P&T Committee Meeting Minutes Medicaid March 19, 2024

Present (via Teams):

Bret Yarczower, MD, MBA - Chair

Amir Antonius, Pharm.D.

Emily Bednarz, Pharm.D.

Kristen Bender, Pharm.D.

Alyssa Cilia, RPh

Kimberly Clark, Pharm.D.

Bhargavi Degapudi, MD

Michael Dubartell, MD

Kelly Faust, Pharm.D.

Tricia Heitzman, Pharm.D.

Jason Howay, Pharm.D.

Keith Hunsicker, Pharm.D.

Kelli Hunsicker, Pharm.D.

Derek Hunt, Pharm.D.

Emily Jacobson, Pharm.D.

Philip Krebs, R.EEG T

Briana LeBeau, Pharm.D.

Ted Marines, Pharm.D.

Lisa Mazonkey, RPh

Tyreese McCrea, Pharm.D.

Perry Meadows, MD

Jamie Miller, RPh

Mark Mowery, Pharm.D.

Austin Paisley, Pharm.D.

Lauren Pheasant, Pharm.D.

Kimberly Reichard, Pharm.D.

Melissa Sartori, Pharm.D.

Kristen Scheib, Pharm.D.

Leslie Shumlas, 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

Ariana Wendoloski, Pharm.D.

Brandon Whiteash, Pharm.D.

Margaret Whiteash, Pharm.D.

Benjamin Andric, PharmD. (non-voting participant)

Biriu Bhatt, MD (non-voting participant)

Alfred Denio, MD (non-voting participant)

Keri Donaldson (non-voting participant)

Jeremy Garris, Pharm.D. (non-voting participant)

Absent:

Jeremy Bennett, MD

Kim Castelnovo, RPh

Michael Evans, RPh

Nichole Hossler, MD

Kerry Ann Kilkenny, MD

Jonas Pearson, RPh

William Seavey, Pharm.D.

Angela Scarantino

Michael Shepherd, MD

Robert Strony, MD MBA

Amanda Taylor, MD

Chidubem Ifeji (pharmacy resident)	
Andrei Nemoianu (non-voting participant)	

Call to Order: Dr. Bret Yarczower called the meeting to order at 1:03 p.m., Tuesday, March 19, 2024.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the January 16,2024 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Jesduvroq (daprodustat)

Review: Jesduvroq is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months. Jesduvroq has not been shown to improve quality of life, fatigue, or patient well-being. It is not indicated for use as a substitute for transfusion in patients requiring immediate correction of anemia and in patients not on dialysis.

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

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

Outcome: Jesduvroq 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 a diagnosis of anemia due to chronic kidney disease AND
- Medical record documentation that member has been receiving dialysis for at least four 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

GPI Level: GPI-12

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

General Guidance:

- 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 12g/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.

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.

Aphexda (motixafortide)

Review: Aphexda is a hematopoietic stem cell mobilizer, indicated with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma. Aphexda inhibits the C-X-C Motif Chemokine Receptor 4 (CXCR4) and blocks the binding of its cognate ligand, stromal-derived factor- 1α (SDF- 1α)/C-X-C Motif Chemokine Ligand 12 (CXCL12) which plays a role in trafficking human hematopoietic stem cells to the marrow compartment. Treatment with Aphexda results in leukocytosis and elevations in circulating hematopoietic stem and progenitor cells into peripheral circulation. In a rodent transplantation model, stem cells mobilized by Aphexda were capable of engraftment with long-term repopulating capacity.

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

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

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

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Aphexda is prescribed by a hematologist or oncologist AND
- Medical record documentation that Aphexda will be used in combination with filgrastim for the mobilization and collection of hematopoietic stem cells for subsequent autologous stem cell transplantation.

Formulary Alternatives: plerixafor **Authorization Duration:** 1 month

QL: 30 day supply per fill

GPI Level: GPI-12

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.

Class Review_			
Fast Facts			
Updates			

Day Supply Update

Recommendation: Medications considered specialty and/or on the specialty tier are limited to a 34 day supply. In order to allow claims to process at the appropriate day supply, we added Ajovy and Keytruda to the maximum day supply list for Medicaid. The following updates were made:

• Ajovy- maximum day supply: 90

• Keytruda- maximum day supply: 42

Outcome: The committee unanimously voted to accept the recommendations.

February ELECTRONIC VOTE

An electronic vote was held from February 15, 2024, to February 23, 2024. 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.

Balfaxar (prothrombin complex concentrate, human-lans)

Review: Balfaxar is a blood coagulation factor replacement product indicated for the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA, e.g., warfarin) therapy in adult patients with need for an urgent surgery/invasive procedure. VKA therapy is used to prevent blood clots in a variety of circumstances, including to prevent deep vein thrombosis (DVT) and pulmonary embolism (PE), to lower the risk of stroke in atrial fibrillation (AF), and after a heart attack or valve surgery. Due to its anti-clotting properties, warfarin increases the risk of bleeding, which could be a serious complication during surgery. The incidence of warfarin-associated hemorrhage is unclear, but some reports indicate that the annual rate of fatal hemorrhage may be approximately 1% (24,000 patients) per year.

Recommendation: Balfaxar is a medical benefit managed by GHP, not requiring prior authorization.

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

Loqtorzi (toripalimab-tpzi)

Review: Loqtorzi is a programmed death receptor-1 (PD-1) blocking antibody indicated in combination with cisplatin and gemcitabine, for first-line treatment of adults with metastatic or with recurrent locally advanced nasopharyngeal carcinoma (NPC) and as a single agent for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy. Loqtorzi is a humanized IgG4 monoclonal antibody that binds the PD-1 receptor, blocking its interaction with PD-L1 and PD-L2, leading to PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response. Loqtorzi is the first and only FDA approved treatment for nasopharyngeal carcinoma. NCCN recommends Loqtorzi as a preferred treatment regimen with cisplatin/gemcitabine for patients with recurrent, unresectable, oligometastatic, or metastatic disease (with no surgery or RT options) (Category 1) or for subsequent-line regimen if disease progression on or after a platinum-containing chemotherapy (Category 2A). Roctavian is the first gene therapy approved for the one-time treatment of severe hemophilia A and offers a novel treatment option beyond standard-ofcare treatments (prophylaxis with FVIII products or Hemlibra). Patients with severe hemophilia A generally receive multiple or once-weekly IV doses of prophylactic FVIII or subcutaneous (SC) administrations of Hemlibra once every 1, 2, or 4 weeks. Treatment with Roctavian has the potential to increase quality of life in these patients because it may free patients from burdensome FVIII IV infusions or scheduled Hemlibra SC injections. Roctavian is unlikely to represent a cure for hemophilia A due to its current durability data, as FVIII activity (which tends to correlate to protection against bleeds) decreases over time in clinical trials.

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

- Medical record documentation that Loqtorzi is prescribed by an oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of one of the following:
 - Medical record documentation that Loqtorzi is being given as first-line treatment in combination
 with cisplatin and gemcitabine AND documentation of a diagnosis of metastatic or recurrent locally
 advanced nasopharyngeal carcinoma (NPC)

OR

 Medical record documentation that Loqtorzi is being used as a single agent AND documentation of a diagnosis of recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.

Authorization Duration: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months 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.

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

Keytruda

Updated Indication: Keytruda received approval for the expansion of the indication for urothelial cancer to the following: Keytruda in combination with enfortumab vedotin for the treatment of adult patients with locally advanced or metastatic urothelial cancer. Previously this indication was an accelerated approval limited to patients who were not eligible for cisplatin-containing chemotherapy.

Recommendation: remove "Patient is not eligible for cisplatin-containing chemotherapy" from the policy criteria

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

Padcev

Updated Indication: Padcev received approval for the expansion of the indication for urothelial cancer to the following: Padcev in combination with pembrolizumab for the treatment of adult patients with locally advanced or metastatic urothelial cancer. Previously this indication was an accelerated approval limited to patients who were not eligible for cisplatin-containing chemotherapy. There are no changes for the indications where Padcev is given as a single agent.

Recommendation: Remove "Medical record documentation that member is ineligible for cisplatin-containing chemotherapy" from the policy criteria.

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

Updated Indication: Voxzogo is a C type natriuretic peptide (CNP) analog that was previously approved to increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses. It is now indicated for all pediatric patients

Recommendation: It is recommended to update the age noted in the policy to be "less than 18 years of age".

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

GHP Family Update

<u>Abrysvo:</u> During the annual formulary review DHS requested we remove the age limit from Abrysvo so it does not deny for pregnant members. The recommendation is to change the age limit to 19 to 999 and retire the policy.

<u>Linezolid</u>: During the annual formulary review DHS questioned our quantity limits on linezolid tablets and suspension. It was noted that during 2023 there were only 9 PA requests and 8 were approved. The recommendation for Commercial and Medicaid is to remove the QL on the tablets and the PA and QL on the suspension. The policy will also be retired for Commercial and Medicaid.

2024 GHP Family Supplemental Formulary: The 2024 GHP Family was submitted to the committee for review.

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

Meeting adjourned at 3:10 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on May 21, 2024 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams