

P&T Committee Meeting Minutes
Medicaid
July 14, 2026

Present (via Teams): Bret Yarczower, MD, MBA – Chair Amir Antonious, Pharm.D. Leslie Astleford, Pharm.D. Emily Bednarz, Pharm.D. Kristen Bender, Pharm.D. Jeremy Bennett, MD Angela Bolesta, Pharm.D. Kim Castelnovo, RPh Keri Donaldson, MD, MSCE Kelly Faust, Pharm.D. Jason Howay, Pharm.D. Keith Hunsicker, Pharm.D. Kelli Hunsicker, Pharm.D. Emily Jacobson, Pharm.D. Dennis Janoszyk, Pharm.D. Alexandra Kempf-Malys, MSW, BSc Kerry Ann Kilkenny, MD Philip Krebs, R.EEG T Lauren Lesh, Pharm.D. Lisa Manoski, Pharm.D. Ted Marines, Pharm.D. Jamie Miller, RPh Mark Mowery, Pharm.D. Andrei Nemoianu, MD Kara Pabst, Pharm.D. Austin Paisley, 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. Ariana Wendoloski, Pharm.D. Brandon Whiteash, Pharm.D.	Absent: Kimberly Clark, Pharm.D. Bhargavi Degapudi, MD Michael Dubartell, MD Tricia Heitzman, Pharm.D. Nichole Hossler, MD Briana LeBeau, Pharm.D. Lisa Mazonkey, RPh Tyreese McCrea, Pharm.D. Perry Meadows, MD Jonas Pearson, RPh Luke Sullivan, DO Kevin Szczecina, RPh Amanda Taylor, MD
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Margaret Whiteash, Pharm.D. Sherry Beagle (non-voting participant) Molly Brautigam, Pharm.D. (non-voting participant) Rebecca Lucas, Pharm.D. (non-voting participant) Jordan Maroszek Pharm.D. (non-voting participant) Sydney Scott Pharm.D. (non-voting participant) Courtney Turowski, Pharm.D. (non-voting participant) Madelyn Zavada, Pharm.D. (non-voting participant)	
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Call to Order: Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday July 14, 2026.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: The March 10, 2026, minutes were approved by electronic vote. The May 12, 2026, minutes were unanimously approved.

DRUG REVIEWS

Myqorzo (aficamten)

Review: Myqorzo is a cardiac myosin inhibitor indicated for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms. Myqorzo reduces cardiac contractility and left ventricular outflow tract (LVOT) obstruction through myosin inhibition. Myqorzo will compete with Camzyos, another cardiac myosin inhibitor indicated for the treatment of adults with oHCM. Although Myqorzo and Camzyos appear to have similar efficacy and labeling, Myqorzo generally appears to have the better safety profile and REMS program. The most recent (2024) American Heart Association (AHA)/American College of Cardiology Foundation (ACC) guidelines recommend CMIs for patients with symptomatic oHCM who remain symptomatic despite having received first-line therapy with β -blockers or nondihydropyridine CCBs (e.g. verapamil, diltiazem).

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

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

Outcome: Myqorzo is a pharmacy benefit, will be managed by GHP, and should be added to GHP Family formulary on the brand tier. The following prior authorization criteria should apply:

- Medical record documentation that Myqorzo is prescribed by a cardiologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of diagnosis of New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy AND

- Medical record documentation of left ventricular ejection fraction (LVEF) greater than or equal to 55% AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two of the following: beta-blockers, non-dihydropyridine calcium channel blockers, or disopyramide

MEDISPAN AUTHORIZATION LEVEL: GPI-12

Quantity Limit: 1 capsule per day, 30-day supply per fill

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 the following:

- Medical record documentation of left ventricular ejection fraction (LVEF) greater than or equal to 50% AND
- Medical record documentation of clinical improvement or maintenance of condition

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.

Yuviwel (navepegritide)

Review: Yuviwel is a C-type natriuretic peptide (CNP) analog indicated to increase linear growth in pediatric patients 2 years of age and older with achondroplasia with open epiphyses. This was an accelerated approval based on an improvement in annualized growth velocity. The only other treatment approved for ACH is Voxzogo which is another CNP analog. Voxzogo is administered daily while Yuviwel is administered once weekly.

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

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

Outcome: Yuviwel is a pharmacy benefit, that will be managed by GHP and should be added to the GHP Family formulary on the brand tier. The following prior authorization criteria should apply:

- Medical record documentation of a diagnosis of achondroplasia with genetic testing confirming a mutation of FGFR3 AND
- Medical record documentation that Yuviwel is prescribed by a pediatric endocrinologist AND
- Medical record documentation that member is greater than 2 years of age to less than 18 years of age AND
- Medical record documentation of evidence that member has open epiphyses AND
- Medical record documentation that member has not received (within the past 18 months) or plans to receive limb-lengthening surgery AND
- Medical record documentation that Yuviwel will not be used in combination with human growth hormone products AND

- Medical record documentation of glomerular filtration rate (GFR) greater than 60 ml/min/1.73m² AND
- Medical record documentation of member's current weight AND
- Medical record documentation that prescribed dose is appropriate for member's current weight AND
- Medical record documentation of baseline annualized growth velocity (AGV), calculated based on standing height measured over the course of 6 months prior to request
- Medical record documentation of therapeutic failure, intolerance, or contraindication to Voxzogo

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: 1.3 mg and 2.8 mg single-dose vials: 4 vials per 28 days, 28 day supply per fill
5.5 mg single-dose vial: 8 vials per 28 days, 28 day supply per fill

AUTHORIZATION DURATION: Each treatment period will be defined as six (6) months. Re-review with occur every six (6) months. Yuviwel will no longer be covered if medical record documentation does not show:

- Medical record documentation of positive response to Yuviwel, as evidenced by improvement in annualized growth velocity (AGV) from baseline AND
- Medical record documentation of evidence that member continues to have open epiphyses AND
- Medical record documentation that member has not received (within the past 18 months) or plans to receive limb-lengthening surgery AND
- Medical record documentation that Yuviwel will not be used in combination with human growth hormone products AND
- Medical record documentation of glomerular filtration rate (GFR) greater than 60 ml/min/1.73m² AND
- Medical record documentation of member's current weight AND
- Medical record documentation that prescribed dose is appropriate for member's current weight

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

Rezenopy (naloxone nasal spray)

Review: Rezenopy is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression in adult and pediatric patients. Rezenopy is intended for immediate administration as emergency therapy in settings where opioids may be present and is not a substitute for emergency care.

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

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

Outcome: Rezenopy is a pharmacy benefit and it is unclear if it will be managed by the PDL. If GHP will manage, Rezenopy will be a pharmacy benefit and should not be added to GHP Family Formulary. It will require a prior authorization and should be reviewed under the existing Policy 4.0F Formulary Exception.

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

Yartemlea (narsoplimab-wuug)

Review: Yartemlea is indicated for the treatment of adult and pediatric patients 2 years of age and older with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA). Yartemlea inhibits mannan-binding lectin-associated serine protease-2 and lectin-dependent activation of complement component 3 (C3) and C4, preventing lectin pathway-mediated cellular injury. Yartemlea does not affect the classical or alternative pathways of complement. Yartemlea is the first FDA approved treatment for TA-TMA.

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

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

Outcome: Yartemlea is a pharmacy benefit and will be managed by GHP. The following prior authorization criteria should apply:

- Medical record documentation of age greater than or equal to 2 years of age AND
- Medical record documentation that Yartemlea is prescribed by a hematologist, oncologist, or a transplant specialist AND
- Medical record documentation of previous hematopoietic stem cell transplant (HSCT) AND
- Medical record documentation of a diagnosis of thrombotic microangiopathy (TMA) confirmed by the following:
 - Platelet count less than or equal to 150,000 / μ L AND
 - Evidence of microangiopathic hemolysis, including but not limited to presence of schistocytes, serum lactate dehydrogenase (LDH) greater than the upper limit of normal (ULN) or haptoglobin less than the lower limit of normal (LLN) AND
 - Evidence of renal dysfunction
- If the initial request is for 370 mg twice weekly: Medical record documentation of inadequate response to signs and symptoms of hematopoietic stem cell transplant (HSCT)-associated thrombotic microangiopathy (TA-TMA) to 370 mg once weekly dosing

GPI Level: GPI-12

Quantity Limits: 28-day supply per fill

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

- Medical record documentation of a positive response to Yartemlea with improvement in the signs and symptoms of hematopoietic stem cell transplant (HSCT)-associated thrombotic microangiopathy (TA-TMA), including but not limited to improvement in platelet count, reduction of serum lactate dehydrogenase (LDH), increase of haptoglobin, improvement or stabilization of organ function, or reduction or elimination of red blood cell or platelet transfusion requirements OR
- Medical record documentation of inadequate response to signs and symptoms of hematopoietic stem cell transplant (HSCT)-associated thrombotic microangiopathy (TA-TMA) AND member requires an escalation in dosing frequency to a maximum of 370 mg administered twice weekly

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

Zycubo (copper histidinate)

Review: Zycubo is a copper replacement product indicated for the treatment of Menkes disease in pediatric patients. Zycubo is not indicated for the treatment of Occipital Horn Syndrome. Zycubo is the first treatment FDA-approved for Menkes disease.

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

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

Outcome: Zycubo will be a pharmacy benefit managed by GHP on the brand tier. The following prior authorization criteria should apply:

- Medical record documentation that the member is less than 17 years of age **AND**
- Medical record documentation that Zycubo is prescribed by or in consultation with a geneticist, neonatologist, neurologist, or a provider who specializes in the diagnosis and treatment of Menkes disease **AND**
- Medical record documentation of a confirmed diagnosis of Menkes disease demonstrated by **ALL** of the following:
 - **One of the following:**
 - Molecular genetic testing confirming *ATP7A* gene mutation **OR**

- Plasma catecholamine analysis findings that are consistent with a diagnosis of Menkes disease (DOPAC:DHPG ratio greater than 5 or DA:NE ratio greater than 0.2)

AND

- Documentation of clinical signs and symptoms consistent with a diagnosis of Menkes disease (e.g., characteristic hair abnormalities [sparse, hypopigmented, brittle, and crinkly hair], osteoporosis, seizures, hypotonia, unstable body temperature, failure to thrive, developmental delay or regression)
- Medical record documentation of baseline serum copper and ceruloplasmin levels to be used to evaluate efficacy upon renewal **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

NOTE TO REVIEWER: Zycubo is not indicated for the treatment of Occipital Horn Syndrome, a milder type of Menkes disease

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 medical record documentation of continued disease improvement or lack of disease progression as evidenced by:

- Improvement in serum copper and ceruloplasmin levels compared to baseline **AND**
- Improvement in signs and symptoms of Menkes disease

The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Quantity Limit: N/A

Require RPH Sign off: Yes

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.

Avopef (etoposide)

Review: Avopef is a new formulation of etoposide supplied in multi-dose vials containing ready to use solution (no reconstitution needed). It is supplied as 100 mg/5mL solution for injection. At this time, Avopef is approved for the treatment of refractory testicular cancer and small cell lung cancer.

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

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

Outcome: Avopef is a medical benefit and will require a prior authorization. The following prior authorization criteria should apply:

- Medical record documentation that Avopef is prescribed by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years of age AND

Medical record documentation of refractory testicular cancer OR Medical record documentation of small cell lung cancer

AND

- Medical record documentation of therapeutic failure, intolerance, or contraindication to generic etoposide products

GPI Level: GPI-12

Authorization Duration: 6 months

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.

Favlyxa (fluorouracil)

Review: Favlyxa is a new formulation of fluorouracil supplied in multi-dose vials containing ready to use solution (no reconstitution needed). It is supplied as 250 mg/10mL single-dose vial solution for injection. Favlyxa is approved for the treatment of adenocarcinoma of the colon and rectum, adenocarcinoma of the breast, gastric adenocarcinoma, and pancreatic adenocarcinoma.

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

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

Outcome: Favlyxa is a medical benefit and will require a prior authorization. The following prior authorization criteria should apply:

- Medical record documentation that Avopef is prescribed by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years of age AND
- Medical record documentation of one of the following:
 - Adenocarcinoma of the Colon and Rectum OR
 - Adenocarcinoma of the Breast OR
 - Gastric Adenocarcinoma OR
 - Pancreatic Adenocarcinoma

AND

- Medical record documentation of therapeutic failure, intolerance, or contraindication to generic fluorouracil products

GPI Level: GPI-12

Authorization Duration: 6 months

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.

Loargys (pegzilarginase-nbln)

Review: Loargys is an arginine-specific enzyme indicated for the treatment of hyperargininemia in adult and pediatric patients 2 years of age and older with arginase 1 deficiency (ARG1-D), in conjunction with dietary protein restriction. This indication is approved under accelerated approval based on reduction of plasma arginine. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

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

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

Outcome: Loargys is a medical benefit managed by GHP. The following prior authorization will apply.

- Prescription written by a metabolic disease specialist AND
- Medical record documentation of age ≥ 2 years AND
- Medical record documentation of a diagnosis of Arginase 1 Deficiency as evidenced by one of the following:
 - Pathogenic variants in ARG1 on molecular genetic testing; OR
 - Diminished erythrocyte arginase enzyme activity (i.e., $<1\%$ of normal in red blood cell extracts)
- Medical record documentation that the member is enrolled in Study IMM-PEG-005 to obtain Immedica Pharma's Nor-NOHA Blood Collection Tubes and Loargys Arginine Assay AND
- Medical record documentation of baseline plasma arginine levels ≥ 250 $\mu\text{mol/L}$ AND
- Medical record documentation that Loargys will be used in conjunction with a protein-restricted diet AND
- Medical record documentation of member's weight AND
- Medical record documentation that the dose does not exceed 0.2 mg/kg once weekly

Authorization Duration: 6 months initial and 12 month subsequent

Re-authorization Criteria:

- Medical record documentation of one of the following:
 - Plasma arginine levels between 50 µmol/L–150 µmol/L OR
 - Plasma arginine levels are outside normal range and medical record documentation that the dose will be adjusted per labeling* AND
- Medical record documentation of member's weight AND
- Medical record documentation that the dose does not exceed 0.2 mg/kg once weekly

**If two consecutive weekly pre-dose (168 hours after prior dose) plasma arginine measurements are not in the desired therapeutic range, increase or decrease the weekly Loargys dosage as follows:*

- *Below 50 micromolar, reduce the weekly Loargys dosage by 0.05mg/kg*
- *Above 150 micromolar, increase the weekly Loargys dosage by 0.05 mg/kg*

RPh Sign-Off: Yes

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

FASTFACTS

Omisirge

Updated Indication: Omisirge is a nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood now indicated for the treatment of adults and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning. Previously, Omisirge was indicated for, and is still also indicated for, adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infections.

Discussion: The committee unanimously voted to accept the recommendations.

Outcome: It is recommended not to update the formulary placement or authorization duration of Omisirge. It is recommended to update the prior authorization criteria of MBP 292.0 Omisirge (omidubicel-only).

MBP 292.0 Omisirge (omidubicel-only)

- Medical record documentation that Omisirge is prescribed by a hematologist and/or oncologist **AND**
- Medical record documentation of age greater than or equal to 12 years of age **AND**
- Medical record documentation of a diagnosis of a hematological malignancy planned for umbilical cord blood transplantation following myeloablative conditioning **AND**

- Medical record documentation that a matched related donor (MRD), matched unrelated donor (MUD), mismatched unrelated donor (MMUD), or haploidentical donor is not readily available
AND
- Medical record documentation that patient has not had a prior allogeneic hematopoietic stem cell transplantation (HSCT)

OR

- Medical record documentation that Omisirge is prescribed by a hematologist and/or oncologist
AND
- Medical record documentation of age greater than or equal to 6 years of age **AND**
- Medical record documentation of a confirmed diagnosis of aplastic anemia (AA) **AND**
- Medical record documentation of severe disease, as defined by two (2) of the following:
 - Absolute neutrophil count (ANC) less than 500/microL (or $0.5 \times 10^9/L$)
 - Platelet count less than 20,000/microL (or $20 \times 10^9/L$)
 - Reticulocyte count less than 60,000/microL (or $60 \times 10^9/L$)**AND**
- Medical record documentation that reduced intensity conditioning will be administered prior to infusion with Omisirge **AND**
- Medical record documentation that an identically matched (12/12) donor (related or unrelated) is not readily available **AND**
- Medical record documentation that patient has not had a prior allogeneic hematopoietic stem cell transplantation (HSCT)

AUTHORIZATION DURATION: One time authorization for one administration of Omisirge

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

UPDATES

Medical Benefit Generic Drug Update

Recommendation It is recommended that the following wording be added to applicable medical benefit policies for drugs that have a therapeutically equivalent generic available.

Discussion: The committee unanimously voted to accept the recommendation.

Outcome: The medical benefit list of drugs will continue to be reviewed annually to identify drugs with newly released generic formulations. Policies identified containing drugs with therapeutically equivalent generics will be updated with the below language.

AND (if a brand drug is being requested when a therapeutically equivalent generic drug exists):

- Medical record documentation of a therapeutic failure on, or intolerance to the generic formulary agent(s) OR
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to the inactive ingredients of the generic formulary agent(s)

Newly Identified Drugs with Available Therapeutically Equivalent Generic Formulations

- Halaven (eribulin mesylate) MBP 88.0
- Sandostatin LAR (octreotide acetate) MBP 99.0
- Dalvance (dalbavancin) MBP 121.0
- Radicava IV (edaravone) MBP 154.0

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

Medical Benefit Policy Update

Yervoy Update

Discussion: Previously, the Yervoy policy criteria for unresectable/metastatic melanoma aligned with NCCN recommendations. After reviewing further, it appears some NCCN recommendations for unresectable/metastatic melanoma and Yervoy are not accounted for in the policy. Additionally, other indications for Yervoy, along with other oncology medication policies, align closely with the FDA approved indication.

Recommendations: It is recommended to update the prior authorization criteria for Yervoy and the indication of unresectable/metastatic melanoma to align with the FDA approved indication, consistent with both other indications within the policy and other oncology policies at Geisinger Health Plan.

MBP 91.0 Yervoy (Ipilimumab)

1. Melanoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 12 years of age or older **AND**
- Medical record documentation that Yervoy will be used as a single agent or in combination with nivolumab (Opdivo) **AND**
- Medical record documentation of unresectable or metastatic melanoma **AND**
- One of the following:
 - ~~Medical record documentation of use in combination with nivolumab for first line therapy~~
 - OR**
 - ~~Medical record documentation of use as a single agent or in combination with nivolumab as second line or subsequent therapy for disease progression if not previously used~~ **OR**

- ~~o Medical record documentation of use as a single agent reinduction therapy in select patients who experienced no significant systemic toxicity during prior ipilimumab therapy and who relapse after initial clinical response or progress after stable disease >3 months~~

OR

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of use as a single agent for adjuvant therapy:
 - o For Stage IIIA with metastases > 1 mm, or Stage IIIB or Stage IIIC cutaneous melanoma with nodal metastases following a complete lymph node dissection or resection **OR**
 - o Following complete lymph node dissection and/or complete resection of nodal recurrence

IVIG Update

Recommendations: It is recommended to update the prior authorization criteria for IVIG and the indication of dermatomyositis and polymyositis to also allow for rheumatologist prescribing.

MBP 4.0 Intravenous Immune Globulin (IVIG)

- **Dermatomyositis and Polymyositis**
All of the following criteria must be met:
 1. Diagnosis of dermatomyositis or polymyositis confirmed by biopsy **AND**
 2. Documented evidence of active disease **AND**
 3. Must be prescribed by a neurologist or rheumatologist **AND**
 4. Documented evidence that the condition is refractory to both of the following therapies:
 - o First line therapy: corticosteroids (at least 4 months of therapy)
 - o Second line therapy: at least two immunosuppressants (e.g. cyclosporine, azathioprine, methotrexate, cyclophosphamide)

Darzalex Faspro Update

Recommendations: It is recommended to update the authorization duration for Darzalex Faspro per PARP recommendations.

MBP 230.0 Darzalex Faspro (daratumumab/hyaluronidase)

AUTHORIZATION DURATION

Multiple Myeloma

Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Continued disease improvement or lack of disease progression **AND**
- ~~An FDA approved dose and dosing interval~~ A dose and dosing interval that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

The medication will no longer be covered if patient experiences toxicity or worsening of disease ~~or a non-FDA approved dose or dosing interval~~ or a dose or dosing interval that is not consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

For requests ~~of a treatment duration~~ exceeding United States Food and Drug Administration (FDA) labeling, National Comprehensive Cancer Network® (NCCN), or indication specific peer-reviewed literature, 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

High-Risk Smoldering Multiple Myeloma

Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Continued disease improvement or lack of disease progression **AND**
- ~~An FDA approved dose and dosing interval~~ A dose and dosing interval that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

The medication will no longer be covered if patient experiences toxicity or worsening of disease ~~or a non-FDA approved dose or dosing interval~~ or a dose or dosing interval that is not consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Authorization of Darzalex Faspro for ~~light chain (AL) amyloidosis~~ **high-risk smoldering multiple myeloma** should not exceed the FDA-approved treatment duration of 3 years (36 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

Light Chain (AL) Amyloidosis

Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Continued disease improvement or lack of disease progression **AND**
- ~~An FDA approved dose and dosing interval.~~ **A dose and dosing interval that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature**

The medication will no longer be covered if patient experiences toxicity, worsening of disease, ~~or a non-FDA approved dose or dosing interval.~~ **or a dose or dosing interval that is not consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature**

Authorization of Darzalex Faspro for light-chain (AL) amyloidosis 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

Portrazza Update

Recommendations: It is recommended to retire MBP 142.0 Portrazza. The manufacturer has let the NDC go inactive on 5/29/26 and the National Cancer Institute lists the NDC as status: no longer used and discontinued as of 5/27/26.

Discussion: 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

June ELECTRONIC VOTE

An electronic vote was held from June 5, 2026, to June 12, 2026. Responses were received from 32 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.

Breyanzi

Updated Indication: Breyanzi is now indicated for relapsed or refractory marginal zone lymphoma (MZL) who have received at least 2 prior lines of systemic therapy.

Recommendation: No changes are needed to the formulary placement. It is recommended to update the prior authorization criteria of MBP 228.0 Breyanzi (lisocabtagene maraleucel) to include the new indication.

Marginal Zone Lymphoma (MZL)

- Medical record documentation that Breyanzi is prescribed by a hematologist/oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy AND
- Medical record documentation of a diagnosis of relapsed or refractory marginal zone lymphoma (MZL) AND
- Medical record documentation of at least 2 prior lines of systemic therapy

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

Cablivi

Updated Indication: Cablivi is now indicated for the treatment of adult and pediatric patients 12 years of age and older with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy. Previously, it was only approved for adults for this same indication

Recommendation: Update the age in Policy 1497.0F from 18 years old to 12 years old.

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

Keytruda/Keytruda Qlex

Updated Indication: Keytruda and Keytruda Qlex are now indicated in combination with paclitaxel, with or without bevacizumab, for the treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA authorized test, and who have received one or two prior systemic treatment regimens.

Recommendation: There are no changes to the formulary placement. The new criteria are listed below.

21. Ovarian Cancer

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is greater than or equal to 18 years of age AND
- Medical record documentation of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA authorized test AND
- Medical record documentation that member has received one to two prior systemic treatment regimens
- Medical record documentation the Keytruda will be used in combination with paclitaxel with or without bevacizumab

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

Livmarli

Updated Dosing: Livmarli was previously approved as a 9.5 mg/mL oral solution for the treatment of ALGS and as a 19 mg/mL oral solution for the treatment of PFIC. Livmarli is now approved as an oral tablet, available in 10 mg, 15 mg, 20 mg, and 30 mg strengths. Livmarli tablets can be used for treatment of both ALGS and PFIC in patients weighing 25 kg and above who can swallow tablets. Select Livmarli Oral Solution or Livmarli Tablets based on the patient's weight and ability to swallow tablets

Recommendation: Livmarli oral solution and tablets are non-formulary medications which requires prior authorization under GHP family policy 1552.0F. It is recommended to update the dosing tables included in the policy.

Table 1: 9.5 mg/mL LIVMARLI Oral Solution for Patients with ALGS: Volume per Dose (mL) by Weight

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

Table 2: LIVMARLI Tablets for Patients with ALGS: Dosage by Weight*

Patient Weight (kg)	Days 1 to 7 (190 mcg/kg QD)	Beginning Day 8 (380 mcg/kg QD)
Less than 25	Use Oral Solution	Use Oral Solution
25 to 32		10 mg
33 to 43		15 mg
44 to 65	10 mg	20 mg
66 or higher	15 mg	30 mg

*Select the appropriate product based on the patient's weight and ability to swallow tablets.

Table 3: 19 mg/mL LIVMARLI Oral Solution for Patients with PFIC: Volume per Dose (mL) by Weight

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

Table 4: LIVMARLI Tablets for Patients with PFIC: Dosage by Weight*

Patient Weight (kg)	285 mcg/kg BID	428 mcg/kg BID	570 mcg/kg BID
Less than 25	Use Oral Solution	Use Oral Solution	Use Oral Solution
25 to 32			15 mg
33 to 43	10 mg	15 mg	20 mg
44 or higher	15 mg	20 mg	20 mg

*Select the appropriate product based on the patient's weight and ability to swallow tablets.

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 the treatment of adult and pediatric (12 years and older) patients with previously untreated, Stage III or IV classical Hodgkin lymphoma in combination with doxorubicin, vinblastine, and dacarbazine (AVD).

Recommendation: There are no changes recommended to the formulary placement for Opdivo. The following additional prior authorization criteria and authorization duration should be made to Medical Benefit 126.0 for Opdivo.

4. Classical Hodgkin Lymphoma (CHL)

- Prescription written by a hematologist/oncologist AND
- Medical Record documentation of one of the following:
 - Medical record documentation that patient is > 18 years of age AND
 - Medical record documentation of a diagnosis of classical Hodgkin lymphoma (CHL) that has relapsed or progressed after:
 - Autologous hematopoietic stem cell transplantation and post-transplantation brentuximab vedotin (Adcetris) OR
 - Three (3) or more lines of systemic therapy that includes autologous HSCT

OR

- Medical record documentation that patient is ≥ 12 years of age AND
- Medical record documentation of a diagnosis of previously untreated Stage III or Stage IV classical Hodgkin lymphoma (CHL) AND
- Medical record documentation that Opdivo will be used in combination with doxorubicin, vinblastine, and dacarbazine (AVD) for 6 cycles

****For Previously Untreated cHL:** One approval will be given for up to 6 cycles (12 doses) for a total duration of 12 months.

Authorization of Opdivo for the treatment of previously untreated classical Hodgkin lymphoma should not exceed the FDA-approved treatment duration of 6 cycles. 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

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

Yescarta

Updated Indication: The U.S. Food and Drug Administration (FDA) approved an update to the Yescarta prescribing information removing the previous Limitations of Use in patients with relapsed or refractory (R/R) primary central nervous system lymphoma (PCNSL).

Recommendation: It is recommended that the prior authorization criteria in the Medical Benefit Policy (MBP) 162.0 Yescarta be updated as outlined below.

Large B-Cell Lymphoma (second-line)

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is 18 years of age or older AND

- Medical record documentation of large B-cell lymphoma that is refractory to first-line chemoimmunotherapy OR that relapses within 12 months of first-line chemoimmunotherapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Large B-Cell Lymphoma (third-line or beyond)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of one of the following diagnoses:
 - Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified **OR**
 - Relapsed or refractory primary mediastinal large B-cell lymphoma **OR**
 - Relapsed or refractory high-grade B-cell lymphoma **OR**
 - Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma

AND

- Medical record documentation of a therapeutic failure on two or more previous lines of therapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Note: Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma.

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

GHP Family Update

The updates noted below were made at the request of DHS during the PARP review. It is recommended the Committee approve the changes.

Sirturo – it was noted that Sirturo is now approved for use in those aged 2 years or greater and weighing at least 3 kg. The following update was made to the policy.

- Prescription is written by a physician specializing in infectious disease **AND**
- Medical record documentation of one of the following:
 - Age greater than or equal to 18 years **OR**
 - Age greater than or equal to 2 years and weighing at least 15 kg **AND**
- Medical record documentation of resistance to isoniazid **AND** rifampin **AND**

- Medical record documentation that an effective treatment regimen cannot be attained with other available treatment options **AND**
- Medical record documentation of one of the following:
 - o Sirturo is being prescribed in combination with at least 3 other drugs to which the patient's multi-drug resistant tuberculosis (MDR-TB) isolate has been shown to be susceptible to in vitro **OR**
 - o If in vitro testing results are unavailable, Sirturo is being prescribed in combination with at least 4 other drugs to which the patient's MDR-TB isolate is likely to be susceptible **OR**
 - o In the case of documented resistance to fluoroquinolones or if fluoroquinolones are unavailable, or there is a contraindication/intolerance to fluoroquinolones, Sirturo is being prescribed with pretomanid and linezolid.

Grastek, Oralair, Odactra, and Ragwitek – it was noted that per UpToDate, further studies are needed to establish safety of administration of multiple SLIT tablets. However, administration of two SLIT tablets simultaneously appears to be well tolerated. The update noted below was made in all three policies:

- Medical record documentation that (DRUG) will not be used in combination with **more than one other** sublingual immunotherapy.

Benlysta SQ – The updates noted below were made to match the prescribing information, indication, and language in other Medicaid policies.

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

Systemic Lupus Erythematosus:

- Medical record documentation of age ≥ 5 years **AND**
- If Benlysta syringes are prescribed: medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of systemic lupus erythematosus **AND**
- Medical record documentation that the patient has active disease **OR** recurrent flares **OR** inability to wean steroids in system lupus erythematosus **AND**
- Positive ANA and/or anti-dsDNA antibody **AND**
- Medical record documentation that Benlysta is being used in combination with, or patient has a contraindication or intolerance to, standard therapy (e.g. corticosteroid, NSAID, anti-malarial or immunosuppressant **AND**
- **No severe active CNS involvement AND**
- **Prescribed by or in consultation with a rheumatologist 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

Lupus Nephritis:

- Medical record documentation of a diagnosis of active lupus nephritis, Class III, IV, V alone or in combination, confirmed by a kidney biopsy **AND**
- Medical record documentation of age ~~greater than or equal to 18~~ ≥ 5 years **AND**
- **If Benlysta syringes are prescribed: medical record documentation of age greater than or equal to 18 years AND**
- Prescription written by or in consultation with a rheumatologist or nephrologist **AND**
- Medical record documentation that Benlysta will be prescribed in combination with standard therapy (e.g. mycophenolate mofetil (MMF), corticosteroids, cyclophosphamide, azathioprine) **AND**

Commented [ALS1]: Please revise to "severe active CNS involvement" to match the PI.

Commented [KS2R1]: Please see update

Commented [ALS3]: Please add "or in consultation with" a rheumatologist.

Commented [KS4R3]: Please see update

Commented [ALS5]: Benlysta subcutaneous autoinjector is now approved for the treatment of LN in patients 5 years of age and older.

Commented [KS6R5]: Please see update

- 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

NOTE: GHP Family follows DHS' quantity limits except for blood glucose meters and strips, injection devices for insulin, condoms, spacers (OptiChamber), injectable anticoagulants (Lovenox), vaccines, medications used to treat low blood sugar (glucagon, GVOKE, etc.), Symbicort, and budesonide-formoterol HFA. Quantity limits are available at <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html> or www.geisinger.org/health-plan/plans/ghp-family/pharmacy-coverage.

Note: Benlysta has not been studied in combination with other biologics. Caution should be exercised if Benlysta is administered in combination with other biologic therapies.

Medispan Auth Level:

Ages 5-18 years: GPI-14 (9942201500D520)

Ages 18 years and older: GPI-14 (must enter 9942201500E520 & 9942201500D520)

NOTE: The safety and efficacy of Benlysta syringes for subcutaneous injection has not been studied in patients under 18 years of age.

Rhapsido – some of the recommendations for Rhapsido didn't match with the most recent treatment guidelines for CSU and are more restrictive than the DHS Statewide PDL CSU guidelines for Xolair. DHS required they be removed for the policy to be approved.

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

- Medical record documentation that Rhapsido is prescribed by an allergist, immunologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of moderate to severe chronic spontaneous urticaria **AND**
- Medical record documentation of at least 6 weeks history of symptoms (e.g., hives associated with itching, angioedema) **AND**
- Medical record documentation of age 18 years or older **AND**
- Medical record documentation of contraindication to, therapeutic failure on, or intolerance to a four-week trial of **ALL** of the following treatment option(s):
 - At least two different high dose antihistamines **AND**
 - ~~Maximum dose antihistamine(s) used in combination with a leukotriene receptor antagonist (e.g. montelukast) **AND**~~
 - ~~High dose antihistamine used in combination with H2 receptor antagonist (e.g. ranitidine) **AND**~~
 - ~~Dose advancement of potent antihistamine (e.g., doxepin or hydroxyzine) **AND**~~
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 2 formulary medications approved for CSU **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

Commented [ALS7]: This criterion is not supported by the most recent treatment guidelines for CSU and is more restrictive than the DHS Statewide PDL CSU guidelines for Xolair. Please remove.

2022 international guidelines:

In general, the level of evidence for the efficacy of leukotriene receptor antagonists in urticaria is low but best for montelukast.

UpToDate:

The 2022 international guidelines excluded leukotriene modifiers from the stepwise approach based on limited evidence of efficacy [1].

In unselected populations of patients with CSU, the data in support of leukotriene modifiers are relatively weak.

...the authors do not recommend using leukotriene receptor antagonists for routine management of CSU. For patients with other comorbid conditions (eg, asthma, allergic rhinitis), they may be considered, but patients should be counseled regarding their limited efficacy for CSU.

Commented [KS8R7]: Please see update

Commented [ALS9]: This criterion is not supported by the most recent treatment guidelines for CSU and is more restrictive than the DHS Statewide PDL CSU guidelines for Xolair. Please remove.

2022 international guidelines:

H₂-antagonists and dapson, recommended in the previous versions of the guideline, are now perceived to have little evidence to maintain them as recommendable in the algorithm but they may still have relevance as they are very affordable in some more restricted healthcare systems.

UpToDate:

Patients whose symptoms are not adequately controlled on H₁ antihistamines alone may experience modest improvement with the addition of an H₂-antagonist antihistamine, although data are conflicting, and international guidelines do not include H₂ antihistamines as an option [1,10]. If not effective, the H₂ antagonist should be discontinued.

Commented [KS10R9]: Please see update

Commented [ALS11]: This criterion is not supported by the most recent treatment guidelines for CSU and is more restrictive than the DHS Statewide PDL CSU guidelines for Xolair. Please remove.

2022 international guidelines:

H₁-antihistamines have been available for the treatment of urticaria since the 1950s. The older 1st generation H₁-antihistamines have pronounced anticholinergic and

Commented [KS12R11]: Please see update

Meeting adjourned at 3:33 PM

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held September 8, 2026.

Meetings will be held virtually via phone/Microsoft Teams