P&T Committee Meeting Minutes
Medicaid
May 13, 2025

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair Amir Antonious, Pharm.D. Leslie Astleford, Pharm.D. Emily Bednarz, Pharm.D. Kristen Bender, Pharm.D. Angela Bolesta, Pharm.D. Kim Castelnovo, RPh Kimberly Clark, Pharm.D. Michael Dubartell, MD Tricia Heitzman, Pharm.D. Jason Howay, Pharm.D. Keith Hunsicker, Pharm.D. Kelli Hunsicker, Pharm.D. Emily Jacobson, Pharm.D. Dennis Janosczyk, Pharm.D. Alexandra Kempf-Malys, MSW, BSc Kerry Ann Kilkenny, MD Philip Krebs, R.EEG T Briana LeBeau, Pharm.D. Ted Marines, Pharm.D. Tyreese McCrea, Pharm.D. 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. Amanda Taylor, MD Ariana Wendoloski, Pharm.D. Brandon Whiteash, Pharm.D. Abigail Chua, DO (non-voting participant) Tiffany O'Hagan, Pharm.D., MBA (non-voting participant)	Jeremy Bennett, MD Bhargavi Degapudi, MD Keri Donaldson, MD, MSCE Kelly Faust, Pharm.D. Nichole Hossler, MD Lisa Mazonkey, RPh Perry Meadows, MD Jamie Miller, RPh Andrei Nemoianu, MD Jonas Pearson, RPh Angela Scarantino Michael Shepherd, MD Jill Stone, Pharm.D. Luke Sullivan, DO Kevin Szczecina, RPh Margaret Whiteash, Pharm.D.

Call to Order: Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday May 13, 2025.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the March 11, 2025 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Hercessi (trastuzumab-strfm)

Review: Hercessi, trastuzumab-strfm is the 6th FDA approved Herceptin biosimilar.

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

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

Outcome: Hercessi is a medical benefit that will be managed by GHP and will not require a prior authorization. Herceptin (trastuzumab) will be considered medically necessary when ALL of the following criteria are met:

- Medical record documentation of a therapeutic failure of, intolerance to, or contraindication to **all** of the following: trastuzumab-anns (Kanjinti), trastuzumab-dkst (Ogivri), trastuzumab-dttb (Ontruzant), trastuzumab-qyyp (Trazimera), Hercessi (trastuzumab-strf), and trastuzumab-pkrb (Herzuma)

AUTHORIZATION DURATION:
For adjuvant treatment:
Authorization will be for one (1) 12-month approval. Authorization of Herceptin for adjuvant treatment should not exceed the FDA-approved treatment duration of 1 year (12 months). 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

For all other indications:
Authorization will be open-ended
Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

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

Grafapex (treosulfan)

Review: Grafapex is indicated for use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (alloHSCT) in adult and pediatric patients 1 year of age and older with acute myeloid leukemia (AML) and for use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation in adult and pediatric patients 1 year of age and older with myelodysplastic syndrome (MDS). Treosulfan is an alkylating agent that has shown hematopoietic stem cell depleting activity as well as immunosuppressive and antitumor activity in mouse models of leukemia.

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

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

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

- Medical record documentation that Grafapex is being prescribed by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 1 year AND

- Medical record documentation of a diagnosis of acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) AND
- Medical record documentation that Grafapex will be used in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation AND
- Medical record documentation that member has not received a prior allogeneic hematopoietic stem cell transplantation

Authorization Duration (Medical Benefit): One time authorization

Medispan Authorization Level: GPI-12

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

Alyftrek (deutivacaftor/tezacaftor/vanzacaftor)

Review: Alyftrek is a cystic fibrosis transmembrane conductance regulator (CFTR) corrector and potentiator that is FDA indicated for the treatment of cystic fibrosis (CF) in patients 6 years of age and older who have at least one F508del mutation or another responsive mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one indicated mutation

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

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

Outcome: Alyftrek is a pharmacy benefit that will be managed by GHP that will require a prior authorization and added to Medicaid formulary to the brand tier.
It is recommended to be added to Trikafta Policy 1521.0F:

- Medical record documentation that the patient is 2 years of age or older if request is for Trikafta OR age greater than or equal to 6 years if request is for Alyftrek **AND**
- Medical record documentation of a diagnosis of cystic fibrosis **AND**
- Medical record documentation that the patient has at least one F508del mutation in the cystic fibrosis transmembrane conductanse regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on in vitro data. (If the patient's genotype is unknown, an FDA-cleared CF mutationtest should be used to confirm the presence of at least one F508del mutation or a mutation that is responsive based on in vitro data) **AND**

Note to reviewer: Please reference the appropriate CFTR mutation tables provided in policy that are responsive to Trikafta or Alyftrek. Responsive mutations approved per FDA are different for each drug.

- Medical record documentation that the medication is prescribed by, or in consultation with, a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.

Authorization Duration: 4 months initial, 12 months reauthorization

Quantity Limit: 28-day supply per fill

Reauthorization Info: Additional authorizations will require medical record documentation of improvement or stabilization in the signs and symptoms of cystic fibrosis. The medication will no longer be covered if the member experiences worsening of disease.

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

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Kebilidi (eladocagene exuparvovec-tneq)

Review: Kebilidi is an adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency. The indication was approved under accelerated approval based on change from baseline in gross motor milestone achievement at 48 weeks post-treatment. Continued approval for the indication is contingent on clinical benefit in a confirmatory clinical trial.

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

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

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

- Medical record documentation of a diagnosis of aromatic L-amino acid decarboxylase (AADC) deficiency, as confirmed by decreased AADC enzyme activity in the plasma AND
- Medical record documentation of an AADC deficiency due to biallelic mutations in the Dopa Decarboxylase (DDC) gene AND
- Medical record documentation of persistent neurological defects* despite standard medical therapy (e.g. dopamine agonists, monoamine oxidase inhibitor, pyridoxine, or other forms of vitamin B6) AND
- Medical record documentation that member is unable to ambulate independently, with or without assistive device AND
- Medical record documentation of age greater than or equal to 16 months AND
- Medical record documentation that the patient has anti-adeno-associated virus serotype 2 (anti-AAV2) antibody titers ≤1:1200 AND
- Medical record documentation of achievement of skull maturity as assessed by neuroimaging AND
- Medical record documentation of completion of, or a plan to complete, brain imaging specifically for stereotactic planning and intraoperative navigation AND
- Medical record documentation that Kebilidi is prescribed by a neurologist, pediatric neurologist, geneticist, or physician specializing in the treatment of inherited metabolic diseases AND
- Medical record documentation of a prescribed dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature AND
- Medical record documentation that the patient has never received Kebilidi treatment in their lifetime AND
- Medical record documentation that the member has not received any previous gene therapy for any disease

*Per NORD, signs and symptoms of AADC deficiency include movement disorders (hypotonia, oculogyric crises, hypokinesia, hypertonia, dystonia, athetosis, chorea, tremors) and/or autonomic disorders (excessive sweating, hypersalivation, ptosis, nasal congestion, temperature instability, hypotension, hypoglycemia, seizures, irritability, excessive crying, insomnia, hypersomnia, hyporeflexia, hyperreflexia).

Note: The dosing of Kebilidi is a single total dose of 1.8×10^{11} vg (0.32 mL), given as four (4) intraputaminal infusions at a dose of 0.45×10^{11} vg (0.08 mL) per infusion.

Authorization Duration: One (1) time approval per lifetime (auth duration: 2 months). Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

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

Attruby (acoramidis)

Review: Sutab is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy for adults. It is a split dose, 2-day regimen that includes 24 tablets total and a water container that is 16 ounces. The patient will take 12 tablets at a time, which is one dose, with 16 ounces of water over 15-20 minutes. Approximately one hour after the last tablet is ingested, the water is filled again with 16 ounces of water and drank over 30 minutes. Approximately 30 minutes after finishing the second container, the container is filled again and drank over 30 minutes. Patients will continue to consume only clear liquids until after the colonoscopy. 5 to 8 hours before the colonoscopy and no sooner than 4 hours from starting dose 1, 12 tablets should be consumed with 16 oz of water over 15-20 minutes. The same directions apply with drinking another 16 ounces of water in two separate parts over 30 minutes just as the first day. The total amount should be consumed at least 2 hours prior to colonoscopy. If patients experience preparation-related symptoms (nausea, bloating, cramping), pause or slow rate of drinking water until these diminish.

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

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

Outcome: Attruby will be a pharmacy benefit and should not be added to the GHP Family Formulary. Attruby should be added to Policy 1506.0F Vyndaqel & Vyndamax and no additional prior authorization criteria should apply.

- Medical record documentation of cardiomyopathy resulting from wild type transthyretin-mediated amyloidosis or hereditary transthyretin-mediated amyloidosis as confirmed by <u>one</u> of the following:
    - Bone scan (scintigraphy) strongly positive for myocardial uptake of 99mTcPYP/DPD* OR

*Note: Strongly positive is defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)

    - Biopsy of tissue of the affected organ to confirm amyloid presence AND chemical typing to confirm presence of transthyretin (TTR) protein

AND

- Medical record documentation that patient is 18 years of age or greater AND
- Medical record documentation that medication is prescribed by or in consultation with a cardiologist AND
- Medical record documentation that the patient has New York Heart Association (NYHA) Class I, II, or III heart failure AND

- Medical record documentation that Attruby and Vyndaqel/Vyndamax will not be used in combination.

AUTHORIZATION DURATION: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months, requiring medical record documentation that the patient continues to benefit from Attruby therapy. The medication will no longer be covered if the member experiences toxicity or progresses to NYHA class IV heart failure.

GPI Level: GPI-12

Quantity Limits:

- Attruby: 28-day supply per fill (add to letter and auth)
- Vyndaqel: 30-day supply per fill (add to letter and auth)
- Vyndamax: 30-day supply per fill (add to letter and auth)

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

Vyalev (foscarbidopa/foslevodopa)

Review: Vyalev is indicated for the treatment of motor fluctuations in adults with advanced Parkinson's disease. It contains a prodrug combination of foscarbidopa and foslevodopa which are converted in vivo to carbidopa and levodopa. Levodopa crosses the blood brain barrier and is converted to dopamine which is thought to treat the symptoms of Parkinson's disease. Carbidopa inhibits decarboxylation of peripheral levodopa, making more of it available for delivery to the brain.

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

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

Outcome: Vyalev 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 greater than or equal to 18 years AND
- Medical record documentation of treatment of motor fluctuations in advanced Parkinson disease AND
- Medical record documentation that Vyalev is prescribed by or in consultation with a neurologist AND
- Medical record documentation of refractory tremor AND
- Medical record documentation of levodopa responsiveness with clearly defined "On" periods AND
- Medical record documentation of persistent motor complications with disabling "Off" periods such as muscle stiffness, slow movements, or difficulty starting movements AND
- Medical record documentation that the member was assessed for and determined for and determined to have no other secondary causes of Parkinson's Disease AND
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to carbidopa-levodopa, and at least two other classes of anti-Parkinson's therapy.

Medispan Authorization Level: GPI 12

Quantity Limit: 28-day supply per fill.

Authorization Duration: 12 months
Reauthorization Info: Medical record documentation of clinical improvement or maintenance of condition.

FORMULARY ALTERNATIVES: per Statewide PDL

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.

FAST FACTS

UPDATES

Medical Benefit Drug Policy Update

Discussion: On PARP review, it was recommended to GHP to closely align policy criteria with the FDA approved limitation of use.

Recommendations: It is recommended to update the prior authorization criteria of MBP 249.0 Saphnelo to align with the FDA approved limitations of use.

MBP 249.0 Saphnelo (anifrolumab-fnia)

- Medical record documentation that member does not have severe active lupus nephritis or severe active central nervous system lupus **AND**

Discussion: The committee unanimously voted to accept the recommendations.

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

DUR/Adherence Update

Discussion: The most recent DUR/Adherence activities were presented to the Committee.

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

April ELECTRONIC VOTE
An electronic vote was held from April 14, 2025, to April 18, 2025. Responses were received from 28 members (out of 50 members) and all voted to approve. Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Imcivree

Updated Indication: Imcivree is a melanocortin 4 (MC4) receptor agonist indicated to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients 2 years of age and older with syndromic or monogenic obesity due to Bardet-Biedl syndrome (BBS), pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS).

Recommendation: Update minimum age in Imcivree policy to 2 years of age

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

Opdivo

Updated Indication: Opdivo is now indicated for adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer and no known EGFR mutations or ALK rearrangements, for neoadjuvant treatment, in combination with platinum-doublet chemotherapy, followed by single-agent OPDIVO as adjuvant treatment after surgery

Recommendation: The following updates are recommended to the criteria and authorization duration of Medical Benefit Policy 126.0.:

~~**If the request is for neoadjuvant treatment of resectable NSCLC:**~~

- ~~Medical record documentation of resectable (tumor size greater than or equal to 4 centimeters or node-positive) non-small cell lung cancer (NSCLC)~~ ~~**AND**~~
- ~~Medical record documentation that Opdivo will be used for neoadjuvant treatment in combination with platinum-doublet chemotherapy.~~

If the request is for neoadjuvant treatment or neoadjuvant/adjuvant treatment of resectable NSCLC:

- Medical record documentation of resectable (tumor size greater than or equal to 4 centimeters or node-positive) non-small cell lung cancer (NSCLC) AND
- Medical record documentation that Opdivo will be used for neoadjuvant treatment in combination with platinum-doublet chemotherapy OR
- Medical record documentation of no known EGFR or ALK rearrangements **AND** that Opdivo will be used for neoadjuvant treatment in combination with platinum-doublet chemotherapy followed by Opdivo monotherapy as adjuvant treatment after surgery.

AUTHORIZATION DURATION:

**For Neoadjuvant/Adjuvant NSCLC: One approval will be given for up to 4 cycles of neoadjuvant treatment (6 months) and up to 13 cycles (12 months) of adjuvant treatment for a total duration of 18 months. Authorization of Opdivo for the neoadjuvant and adjuvant treatment of NSCLC should not exceed the FDA-approved treatment duration of 4 cycles for neoadjuvant treatment and 13 cycles of adjuvant treatment.

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

Sarclisa

Updated Indication: It is now also indicated for use in combination with bortezomib, lenalidomide and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant (ASCT).

Recommendation: No changes recommended for either the formulary placement or the prior authorization criteria.:

Multiple Myeloma

Medical record documentation that Sarclisa 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 diagnosis of multiple myeloma AND

.Medical record documentation of one of the following:

Medical record documentation of use in combination with pomalidomide and dexamethasone AND

Medical record documentation of prior treatment with at least two therapies which include lenalidomide and a proteasome inhibitor (including but not limited to Velcade, Kyprolis, or Ninlaro) OR

Medical record documentation that the member is not eligible for stem-cell transplantation AND

Medical record documentation that Sarclisa will be given in combination with bortezomib, lenalidomide and dexamethasone

Relapsed or Refractory Multiple Myeloma

Medical record documentation that Sarclisa 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 diagnosis of relapsed or refractory multiple myeloma AND

Medical record documentation of one of the following:

- Medical record documentation that Sarclisa will be used in combination with carfilzomib (Kyprolis)* and dexamethasone **AND**
- Medical record documentation of prior treatment with one to three lines of therapy

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

April 2025 GHP Family Update

Linezolid

DHS pointed out while reviewing the 2025 Medicaid formulary that a quantity limit for linezolid tablets appear in the online search, but DHS doesn't have a quantity limit in place. Recommend terming the quantity limit for Medicaid to match what is in place for DHS.

Ragwitek

While reviewing the Medicaid Ragwitek policy DHS pointed out that the medication is now indicated for ages ≥ 5 years and ≤ 65 years. Recommend updating the Medicaid policy to match the indication.

Adacel

Adacel is on formulary for the Clinical Enterprise, but there was an age limit in place that prevented claims for processing for members older than age 65 years. However, the Advisory Committee on Immunization Practices (ACIP) concluded that either Adacel or Boostrix administered to a person age 65 or older is immunogenic and will provide protection. A dose of either vaccine is considered valid. Recommend updating the age limit in place to be age 19 and older.

Solu-Cortef

All strengths of Solu-Cortef are on the Medicaid formulary on the brand tier, except for the 100 mg vial because there is a generic version available. However, the generic does not come with diluent. Recommend adding Solu-Cortef be added to the Medicaid formulary on the band tier to match other available strengths.

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

Meeting adjourned at 3:57 PM

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held July 8, 2025.

Meetings will be held virtually via phone/Microsoft Teams