFIC is shown in the table below

Patient Weight (kg)	285 mcg/kg (once daily titrated to twice daily)	428 mcg/kg (twice daily)	570 mcg/kg (twice daily as tolerated)
	19 mg/mL Solution (for PFIC) Volume per Dose (mL)		
5	0.1	0.1	0.15
6 to 7	0.1	0.15	0.2
8	0.1	0.2	0.25
9	0.15	0.2	0.25
10 to 12	0.15	0.25	0.3
13 to 15	0.2	0.3	0.4
16 to 19	0.25	0.4	0.5
20 to 24	0.3	0.5	0.6
25 to 29	0.4	0.6	0.8
30 to 34	0.45	0.7	0.9
35 to 39	0.6	0.8	1
40 to 49	0.6	0.9	1
50 to 59	0.8	1	1
60 or higher	0.9	1	1

Authorization duration: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require the following:

- Medical record documentation of improvement in pruritus from baseline AND
- Medical record documentation that the member is receiving an appropriate dose* based on the patient's weight

Formulary Alternatives: ursodiol

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

Palforzia

Updated Indication: PALFORZIA is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA is approved for use in patients ages 1 through 17 years of age with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 1 through 17 years. Up-Dosing and Maintenance may be continued in patients 1 year of age and older. PALFORZIA is to be used in conjunction with a peanut-avoidant diet.

Recommendation: Recommend the following changes to GHP Medicaid policy 1528.0F to reflect the new age indication. Recommend no changes to the auth duration or quantity limits.

- Medical record documentation that Palforzia is prescribed by an allergist, immunologist, or a physician qualified to prescribe allergy immunotherapy **AND**
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- If the request is for initial dose escalation: Medical record documentation that member is greater than or equal to 1 year of age to less than 18 years of age **OR**

- If the request is for up-dosing or maintenance dose: Medical record documentation that member is greater than or equal to 1 year of age

AND

- Medical record documentation of confirmed diagnosis of peanut-allergy with history of allergic reaction from peanuts **AND** one of the following:
    - positive skin test **OR**
    - *in vitro* testing for peanut-specific IgE antibodies

AND

- Medical record documentation that Palforzia will be used in conjunction with peanut-avoidant diet **AND**
- Medical record documentation that the member has (or will receive) a prescription for an epinephrine auto-injector **AND**
- Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma **AND**
- Medical record documentation that the member has not experienced severe or life-threatening anaphylaxis within 60 days of Palforzia initiation

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

Sirturo

Updated Indication: Sirturo is a diarylquinoline antimycobacterial drug and has now received full approval for use as part of combination therapy in adult and pediatric patients (5 years and older and weighing at least 15 kg) with pulmonary tuberculosis (TB) due to Mycobacterium tuberculosis resistant to at least rifampin and isoniazid. It was previously approved for under accelerated approval as part of combination therapy in adult and pediatric patients (5 years and older and weighing at least 15 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB). A limitation of use for Sirturo remains that it should not be used for the treatment of latent, extra-pulmonary or drug-sensitive TB or for the treatment of infections caused by nontuberculous mycobacteria.

Recommendation: No changes recommended to the formulary placement, prior authorization criteria, and authorization duration of Sirturo at this time due to Sirturo receiving full approval of its indication.

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

Lutathera

Upon discussion with medical directors, it was decided that the prior authorization criteria point regarding discontinuation of long-acting somatostatin analogs did not completely assess the information in the package insert. The package insert notes that long-acting somatostatin analogs must be discontinued or held for 4 weeks prior to administration of Lutathera

Recommendation: Criteria point #5 in the policy will be changed to include "/held" to clarify the appropriate measures that must be taken by providers prior to administration of Lutathera.

- Prescribed by a hematologist/oncologist **AND**
- Patient is 12 years of age or older **AND**

- Medical record documentation of a diagnosis of gastroenteropancreatic neuroendocrine tumor (GEP-NET) (including foregut, midgut, and hindgut tumors) **AND**
- Medical record documentation of presence of somatostatin receptors on all lesions (somatostatin receptor positive disease) **AND**
- Medical record documentation that long-acting somatostatin analogs have been (or will be) discontinued/held at least 4 weeks prior to initiation of treatment with Lutathera

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

Keytruda Update

Discussion: After review of the Keytruda medical benefit policy, it was determined that the criteria for NSCLC in combination with carboplatin and paclitaxel for first-line use can be updated to more closely reflect the package labeling (squamous cell) and what is recommended in NCCN guidelines (EGFR/ALK).

Recommendations: It is recommended to update the criteria for Keytruda NSCLC, specifically to add the specific indication that the carboplatin/paclitaxel combination is indicated for, and to add the EGFR/ALK monitoring requirement.

MBP 119.0 Keytruda (pembrolizumab)

1. **Metastatic Non-Small Cell Lung Cancer (NSCLC)**
   - Prescription written by a hematologist/oncologist **AND**
   - Medical record documentation that patient is ≥ 18 years of age **AND**
   - Medical record documentation of a diagnosis of metastatic NSCLC meeting one of the following situations:
     - Medical record documentation of stage III NSCLC, metastatic NSCLC, OR that the member is not a candidate for surgical resection or definitive chemoradiation **AND**
     - Medical record documentation that Keytruda is being used as first-line treatment **AND**
     - Medical record documentation that Keytruda is being given as monotherapy **AND**
     - Medical record documentation that tumors express PD-L1 (TPS) ≥1% as determined by an FDA-approved test **AND**
     - Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

     OR

     - Medical record documentation that Keytruda is being given as monotherapy **AND**
     - Medical record documentation that tumors express PD-L1 (TPS) ≥1% as determined by an FDA-approved test **AND**
     - Medical record documentation of disease progression on or after platinum-containing chemotherapy **AND**

- For patients with EGFR or ALK genomic tumor aberrations: medical record documentation of disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.

OR

- Medical record documentation of metastatic nonsquamous NSCLC **AND**
- Medical record documentation that Keytruda will be given in combination with pemetrexed AND either carboplatin or cisplatin **AND**
- Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

OR

- Medical record documentation of metastatic squamous NSCLC **AND**
- Medical record documentation that Keytruda will be given in combination with carboplatin AND either paclitaxel or nab-paclitaxel **AND**
- Medical record documentation that Keytruda, carboplatin, and paclitaxel (or nab-paclitaxel) are being used as first-line treatment **AND**
- Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

Erwinaze Update

Discussion: After discussion with DHS and internal sources, it was determined that there is most likely no remaining Erwinaze product left on the market. The Labeler reported their NDC as obsolete on 7/31/2021, then terminated their CMS rebate agreement on 4/1/2022. An FDA file lists the market end date as 7/23/2021.

Recommendations: It is recommended to retire MBP 95.0 Erwinaze (asparaginase).

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

GHP Family Update

Xolrembi

During the review of the GHP Family Xolrembi policy DHS requested we update the renewal criteria as noted below to align with its updated indication. It is recommended the Committee approve the update.

- Medical record documentation of a diagnosis of WHIM (warts, hypogammaglobulinemia, infections, and myelokathexis) syndrome **AND**
- Medical record documentation of symptoms and complications associated with WHIM syndrome **AND**
- Medical record documentation that member is 12 years of age or greater **AND**
- Medical Record documentation that Xolremdi is being prescribed by an immunologist, dermatologist, genetic specialist, or hematologist **AND**
- Medical record documentation of member's weight **AND**
- Medical record documentation of baseline absolute neutrophil count (ANC) and absolute lymphocyte count (ALC) **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

AUTHORIZATION DURATION: Approval will be given for an **initial duration of six (6) months** or less if the reviewing provider feels it is medically appropriate. After the initial six (6) month approval, subsequent approvals will be for a **duration of twelve (12) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- Medical record documentation of sustained improvement in absolute neutrophil count (ANC) and/or absolute lymphocyte count (ALC) from baseline **OR**
- Medical record documentation of clinical rationale for continuation of treatment (e.g. other benefits such as a decrease in infections)

Winrevair

During the review of the GHP Family Winrevar policy DHS requested we update the renewal criteria as noted below to align with its updated indication. DHS' rationale for the changes are:

- While the STELLAR trial (NCT04576988) only evaluated patients with functional class II or III symptoms, the FDA-approved indication for Winrevair does not exclude patients with class IV symptoms. PA DHS reached out to a pulmonary hypertension specialist from the University of Pennsylvania who told us patients with WHO functional class IV symptoms should be eligible for treatment.
- The pulmonary hypertension specialist that we reached out to provided feedback that it is not appropriate to utilize a six-minute walking distance test alone to assess benefit of therapy. The specialist said, "Sometimes hemodynamics improve and the functional status of the patient improves, but the six-minute walking distance does not improve.
- Winrevair is the first FDA-approved activin signaling inhibitor therapy for PAH, representing a new class of therapy that works by improving the balance between pro- and anti-proliferative signaling to regulate vascular cell proliferation underlying PAH. It was granted Breakthrough Therapy Designation by the FDA. Members should not be required to experience "therapeutic failure" on other therapies prior to eligibility to receive Winrevair. Also, the pulmonary hypertension specialist told us patients are demonstrating such dramatic improvements on Winrevair (sotatercept) that they are having discussions about removing one or more of the patients' other PAH therapies. Please confirm that this prior authorization guideline evaluating use in combination with at least two PAH therapies from different categories would only be applied to initial reviews for patients newly starting therapy with Winrevair (sotatercept) and not requests for patients who are new to the plan, but already established on Winrevair therapy OR reauthorization requests.
- The pulmonary hypertension specialist that we consulted with confirmed that prostacyclin analogues should be included as an additional therapy option.

It is recommended the Committee approve the update.

- Medical record documentation that Winrevair is prescribed by a cardiologist or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of World Health Organization (WHO) Group 1 pulmonary arterial hypertension **AND**
- Medical record documentation of World Health Organization (WHO) functional class II, III, or IV symptoms at baseline **AND**
- ~~Medical record documentation of a baseline 6-minute walking distance **AND**~~
- ~~Medical record documentation of therapeutic failure, intolerance to, or contraindication to one (1) formulary endothelin receptor antagonist (ERA) in combination with one (1) formulary phosphodiesterase-5 inhibitor (PDE5i) or one (1) soluble guanylate cyclase (sGC) stimulator~~
- Medical record documentation of **ONE** of the following:

    - Member is currently receiving at least 2 other PAH therapies from different pharmacologic categories [i.e., endothelin receptor antagonist (ERA), phosphodiesterase-5 inhibitor (PDE5i), soluble guanylate cyclase (sGC) stimulator, or prostacylin analogue)]
      OR
    - The member is currently receiving at least one other PAH therapy and the prescriber attests the member is unable to tolerate combination therapy with a phosphodiesterase type 5 inhibitors (PDE5i), endothelin receptor antagonists (ERAs), a soluble guanylate cyclase stimulator (sGCs), or prostacyclin analogues **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

AUTHORIZATION DURATION: Initial authorization will be for 6 months. Subsequent authorizations will be for ~~6~~ 12 months and will require:

- Medical record documentation ~~of a 6-minute walking distance improved from baseline~~ that the member's condition has improved or stabilized, or the member continues to benefit from therapy based on the prescriber's assessment

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

Meeting adjourned at 3:26 PM

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held March 11, 2025.

Meetings will be held virtually via phone/Microsoft Teams