P&T Committee Meeting Minutes
Medicaid
March 11, 2025

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Michael Evans, RPh
Amir Antonious, Pharm.D.	Nichole Hossler, MD
Leslie Astleford, Pharm.D.	Jason Howay, Pharm.D.
Emily Bednarz, Pharm.D.	Jamie Miller, RPh
Kristen Bender, Pharm.D.	Andrei Nemoianu, MD
Jeremy Bennett, MD	Jonas Pearson, RPh
Angela Bolesta, Pharm.D.	
Kim Castelnovo, RPh	
Kimberly Clark, Pharm.D.	
Bhargavi Degapudi, MD	
Keri Donaldson, MD, MSCE	
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, MSW, BSc	
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.	
Michael Shepherd, MD	
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. Jeremy Garris, Pharm.D. (non-voting participant) Abigail Chua, MD (non-voting participant) Scott Friedenberg, MD (non-voting participant) Jonathan Spahr, MD (non-voting participant) Abigail Perriello, PharmD. (pharmacy resident)	

Call to Order: Kimberly Clark called the meeting to order at 1:03 p.m., Tuesday March 11, 2025.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the January 14, 2025 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Miplyffa (arimoclomol)

Review: Miplyffa is indicated for the use in in combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older. It is the first FDA approved treatment for NPC in the United States.

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

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

Outcome: Miplyffa is a pharmacy benefit and will be managed by GHP. It is recommended that Miplyffa be added to the Medicaid formulary at the Brand Tier. The following prior authorization criteria should apply:

- Medical record documentation of age ≥2 years of age AND
- Medical record documentation of weight ≥ 8 kg and dose is weight appropriate AND
- Medical record documentation that medication is being prescribed by or in collaboration with a physician who specializes in the treatment of Niemann-Pick disease type C (NPC) or related disorders AND
- Medical record documentation of a diagnosis of NPC1 or NPC2, confirmed by genetic testing demonstrating one of the following:
    - Mutations in both alleles of NPC1 or NPC2 OR
    - Mutation in one allele AND either a positive filipin-staining or elevated cholestane triol/oxysterols (>2× ULN) AND
- Medical record documentation of at least one neurological sign of NPC (e.g., loss of fine motor skills, swallowing, speech, ambulation) AND
- Medical record documentation of ability to walk independently or with assistance AND
- Medical record documentation that member has completed the NPC Clinical Severity Scale (NPCCSS) assessment to determine baseline score of disease severity (note: higher score indicates greater impairment) AND
- Medical record documentation that member is currently receiving miglustat and Miplyffa will be used in combination with miglustat AND
- Medical record documentation that member is NOT using Miplyffa in combination with Aqneursa

GPI Level: GPI-12

RPH Signoff: RPh Signoff will be required to ensure appropriate utilization

Quantity Limits: limited to 1 month supply

Authorization Duration: 12 months

Reauthorization info: Subsequent approvals will be given for a duration of twelve (12) months. For continuation of coverage, the following criteria must be met:

- Medical record documentation of clinical improvement or lack of progression in neurological signs of NPC (e.g. stabilization or improvement of NPCCSS score, fine motor skills, swallowing, speech, and/or ambulation) AND
- Medical record documentation that Miplyffa continues to be prescribed in combination with miglustat AND
- Medical record documentation that Miplyffa continues to be prescribed by or in collaboration with a physician who specializes in the treatment of NPC or related disorders AND
- Medical record documentation that member is NOT using Miplyffa in combination with Aqneursa

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

Aqneursa (levacetylleucine)

Review: Aqneursa is indicated for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing ≥15 kg. Aqneursa is indicated for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing ≥15 kg.

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

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

Outcome: Aqneursa is a pharmacy benefit and will be managed by GHP. It is recommended that Aqneursa be added to the Medicaid formulary. The following prior authorization criteria should apply:

- Medical record documentation of weight ≥ 15 kg and dose is weight appropriate **AND**
- Medical record documentation that medication is being prescribed by or in collaboration with a physician who specializes in the treatment of Niemann-Pick disease type C (NPC) or related disorders **AND**
- Medical record documentation of a diagnosis of NPC1 or NPC2, confirmed by genetic testing demonstrating one of the following:
  - Mutations in both alleles of NPC1 or NPC2 **OR**
  - Mutation in one allele AND either a positive filipin-staining or elevated cholestane triol/oxysterols (>2× ULN) **AND**
- Medical record documentation of at least one neurological sign of NPC (e.g., loss of fine motor skills, swallowing, speech, ambulation) **AND**
- Medical record documentation that member has completed the NPC Clinical Severity Scale (NPCCSS) assessment to determine baseline score of disease severity (note: higher score indicates greater impairment) **AND**
- Medical record documentation that member is NOT using Aqneursa in combination with Miplyffa

GPI Level: GPI-12

RPH Signoff: RPh Signoff will be required to ensure appropriate utilization

Quantity Limits: limited to 1 month supply

Authorization Duration: 12 months

Reauthorization info: Subsequent approvals will be given for a duration of twelve (12) months. For continuation of coverage, the following criteria must be met:

- Medical record documentation of clinical improvement or lack of progression in neurological signs of NPC (e.g. stabilization or improvement of NPCCSS score, fine motor skills, swallowing, speech, and/or ambulation) **AND**
- Medical record documentation that Miplyffa continues to be prescribed by or in collaboration with a physician who specializes in the treatment of NPC or related disorders **AND**
- Medical record documentation that member is NOT using Aqneursa in combination with Miplyffa

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

Audenz (Influenza A [H5N1] Vaccine)

Review: Audenz is an inactivated vaccine indicated for active immunization for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine. Audenz is approved for use in persons 6 months of age and older at increased risk of exposure to the influenza A H5N1 virus subtype contained in the vaccine. Currently, Audenz is not available commercially, but would be available in the event of a pandemic caused by influenza A H5N1 virus subtype.

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

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

Outcome: Audenz 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 Audenz becomes commercially available, it will be a medical or pharmacy benefit. Audenz will be excluded from the GHP Family Formulary. No prior authorization criteria will apply.

<u>If Made Commercially Available</u>:
Authorization Limitations: Approval is for one vaccine series per lifetime (Two 0.5 ml doses)
Quantity Limit: 1 ml per 999 days
Age Limit: 6 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.

Opdive Qvantig (nivolumab/hyaluronidase-nvhy)

Review: Opdivo Qvantig is a subcutaneous formulation of Opdivo (nivolumab).

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

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

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

Melanoma

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is > 18 years of age AND
- Medical record documentation of one of the following:
    - A diagnosis of unresectable or metastatic melanoma AND
    - Opdivo Qvantig is being used as a single agent following combination treatment with intravenous nivolumab and ipilimumab

    OR
    - A diagnosis of completely resected (no evidence of disease) Stage IIB, Stage IIC, Stage III, or Stage IV melanoma AND
    - Opdivo Qvantig is being used in the adjuvant setting AND
    - Opdivo Qvantig is being used as a single agent

    **(*Note: The FDA-approved treatment duration for use of Opdivo Qvantig in the adjuvant setting for completely resected stage IIB, stage IIC, stage III, and stage IV melanoma is for up to 1 year, see specific reauthorization criteria below.)*

Non-Small Cell Lung Cancer (NSCLC)

If the request is for metastatic NSCLC with progression after platinum-based chemotherapy:

- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) with disease progression while on or after platinum-based chemotherapy AND
- Medical record documentation that Opdivo Qvantig is not being used in combination with any other agents for the treatment of metastatic non-small cell lung cancer (NSCLC)

OR

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 Qvantig 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 Qvantig will be used for neoadjuvant treatment in combination with platinum-doublet chemotherapy followed by Opdivo Qvantig monotherapy as adjuvant treatment after surgery.

Renal Cell Carcinoma

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is ≥ 18 years of age AND
- Medical record documentation of use as a single agent for relapse or for surgically unresectable advanced or metastatic renal cell carcinoma AND
- Medical record documentation of a therapeutic failure on or intolerance to prior anti-angiogenic therapy, including, but not limited to, Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), Afinitor (everolimus), or Torisel (temsirolimus).

OR

- Medical record documentation of previously untreated advanced renal cell carcinoma AND one of the following: Medical record documentation that Opdivo Qvantig will be given in combination with cabozantinib (Cabometyx)

OR

- Medical record documentation that the patient is at intermediate to poor risk (defined as having 1 or more 6 prognostic risk factors as per the IMDC criteria*) AND Medical record documentation that Opdivo Qvantig will be given as monotherapy following combination treatment with intravenous nivolumab and ipilimumab

*IMDC Criteria risk factors include:

1. Less than one year from time of initial renal cell carcinoma diagnosis to randomization
2. Karnofsky performance status <80%
3. Hemoglobin less than the lower limit of normal
4. Corrected calcium of greater than 10 mg/dL
5. Platelet count greater than the upper limit of normal
6. Absolute neutrophil count greater than the upper limit of normal

Squamous Cell Carcinoma of the Head and Neck (SCCHN)

- 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 recurrent or metastatic squamous cell carcinoma of the head and neck AND
- Medical record documentation of disease progression while on or after receiving a platinum-based therapy

Urothelial Carcinoma

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient ≥ 18 years of age AND
- Medical record documentation of one of the following:
    - Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma AND
    - Medical record documentation that Opdivo Qvantig is NOT being used in combination with any other agent AND
    - One of the following:
        - Disease progression during or following platinum-containing chemotherapy OR
        - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

      OR

    - Medical record documentation of a diagnosis of unresectable or metastatic urothelial carcinoma AND
    - Medical record documentation that Opdivo Qvantig is being used as first-line treatment AND
    - Medical record documentation that Opdivo Qvantig is being used in combination with cisplatin and gemcitabine for up to six (6) cycles, after which it will be administered as a single agent.

OR

    - Medical record documentation that Opdivo Qvantig is being used in the adjuvant setting for a diagnosis of urothelial carcinoma AND
    - Medical record documentation that Opdivo Qvantig is NOT being used in combination with any

other agent AND
    - Both of the following:
        - Medical record documentation of radical resection of urothelial carcinoma AND
        - Medical record documentation of high risk of recurrence of urothelial carcinoma*

**Note in clinical trials high risk of recurrence of urothelial carcinoma was defined as pathological stage of ypT2-ypT4a or ypN+ for patients who received neoadjuvant cisplatin or pathological stage of pT3-pT4a or pN+ for patients who did not receive neoadjuvant cisplatin due to ineligibility for or refusal of adjuvant cisplatin.*

Colorectal Cancer

- 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 colorectal cancer AND
- Medical record documentation of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease AND
- Medical record documentation of progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan AND
- Medical record documentation that Opdivo Qvantig is being used as a single agent or as a single agent following combination treatment with intravenous nivolumab and ipilimumab (Yervoy).

Hepatocellular Carcinoma (HCC)

- Prescription written by a hematologist/oncologist AND
- Medical record documentation of a diagnosis of hepatocellular carcinoma AND
- Medical record documentation of a therapeutic failure on or intolerance to sorafenib (Nexavar) AND
- Medical record documentation that Opdivo Qvantig will be used as a single-agent following combination treatment with intravenous nivolumab and ipilimumab (Yervoy).

Esophageal Squamous Cell Carcinoma

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is 18 years of age or older AND
- One of the following:
    - Medical record documentation of unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC) AND
    - Medical record documentation of previous trial of fluoropyrimidine- and platinum-based chemotherapy.

OR

    - Medical record documentation of unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) AND
    - Medical record documentation that Opdivo Qvantig will be given in combination with fluoropyrimidine- and platinum-containing chemotherapy AND
    - Medical record documentation that the regimen is being given as first-line treatment

Adjuvant Treatment of Resected Esophageal or Gastroesophageal Junction Cancer

- Prescription written by a hematologist/oncologist AND
- Medical record documentation of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease AND
- Medical record documentation that patient has received neoadjuvant chemoradiotherapy AND
- Medical record documentation Opdivo Qvantig is being used in the adjuvant setting AND
- Medical record documentation Opdivo Qvantig is being used as a single agent

(Note: The FDA-approved treatment duration for use of Opdivo Qvantig in the adjuvant setting for resected esophageal or gastroesophageal junction cancer is for up to 1 year, see specific reauthorization criteria below.)

Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma

- Prescription written by a hematologist/oncologist AND
- Medical record documentation of advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma AND
- Medical record documentation that Opdivo Qvantig will be used in combination with fluoropyrimidine- and platinum-based chemotherapy.

AUTHORIZATION DURATION:

****For adjuvant treatment of melanoma *(completely resected melanoma*), adjuvant treatment of resected esophageal or gastroesophageal junction cancer, and adjuvant urothelial carcinoma:**

Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Opdivo Qvantig for the adjuvant treatment of melanoma, adjuvant treatment of resected esophageal or gastroesophageal junction cancer, or adjuvant treatment of urothelial carcinoma 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 first-line unresectable or metastatic urothelial carcinoma and treatment of gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma:**

Initial approval:

Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional 18 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Opdivo Qvantig for the first line treatment of unresectable or metastatic urothelial carcinoma and gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma: should not exceed the FDA-approved treatment duration of 2 years (24 months) in patients without disease progression. 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 Neoadjuvant NSCLC:** One approval will be given for up to 3 cycles for a total duration of 6 months. Authorization of Opdivo Qvantig for the neoadjuvant treatment of NSCLC should not exceed the FDA-approved treatment duration of 3 cycles. For requests exceeding the above limit, medical record documentation of the following is required:

****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 Qvantig 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. For requests exceeding the above limit, medical record documentation of the following is required:

For all other indications:
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 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

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

Sutab 1.476g/0.225g/0.188g (Sodium sulfate, magnesium sulfate, potassium chloride)

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: Sutab is a pharmacy benefit managed by GHP. It should be added to the formulary. No prior authorization should apply.

GPI Level: GPI-12
Quantity Limits: RX count of 1
Age: 18 or older

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

Quzyttir (cetirizine)

Review: Quzyttir is a prescription only cetirizine hydrochloride injection for intravenous use only. Cetirizine hydrochloride is a second generation, selective histamine-1 (H1) receptor antagonist. It is FDA indicated for the

treatment of acute urticaria in adults and in children 6 months of age and older. Use is not recommended in pediatric patients less than 6 years of age with impaired renal or hepatic function.

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

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

Outcome: Medical Benefit. Prior authorization required.

- Medical record documentation of a diagnosis of acute urticaria **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to intravenous diphenhydramine **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to 2 preferred antihistamine alternatives per the PDL.

Medical Preferred Alternatives: intravenous diphenhydramine

Pharmacy Preferred Alternatives: Refer to PDL

GPI-Level: GPI-14

Authorization Duration: 6 weeks

Quantity Limit: 1 mL per day

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

Bizengri (zenocutuzumab-zbco)

Review: Bizengri is indicated for the treatment of adults with advanced, unresectable, or metastatic non-small cell lung cancer (NSCLC) harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy and in adults with advanced, unresectable, or metastatic pancreatic adenocarcinoma harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy. These indications were accelerated approvals based on overall response rate and duration of response. Bizengri is a bispecific antibody that binds extracellular domains of HER2 and HER3 expressed on the surface of cells, including tumor cells, and prevents NRG1 binding to HER3. It demonstrated decreased cell proliferation and signaling, and antitumor activity in mouse models of NRG1 fusion-positive lung and pancreatic cancers. Bizengri is the first targeted drug therapy for NRG1 gene fusions.

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

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

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

- Medical record documentation of an age greater than or equal to 18 years AND
- Medical record documentation that Bizengri is prescribed by a hematologist or oncologist AND
- Medical record documentation of a one of the following:
    - Documentation of a diagnosis of advanced, unresectable, or metastatic non-small cell lung cancer

OR

- Documentation of a diagnosis of advanced, unresectable, or metastatic pancreatic adenocarcinoma

AND

- Medical record documentation of the presence of neuregulin 1 (NRG1) gene fusion AND
- Medical record documentation of disease progression on or after at least one prior systemic therapy

Medispan Authorization Level: GPI-12
Quantity Limits: 75 milliliters per 28 days

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 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.

Datroway (datopotamab deruxtecan-dlnk)

Review: Breast cancer (BC) is the second most common cancer and the second leading cause of cancer death among women in the United States of America. Treatment of BC is dependent upon the type of breast cancer present and how far the cancer has spread. Most patients will receive more than one kind of breast cancer medication throughout their treatment regimen(s). Hormonal therapy prevents cancer cells from getting the hormones they need to proliferate and grow.

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

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

Outcome: Datroway is a medical benefit that will be managed by GHP. A prior authorization will be required for GHP Family, and the following criteria will apply:

- Medical record documentation of at least 18 years of age or older **AND**
- Medical record documentation that Datroway is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of a diagnosis of unresectable locally advanced or metastatic hormone receptor positive/human epidermal growth factor 2 negative (HR+/HER2-) breast cancer **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to systemic chemotherapy for unresectable or metastatic breast cancer **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to systemic endocrine therapy

Authorization Duration: Initial authorization 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. Medical record documentation of continued disease improvement or lack of disease progression will be required for subsequent approvals. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Quantity Limit: 6 (100 mg) vials per 21-day cycle

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

PiaSky (crovalimab-akkz)

Review: Piasky is a new complement C5 inhibitor indicated for the treatment of adult and pediatric patients 13 years of age and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg. PiaSky binds complement protein C5 with high affinity, inhibits its cleavage, and prevents the formation of the membrane attack complex (MAC). It inhibits terminal complement-mediated intravascular hemolysis in patients with PNH. Piasky offers a similar mechanism of action in PNH as Soliris and Ultomiris, previously approved C5 complement inhibitors which are considered standard of care in PNH.

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

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

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

- Medical record documentation of a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) AND
- Physician provided documentation of flow cytometry confirming diagnosis AND
- Physician provided documentation that PiaSky is prescribed by a hematologist AND
- Physician provided documentation of the insured individual being vaccinated with the meningococcal vaccine AND
- Physician documentation of one of the following:
    - member is transfusion-dependent (i.e., has at least 1 transfusion in the 24 months prior to initiation of crovalimab due to documented hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 9 g/dL in persons with symptoms from anemia) prior to initiation of crovalimab treatment; OR
    - there is a significant adverse impact on the insured individual's health such as end organ damage or thrombosis without other cause.

AND

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to the preferred eculizumab product

AUTHORIZATION DURATION: Approval will be given for 6 months. Additional coverage will only be provided when documentation of the following is provided:

- Member requires fewer transfusions or has stabilization of Hb levels AND
- Reduction in intravascular hemolysis as evidenced reduction in elevated LDH levels from baseline AND
- No recurrent infections

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

FAST FACTS

UPDATES

Imfinzi Update

Discussion: The authorization duration for limited stage small cell lung cancer (LS-SCLC) should align with other indications that have a maximum treatment duration. In the ADRIATIC study, patients received treatment until disease progression, until unacceptable toxicity, or for a maximum of 24 months. The median overall survival (OS) in the Imfinzi group was 55.9 months (or over 4 years).

Recommendations: It is recommended to add the following authorization duration to MBP 156.0 Imfinzi for the indication of LS-SCLC. No other changes are recommended to the policy criteria or formulary placement of Imfinzi.

MBP 156.0 Imfinzi (durvalumab)

4. Extensive-Stage Small Cell Lung Cancer (ES-SCLC)

AUTHORIZATION DURATION (LS-SCLC): One approval for 12 months or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Imfinzi for the treatment of non-small cell lung cancer should not exceed the FDA-approved treatment duration of 2 years (24 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

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.

Voquenza Update

Discussion: The following updates are recommended for Voquezna:

Recommendations:

Healing and Maintenance of Erosive Esophagitis

Medispan Authorization Level: GPI-14

Quantity Limit: *Two authorizations must be entered. Enter Both GPI 49275087100320 (Voquezna 10 mg) and 49275087100340 (Voquezna 20 mg)*

- Voquezna 20 mg tablet: 28-day supply per fill, number of claims authorized 2, with a duration of 56 days
- Voquezna 10 mg tablet: 30-day supply per fill, number of claims authorized 6, with a duration of 8 months

Heartburn associated with Non-Erosive Gastroesophageal Reflux Disease

Medispan Authorization Level: GPI-14

- Voquezna 10 mg tablets: 28-day supply per fill, number of claims authorized 1, with a duration of 28 days

H.pylori infection

Medispan Authorization Level: GPI-14.

- 14-day supply per fill, number of claims authorized 1, with a duration of 14 days

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.

February ELECTRONIC VOTE
An electronic vote was held from February 12, 2025, to February 19, 2025. Responses were received from 29 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.

Tolak (fluorouracil)

Tolak (fluorouracil) cream, 4%, is a nucleoside metabolic inhibitorindicated for the topical treatment of actinic keratosis lesions of the face, ears, and scalp.

Recommendation: Tolak is a pharmacy benefit and should be added to the GHP Family formulary. No prior authorization criteria based on cost analysis should apply.

Authorization Duration: Open-ended
Reauthorization info: None
RPh Sign Off: No

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

Ziihera (zanidatamab-hrii)

Ziihera is a bispecific HER2-directed antibody indicated for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC), as detected by an FDA-approved test. Ziihera was approved under accelerated approval based on overall response rate and duration of response. Recommendation: Ziihera will process as a medical benefit and will be managed by GHP. The following prior authorization criteria should apply:

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Ziihera is prescribed by a hematologist or oncologist AND
- Medical record documentation of a diagnosis of unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC), as detected by an FDA-approved test* AND
- Medical record documentation of treatment with at least one prior therapy

***NOTE:** The FDA approved companion diagnostic for the detection of HER2-positive (IHC3+) Biliary Tract Cancer is PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody.

Authorization Duration: Initial approval will be for 6 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of 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.

Filispari

Updated Indication: Filspari is now indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy who are at high risk for disease progression. Previously, it was approved to reduce proteinuria in adults with primary immunoglobulin A nephropathy who are at high risk for disease progression.

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

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

Imfinzi

Updated Indication: Imfinzi is now indicated as a single agent for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

Recommendation: No changes are recommended to the formulary placement and authorization duration of Imfinzi. The following prior authorization criteria should be added to Medical Benefit Policy 156.0.

Limited-Stage Small Cell Lung Cancer
• Medical record documentation that Imfinzi 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 a diagnosis of limited-stage small cell lung cancer (LS-SCLC) that has not progressed following concurrent platinum-based chemotherapy and radiation therapy **AND**
• Medical record documentation that Imfinzi will be used as a single agent

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

committee.

Lumryz

Updated Indication: LUMRYZ is a central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.

Recommendation: Update age in policy from 18 years of age to 7 years of age.

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

Pevymis IV

Updated Indication: Prevymis is a CMV DNA terminase complex inhibitor indicated for:
(1) (CMV) infection and disease in adults with an updated age for use in **pediatric patients 6 months of age and older weighing at least 6 kg** who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
(2) prophylaxis of CMV disease in adults with an updated age for use **in pediatric patients 12 years of age and older weighing at least 40 kg** who are kidney transplant

Recommendation: For Prevymis tablets (pharmacy): PDL managed, Preferred, QL. For Prevymis IV formulation (medical) not PDL managed, prior authorization required.
Stem Cell Transplant
• Prescription written by or in consultation with a hematologist/oncologist, infectious disease, or transplant specialist **AND**
• Medical record documentation of age greater than or equal to ~~18 years~~ 6 months of age and older and weighing at least 6 kg **AND**
• Medical record documentation that the member is a recipient of an allogeneic hematopoietic stem cell transplant **AND**
• Medical record documentation that the member is a confirmed CMV seropositive recipient (R+) **AND**
• Medical record documentation that Prevymis is being used for CMV prophylaxis **AND**
• Medical record documentation that Prevymis is being initiated between Day 0 and Day 28 post-transplantation **AND**
• Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine) **AND**
• Medical record documentation of intolerance to or contraindication to Prevymis tablets or pellet pak based on age and weight.

OR

Kidney Transplant
• Medical record documentation that Prevymis
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• Medical record documentation of age greater than or equal to ~~18 years~~ 12 years of age and older AND weighing at least 40 kg **AND**
• Medical record documentation that member is a recipient of a kidney transplant **AND**

• Medical record documentation that member is at high risk of CMV [defined as CMV seropositive donor and CMV seronegative recipient (D+/R-)] **AND**
• Medical record documentation that Prevymis is being used for cytomegalovirus (CMV) prophylaxis **AND**
• Medical record documentation that Prevymis is being initiated between Day 0 and Day 7 post-transplantation **AND**
• Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine) **AND**
• Medical record documentation of intolerance to or contraindication to Prevymis tablets or pellet pak based on age and weight.

AUTHORIZATION DURATION:
• **Stem Cell Transplant:** If approved, a one-time authorization for 100 days with a maximum of 100 doses will apply.
• **Kidney Transplant:** If approved, a one-time authorization for 200 days with a maximum of 200 doses will apply.

QUANTITY LIMIT:
• **Stem Cell Transplant:** 100 doses per 100 days
• **Kidney Transplant:** 200 doses per 200 days

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

Tevimbra

Updated Indication: Tevimbra is now indicated in combination with platinum and fluoropyrimidine-based chemotherapy in adults for the first-line treatment of unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 (≥1). Previously Tevimbra was indicated in esophageal squamous cell carcinoma.

Recommendation: No changes are recommended to formulary placement and authorization duration of Tevimbra. The following criteria should be added to the Medical Benefit Policy 331.0.
Gastric Cancer
• Medical record documentation of age greater than or equal to 18 years AND
• Medical record documentation that Tevimbra is prescribed by a hematologist or oncologist AND
• Medical record documentation of unresectable or metastatic HER2- negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 AND
• Medical record documentation that Tevimbra

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

Trodelvy

Updated Indication: Gilead Sciences voluntarily withdrew the US indication for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. Sacituzumab govitecan was granted approval for that indication under the FDA's accelerated approval program in 2021.

Recommendation: No changes recommended to the formulary placement or authorization duration of Trodelvy at this time. However, it is recommended to update policy MBP 216.0 to remove criteria for treating urothelial cancer. Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Darzalex Faspro

Discussion: Darzalex Faspro was identified as a medication that was potentially being administered at incorrect dosing intervals. Darzalex Faspro is administered once weekly for a predetermined number of weeks based on diagnosis. The dosing is then extended to 14 days for a predetermined number of weeks, then extended again to 28 days. A medication utilization review evaluated the number of doses given at specific dosing intervals. The information was reviewed and numerous patients in the past year were identified that have received significantly more weekly and biweekly doses than FDA approved. For a diagnosis of light-chain (AL) amyloidosis, it was also brought to the attention of GHP that providers are attempting to continue dosing Darzalex Faspro for a duration that exceeds the FDA-approved duration of 2 years. Specialists from Geisinger Hematology/Oncology and OncoHealth reviewed the approved dosing and literature and did not identify any reason why the approved dosing intervals should be exceeded. The AWP of Darzalex Faspro is $12,027.16 so the financial impact of doubling or quadrupling the spend is high.

Recommendation: It is recommended to add a criteria point to MBP 230.0 Darzalex Faspro to ensure that the reviewer is ensuring that the dosing is appropriate based on the FDA approved dosing. It is also recommended to shorten the initial and renewal authorization duration so that the dosing can be reviewed more frequently to ensure appropriate utilization. Also, for light-chain (AL) amyloidosis, the authorization duration will be limited to 2 years.

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

February 2025 GHP Family Update

Fabhalta

Based on DHS' comment while reviewing Fabhalta, it is recommended that the Committee approve the highlighted addition to account for members who cannot take an RAS inhibitor.

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 OR
    - Has a contraindication to three RAS inhibitors (ACE inhibitor or ARB) OR

- Has an intolerance to three RAS inhibitors (ACE inhibitor or ARB) 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.

Duvyzat

Based on DHS' comments while reviewing Duvyzat, it is recommended that the Committee approve the updates as presented below.

- Medical record documentation that Duvyzat is prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation of interdisciplinary team involvement including, but not limited to, neurology, pulmonology, and cardiology **AND**
- Medical record documentation of a diagnosis of Duchenne muscular dystrophy (DMD), confirmed by genetic testing **AND**
- ~~Medical record documentation of provider attestation that the member is ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent)~~ ~~**AND**~~
- Medical record documentation that the member has not received any previous gene therapy for Duchenne muscular dystrophy. If the member has previously received any gene therapy for treatment of DMD: Documentation of FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature that supports use of Duvyzat after treatment with any previous gene therapy for the treatment of DMD **AND**
- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation that member has been established on stable corticosteroid treatment for at least 6 months **AND**
- ~~Medical record documentation of a therapeutic failure on prednisone or deflazacort~~ ~~**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

2025 GHP Family Formulary

It is recommended that the Committee approve the 2025 GHP Family Formulary.

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

Meeting adjourned at 4:14 PM

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held May 13, 2025.

Meetings will be held virtually via phone/Microsoft Teams