P&T Committee Meeting Minutes
Medicaid
March 21, 2023

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Kristen Bender, Pharm.D.
Amir Antonious, Pharm.D.	Jeremy Bennett, MD
Emily Antosh, Pharm.D.	Kim Castelnovo
Alyssa Cilia, RPh	Kimberly Clark, Pharm.D.
Bhargavi Degapudi, MD	Holly Bones, Pharm.D.
Michael Dubartell, MD	Michael Evans, RPh
Kelly Faust Pharm.D.	Rajneel Farley, Pharm.D.
Tricia Heitzman, Pharm.D.	Jason Howay, Pharm.D.
Nichole Hossler, MD	Derek Hunt, Pharm.D.
Emily Hughes, Pharm.D.	Kerry Ann Kilkenny, MD
Keith Hunsicker, Pharm.D.	Briana LeBeau, Pharm.D.
Kelli Hunsicker, Pharm.D.	Tyreese McCrea, Pharm.D.
Philip Krebs, R.EEG T	Jamie Miller, RPh
Ted Marines, Pharm.D.	Jonas Pearson, RPh
Lisa Mazonkey, RPh	William Seavey, Pharm.D.
Perry Meadows, MD	Michael Shepherd, MD
Mark Mowery, Pharm.D.	Kevin Szczecina, RPh
Austin Paisley, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Sartori, Pharm.D.	
Angela Scarantino	
Kristen Scheib, Pharm.D.	
Leslie Shumlas, Pharm.D.	
Aubrielle Smith Pharm.D.	
Kirsten Smith, Pharm.D.	
Michael Spishock, RPh	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
Robert Strony, MD, MBA	
Luke Sullivan, DO	
Amanda Taylor, MD	
Ariana Wendoloski, Pharm.D.	
Brandon Whiteash, Pharm.D.	
Margaret Whiteash, Pharm.D.	
Jeremy Garris, Pharm.D. (non-voting participant)	
Marianne Linko (non-voting participant)	
Dionardo Medina Encarnacion, MD (non-voting participant)	
Mary Hoang (student)	
Devaney Taylor (Wood) (student)	
Sarah Tucker (Pharmacy Resident)	

Call to Order: Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, March 21, 2023.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the January 17th, 2023 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Pedmark (sodium thiosulfate)

Review: Pedmark is the first and only FDA-approved medication indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors. The safety and efficacy of Pedmark have not been established when administered following cisplatin infusions longer than 6 hours. Pedmark may not reduce the risk of ototoxicity when administered following longer cisplatin infusions, because irreversible ototoxicity may have already occurred. Pedmark is not substitutable with other sodium thiosulfate products.

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

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

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

- Documentation of age greater than or equal to 1 month but less than 18 years of age AND
- Prescribed by or in consultation with a hematologist or oncologist AND
- Medical record documentation of a localized, non-metastatic solid tumor AND
- Medical record documentation that the patient will receive a cisplatin infusion with an infusion time less than or equal to 6 hours AND
- Medical record documentation that Pedmark is being used to reduce the risk of ototoxicity associated with cisplatin 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 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 and will require medical record documentation of clinical improvement or lack of progression and documentation that the patient is continuing to receive a cisplatin-based chemotherapy regimen. The medication will no longer be covered if the patient experienced toxicity. worsening of disease, or if the member is not to continue on a cisplatin-based chemotherapy regimen

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

Sezaby (phenobarbital sodium)

Review: Sezaby is the injectable formulation of phenobarbital indicated specifically for neonatal seizures approved on November 17th, 2022. With the approval, Sezaby becomes the first and only medication specifically approved for the indication of neonatal seizures in term and preterm infants

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

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

Outcome: Sezaby is a medical benefit managed by GHP, not requiring prior authorization. No prior authorization criteria will apply.

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

Relyvrio (sodium phenylbutyrate/taurursodiol)

Review: On September 29, 2022, the U.S. Food and Drug Administration (FDA) approved Amylyx Pharmaceuticals' Relyvrio (sodium phenylbutyrate/taurursodiol) oral suspension for the treatment of amyotrophic lateral sclerosis (ALS) in adults. Relyvrio provides an additional treatment option for ALS. Riluzole and Radicava/Radicava ORS are the only other two FDA-approved therapies for the treatment of ALS; however, each only modestly slows disease progression. Riluzole has been shown to prolong survival by an average of 2 to 3 months; however, Radicava has not been shown to have an effect on survival. Radicava has only been shown to slow disease progression in a small subset of patients with early stage ALS with a disease duration of 2 years or less and a slower rate of progression. The FDA approved an oral version of edaravone (Radicava ORS) on May 12, 2022, based on bioequivalence with the intravenous (IV) formulation. Oral administration of edaravone will overcome many of the risks and hurdles of the IV route of administration

Clinical Discussion: Kim Reichard, PharmD, stated she was in favor of removing the baseline functional status criterion from Relyvrio and Radicava. Keith Hunsicker, PharmD, offered insight as to why the decision was made to include this upon the initial review of Radicava in 2017 but said he would be okay removing it. Aubrielle Smith, PharmD, stated she did not think it was necessary to include in initial criteria if we aren't looking at it upon reauthorization. Dr. Nichole Hossler agreed. No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

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

- Medical record documentation of a diagnosis of amyotrophic lateral sclerosis (ALS) AND
- Medical record documentation that Relyvrio is prescribed in consultation with a neurologist 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.

Authorization Duration: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require the following criteria:

- Medical record documentation that member is tolerating and compliant with prescribed Relyvrio regimen AND
- Medical record documentation of regular physician follow-up

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

Zynteglo (betibeglogene autotemcel)

Review: On August 17, 2022, the U.S. Food and Drug Administration (FDA) approved bluebird bio's Zynteglo (betibeglogene autotemcel), formerly known as beti-cel. It is the first cell-based gene therapy for the treatment of adult and pediatric patients with beta-thalassemia who require regular red blood cell (RBC) transfusions. In the Zynteglo Phase 3 trials, 89% (32/26) achieved TI. Longer-term results show up to 7 years of treatment effect, including TI and stable hemoglobin levels. On June 9–10, 2022, the FDA's Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) met to review bluebird's LVV gene therapies, eli-cel and beti-cel. The CTGTAC unanimously voted to recommend both treatments, deciding that the benefits of treatment outweigh the risks. Still, patients with TDT face lifelong disease burden, and it remains unclear how long Zynteglo will last. Due to the small sample size, detection of more rare adverse effects (such as malignancies and insertional oncogenesis) is difficult, although none have been reported so far with Zynteglo. At this point, HSCT is the only other potentially curative therapy for TDT. While HSCT has more data supporting its use, this option requires a matched donor and carries the risks of mortality, GVHD, graft failure, and graft rejection. Additionally, younger patients have better outcomes with HSCT: overall thalassemia-free survival is >85% in children and 65% in adults. While Zynteglo does not require a matched donor, myeloablative therapy is required for both HSCT and Zynteglo and also carries significant risks. Also, the evidence supporting use of Zynteglo is only in a small clinical trial population, and enrollment in the Zynteglo clinical trials was limited to those who do not have a matched sibling donor. At this point, the place in therapy for Zynteglo is likely as an alternative to HSCT in patients who do not have a matched sibling donor.

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

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

Outcome: Zynteglo will be a medical benefit. Zynteglo will require a prior authorization with the following criteria:

- Prescription written by a hematologist and/or stem cell transplant specialist AND
- Medical record documentation of age greater than or equal to 4 years and less than or equal to 50 years AND
- Medical record documentation of a diagnosis of transfusion dependent beta-thalassemia AND one of the following:
    - Medical record documentation of a history of ≥ 100 mL/kg/year of packed red blood cells in the prior 2 years OR
    - Medical record documentation of a history of ≥ 8 transfusions of packed red blood cells per year in the prior 2 years AND
- Medical record documentation that the member has not had a prior hematopoietic stem cell transplant AND
- Medical record documentation the member is a candidate for a hematopoietic stem cell transplant but ineligible due to absence of Human Leukocyte Antigen (HLA)-matched family donor* AND
- Medical record documentation that the member has a negative serology test for Human Immunodeficiency Virus (HIV)

Authorization Duration: One (1) time approval per lifetime; 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.

Fast Facts

N/A

Updates

Nulojix

Recommendation: It is recommended to update the criteria for use of the Nulojix policy MBP 93.0 with the addition of policy criteria and one note, and the Part D policy 211.0D with the addition of policy criteria. The update to the Nulojix policy is intended to capture clinical scenarios when an immunosuppressive agent other than mycophenolate is being used in combination with Nulojix. The update is also intended to capture the medically accepted off label use of conversion from a calcineurin inhibitor to Nulojix

Nulojix (belatacept) will be considered medically necessary for the prophylaxis of organ rejection in adult patients with:

- Physician provided documentation of kidney transplant; **AND**
- Documentation of Epstein-Barr virus (EBV) seropositivity; **AND**
- ~~Documentation of planned use in combination with basiliximab induction, mycophenolate, and corticosteroids~~
- Documentation of planned use in combination with a complete immunosuppressive regimen including basiliximab induction (for patients new to immunosuppressive therapy), corticosteroids, AND mycophenolate (or other immunosuppressant such as azathioprine, everolimus, or sirolimus)

AUTHORIZATION DURATION: Initial approval will be for 1 year or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 1 year or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued use in combination with mycophenolate (or other immunosuppressant such as azathioprine, everolimus, or sirolimus) & corticosteroids, lack of organ rejection, and lack of toxicity. The medication will no longer be covered if patient discontinues mycophenolate(or other immunosuppressant such as azathioprine, everolimus, or sirolimus) and/or corticosteroids, experiences toxicity, or symptoms of organ rejection.

LIMITATIONS:

- Nulojix® (belatacept) is contraindicated in transplant recipients who are EBV seronegative or are of unknown serostatus.
- Nulojix® (belatacept) is contraindicated for all transplants other than kidney.

NOTE: According to Lexi-Drugs, phase 2 and 3b randomized controlled trials showed that patients 6 to 60 months post kidney transplant can be safely converted from a calcineurin inhibitor to Nulojix. Patients had stable kidney function (eGFR 30 to 75 mL/minute/1.73 m^2) or absence of proteinuria (≤500 mg/day in diabetic patients or ≤1,000 mg/day in nondiabetic patients) for at least 3 months without a history of rejection. In clinical trials, mycophenolate or other immunosuppressant was continued in combination with Nulojix

Outcome: The committee unanimously voted to accept the recommendation

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

First Compounding Kits Update

Recommendation: It is recommended to add Mouthwash BLM to the Brand Tier for Medicaid**.**

First Omeprazole and First Vancomycin are being utilized at the health system pharmacies and we wanted to review First compounding kits to see if they should be added to Geisinger Health Plan coverage.

- **Mouthwash BLM**
  - There is no other FDA approved product available.
  - After cross checking Azurity's pipeline product page, it does not appear they will have a commercially available product that will be released in the near future.
  - Cost: $90 per kit for the 119 mL package size, $114 per kit for the 237 mL package size

Outcome: The committee unanimously voted to accept the recommendation

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

Medical Benefit Policy Updates

Recommendation: It is recommended to approve the following policies, which were updates at the direction of DHS during the PARP submission process:

MBP 2.0 Synagis (palivizumab)
AUTHORIZATION DURATION:
Prophylaxis of up to 5 doses should be initiated on November 1 (prior to RSV season) and continue until March 31. Listed indications would need to be met on November 1 of the calendar year that prophylaxis is initiated. Members born after November 1 during RSV season who meet criteria will receive monthly prophylaxis until March 31st.

In the event of an atypical RSV season (i.e. unpredicted, early, or late, high rates of RSV circulation), prophylaxis of up to 5 doses should be initiated and continued until the dates deemed appropriate by Geisinger Health Plan in conjunction with guidance from the American Academy of Pediatrics (AAP) and other applicable clinical resources. Members born after the start of the atypical RSV season who meet criteria will receive monthly prophylaxis until the date deemed appropriate by Geisinger Health Plan in conjunction with guidance from the American Academy of Pediatrics (AAP) and other applicable clinical resources.

Dosing beyond 5 consecutive doses will be reviewed on a case-by case basis based on CDC surveillance reports, state/local health department recommendations, and other current medical literature.

MBP 15.0 Zevalin (Ibritumomab tiuxetan (IDEC Y2B8))

1 Zevalin® is approved for the treatment of patients with relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL) including patients with Rituxan (rituximab) refractory follicular non-Hodgkin's lymphoma, when **ALL of the following criteria are met:**
   - Zevalin® must be requested by an Oncologist/Hematologist.
   - Physician provided documentation of use in combination with rituximab 250 mg/m^2 given on days 1 and 7, 8, or 9 of therapy
   - Physician provided documentation of a neutrophil count $\geq$1500 cells/mm^3

- Physician provided documentation of a platelet count of ≥100,000 cells/mm^3
- No evidence of ≥ 25% lymphoma marrow involvement
- No evidence of hypocellular bone marrow (15% or less cellularity or marked reduction in bone marrow precursors)
- No history of failed stem cell collection
- No history of a prior bone marrow transplantation

MBP 36.0 Abraxane (paclitaxel protein bound particles)

- Medical record documentation that the member has a baseline neutrophil count > greater than or equal to 1,500 cells/mm3 **AND**

MBP 180.0 Kanuma (sebelipase alfa)
QUANTITY LIMITS:
Rapidly progressing/Wolman disease (patients initially presenting within the first 6 months of life): Kanuma will initially be approved for quantity sufficient for up to 3 5 mg/kg once weekly. These requests should be approved for a total of 4 visits per month.

Late onset/CESD: Patients 4 years of age and older will be approved for 1 up to 3 mg/kg every other week. These requests should be approved for a total of 2 visits per month.

Outcome: The committee unanimously voted to accept the recommendation

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

February ELECTRONIC VOTE
An electronic vote was held from February 16, 2023, to February 24, 2023. Responses were received from 33 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.

Firdapse (amifampridine**)**

Updated Indication: On September 29, 2022, Firdapse was approved for use in pediatric patients age 6 to less than 17 years with Lambert-Eaton myasthenic syndrome (LEMS). This approval now permits use of Firdapse in patients six years of age and above.

There are no recommended changes to the formulary status of Firdapse. The following changes are recommended to both the medical and pharmacy policy:

1. Medical record documentation of age 6 years or older AND
2. Medical record documentation that Firdapse is being prescribed by a neurologist AND
3. 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

4. Medical record documentation of diagnosis of Lambert-Eaton myasthenic Syndrome confirmed by one of the following:
    a. Medical record documentation of post-exercise facilitation test showing increase in compound muscle action potential (CMAP) amplitude of at least 60 percent compared to pre-exercise baseline value OR
    b. Medical record documentation of high-frequency Repetitive Nerve Stimulation (RNS) showing increase in compound muscle action potential (CMAP) of at least 60 percent OR

c. Medical record documentation of positive anti-P/Q type voltage-gated calcium channel antibody test.

Keytruda (pembrolizumab)

Updated Indication: Keytruda is now indicated as a single agent, for adjuvant treatment following resection and platinum-based chemotherapy for adult patients with Stage IB (T2a ≥ 4 cm), II, or IIIa non-small cell lung cancer.

No changes to the formulary are recommended. It is recommended the highlighted update be made to the medical policy:

Stage IB (T2a ≥ 4 cm), II, or IIIa Non-Small Cell Lung Cancer

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is ≥ 18 years of age AND
- Medical record documentation of Stage IB (T2a ≥ 4 cm), II, or IIIa non-small cell lung cancer (NSCLC) AND
- Keytruda is being used in the adjuvant setting following resection and platinum-based chemotherapy AND
- Keytruda is being used as a single agent

AUTHORIZATION DURATION:

For adjuvant treatment of metastatic melanoma (completely resected melanoma), neoadjuvant/adjuvant treatment of early-stage triple negative breast cancer, adjuvant treatment of renal cell carcinoma, adjuvant treatment of non-small cell lung cancer:

Initial approval will be for 6 months. One subsequent approval will be for an additional 6 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.
Authorization of Keytruda for the adjuvant treatment of metastatic melanoma, renal cell carcinoma, and non-small cell lung cancer should not exceed the FDA-approved treatment duration of 1 year (12 months). Authorization of Keytruda for the treatment of early-stage triple negative breast cancer should not exceed the approved treatment duration of 24 weeks for neoadjuvant therapy and 27 weeks for adjuvant therapy. For requests exceeding the above limit, medical record documentation of the following is required:

- o 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

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Oxlumo (lumasiran)

Updated Indication: Oxlumo is now indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower plasma oxalate levels in pediatric and adult patients. Previously, it was approved to lower urinary oxalate levels in pediatric and adult patients.

No changes are recommended to the formulary placement or policy based on the updated indication.

Tecentriq (atezolizumab)

Updated Indication: Tecentriq is a programmed death-ligand 1 (PD-L1) blocking antibody that is now indicated for the treatment of unresectable or metastatic Alveolar Soft Part Sarcoma (ASPS) in adults and pediatric patients aged

2 years and older. Previously, Tecentriq was indicated for the treatment of Non-Small Cell Lung Cancer (NSCLC), Small Cell Lung Cancer (SCLC), Hepatocellular Carcinoma (HCC), melanoma, and has had its indication for Urothelial Carcinoma removed.

There are no changes to the formulary status. However, it is recommended to add the following criteria to the Medical Benefit Policy:

Alveolar Soft Part Sarcoma (ASPS)

- Prescription written by an oncologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of diagnosis of unresectable or metastatic alveolar soft part sarcoma (ASPS)

GHP Family Update

Discussion: It was anticipated that three medications, Verquvo, Vijoice, and Darstila ODT would be added to the Statewide PDL, but that did not occur. Policies for these medications were created with criteria that were presented at a previous P&T Meeting.

Recommendation: It is recommended the Committee approve the policies as presented below and the medications being non-formulary for the Medicaid LOB.

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

- Medical record documentation that Verquvo is prescribed by or in consultation with a cardiologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of symptomatic chronic New York Heart Association Class II-IV heart failure **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of hospital admission due to heart failure within the previous 6 months **OR**
    - Medical record documentation of outpatient intravenous (IV) diuretic treatment for heart failure within the previous 3 months

AND

- Medical record documentation of a left ventricular ejection fraction (LVEF) less than or equal to 45% **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one formulary angiotensin converting enzyme inhibitor (ACEi), angiotensin receptor blocker (ARB) or angiotensin receptor and neprilysin inhibitor (ARNI) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one formulary beta-blocker **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

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

- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) **AND**

- Medical record documentation of mutation in the catalytic α-subunit of PI3K (PIK3CA) gene **AND**
- Medical record documentation of severe or life-threatening disease which requires systemic treatment **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

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

- Medical record documentation that Dartisla ODT will be given as an adjunct to treatment of peptic ulcer disease **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 of difficulty swallowing **OR**
  - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to glycopyrrolate tablets

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

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Meeting adjourned at 4:15 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on May 16th, 2023 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams