P&T Committee Meeting Minutes
Medicaid
July 16, 2024

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Kristen Bender, Pharm.D.
Amir Antonius, Pharm.D.	Marika Bergenstock, DO (non-voting participant)
Emily Bednarz, Pharm.D.	Alyssa Cilia, RPh
Jeremy Bennett, MD	Michael Evans, RPh
Kim Castelnovo, RPh	Nichole Hossler, MD
Kimberly Clark, Pharm.D.	Jason Howay, Pharm.D.
Bhargavi Degapudi, MD	Perry Meadows, MD
Michael Dubartell, MD	Jamie Miller, RPh
Kelly Faust, Pharm.D.	Andrei Nemoianu, MD (non-voting participant)
Tricia Heitzman, Pharm.D.	William Seavey, Pharm.D.
Keith Hunsicker, Pharm.D.	Michael Shepherd, MD
Kelli Hunsicker, Pharm.D.	Leslie Shumlas, Pharm.D.
Derek Hunt, Pharm.D.	Todd Sponenberg, Pharm.D.
Emily Jacobson, Pharm.D.	Jill Stone, Pharm.D.
Dennis Janosczyk, Pharm.D.	Margaret Whiteash, Pharm.D.
Alexandra Kempf-Malys	
Kerry Ann Kilkenny, MD	
Philip Krebs, R.EEG T	
Briana LeBeau, Pharm.D.	
Ted Marines, Pharm.D.	
Lisa Mazonkey, RPh	
Tyreese McCrea, Pharm.D.	
Mark Mowery, Pharm.D.	
Austin Paisley, Pharm.D.	
Jonas Pearson, RPh	
Lauren Pheasant, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Sartori, Pharm.D.	
Kristen Scheib, Pharm.D.	
Kirsten Smith, Pharm.D.	
Aubrielle Smith-Masri, Pharm.D.	
Michael Spishock, RPh	
Luke Sullivan, DO	
Kevin Szczecina, RPh	
Amanda Taylor, MD	
Ariana Wendoloski, Pharm.D.	
Brandon Whiteash, Pharm.D.	
Benjamin Andrick, Pharm.D. (non-voting participant)	
Birju Bhatt, MD (non-voting participant)	
Shannon Brown (pharmacy resident)	

Tina Cao (pharmacy resident) Alfred Denio, MD (non-voting participant) Keri Jon Donaldson, MD (non-voting participant) Jeremy Garris, Pharm.D. (non-voting participant) Ciera Helsel (pharmacy resident) Katelyn Kinczel (pharmacy student) Lindsey Kisielewski (pharmacy resident) Nicholas Norman (pharmacy student) Abigail Perriello (pharmacy resident) Ayne Stevenson (pharmacy resident)	

Call to Order: Dr. Bret Yarczower called the meeting to order at 1:03 p.m., Tuesday July 16, 2024.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the May 21, 2024 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Hepzato Kit (melphalan/hepatic deliver system[HDS]))

Review: Hepzato is indicated as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation. Melphalan is an alkylating drug that works by targeting both resting and rapidly dividing tumor cells.

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

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

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

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of unresectable metastatic uveal melanoma **AND**
- Medical record documentation of unresectable hepatic metastases affecting less than 50% of the liver AND
    - Documentation of no extrahepatic disease OR
    - Documentation of extrahepatic disease limited to bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation

GPI Level: GPI-12
Quantity Limits: 6 Kits per lifetime, Facets RX Count 1500
Authorization Duration: 24 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.

Rezdiffra (resmetirom)

Review: Rezdiffra is a thyroid hormone receptor-beta (THR-beta) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). Rezdiffra should be avoided in patients with decompensated cirrhosis. NASH is the most severe form of nonalcoholic fatty liver disease (NAFLD). As of June 2023, the nomenclature changed from NAFLD and NASH to metabolic dysfunction-associated steatotic liver disease (MASLD) and metabolic dysfunction-associated steatohepatitis (MASH), respectively. This review will match the old nomenclature to coincide with language used in the Rezdiffra prescribing information. Rezdiffra was approved under accelerated approval based on NASH and fibrosis improvement, but continued approval may be contingent on verification and description of clinical benefit from additional trials..

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

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

Outcome: Rezdiffra is a pharmacy benefit and should be added to the GHP Family pharmacy formulary at the Brand tier. The following prior authorization criteria should apply:

- Medical record documentation of age 18 years or older **AND**
- Medical record documentation of a diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) [formerly known as noncirrhotic nonalcoholic steatohepatitis (NASH)] **AND**
- Medical record documentation of moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) **AND**
- Medical record documentation of chart notes showing that diagnosis is confirmed by 1 of the following:
    - Liver biopsy **OR**
    - Non-invasive test (NIT) (e.g. – ultrasound elastography [i.e., Fibroscan], magnetic resonance elastography [MRE], biomarker labs [i.e., Enhanced Liver Fibrosis (ELF) test, Fibrosure])

AND

- Medical record documentation that Rezdiffra will be used in combination with diet and exercise **AND**
- Medical record documentation that the patient does not have decompensated cirrhosis **AND**
- Medical record documentation that Rezdiffra is prescribed by or in consultation to an appropriate specialist (hepatologist or gastroenterologist).

GPI Level: GPI-12

Authorization Duration Initial approval will be for 6 months.
Reauthorization info: Subsequent approvals will be for an additional 12 months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression as evidenced by one of the following:
    - NASH (MASH) resolution AND no worsening of fibrosis **OR**
    - No worsening of NASH (MASH) AND improvement in fibrosis by at least 1 stage

RPh Sign Off: Yes

Note to Reviewer: As of June 2023, the nomenclature changed from nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH) to metabolic dysfunction-associated steatotic liver disease (MASLD) and metabolic dysfunction-associated steatohepatitis (MASH), respectively. There is not yet an ICD-10 code for MASH or MASLD. The wording used in the review matches the old nomenclature as used in the package labeling. Either NASH or MASH should be accepted during clinical review.

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

Rivfloza (nedosiran)

Review: Rivfloza is a double-stranded small interfering RNA (siRNA) indicated to lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function (e.g., estimated glomerular filtration rate [eGFR] ≥30 mL/min/ 1.73 m^2).

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

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

Outcome: Rivfloza will be a pharmacy benefit and should not be added to the GHP Family Formulary. The following prior authorization criteria should apply:

- Medical record documentation of primary hyperoxaluria type 1 (PH1) as confirmed by one of the following:
    - Molecular genetic testing that confirms a mutation of alanin:glyoxylate aminotransferase (*AGXT*) gene* OR
    - A liver biopsy to confirm absent or significantly reduced alanin:glyoxylate aminotransferase (AGT)

*Note: *AGXT* genotypes include but are not limited to: PR/RR, PR/M, PR/N, M/M, M/N, N/N
AND

- Medical record documentation that Rivfloza is prescribed by or in consultation with an appropriate specialist with experience managing hyperoxaluria (i.e., a nephrologist, urologist, geneticist, or hepatologist) **AND**
- Medical record documentation of age greater than or equal to 9 years **AND**

- Medical record documentation of increased urinary oxalate excretion (i.e., generally greater than 0.7 mmol/1.73 m^2 per day or greater than the upper limit of normal) **AND**
- Medical record documentation of relatively preserved kidney function as defined by one of the following:
    - Medical record documentation patient has an eGFR ≥30 mL/min/1.73m^2 OR
    - If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range

AND

- Medical record documentation that the patient does not have a history of a liver transplant **AND**
- Medical record documentation that the member will not be receiving Rivfloza in combination with Oxlumo **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 **AND**
- Medical record documentation of failure, contraindication, or intolerance to Oxlumo.

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 twelve (12) months** or less if the reviewing provider feels it is medically appropriate, requiring:

- Medical record documentation of reduction in urinary oxalate excretion from baseline **AND**
- Medical record documentation of relatively preserved kidney function as defined by ONE of the following:
    - Medical record documentation patient has an eGFR ≥30 mL/min/1.73m^2 OR
    - If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range

  AND
- Medical record documentation that the patient does not have a history of liver transplant **AND**
- Medical record documentation that the member will not be receiving Rivfloza in combination with Oxlumo.

NOTE TO REVIEWER: If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range would be considered acceptable for relatively preserved kidney function.

GPI Level: GPI-10

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

Anktiva (nogapendekin alpha inbakicept-pmln)

Review: Anktiva is the first-in-class interleukin (IL)-15 superagonist consisting of an IL-15 mutant (IL-15N72D) fused with an IL-15 receptor alpha. Anktiva is administered intravesically with BCG for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors. Anktiva was approved as both induction and maintenance therapy in combination with BCG.

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

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

Outcome: Opfolda is a pharmacy benefit and should not be added to the GHP Family formulary. No additional prior authorization criteria based on cost will apply.

Pombiliti is a medical benefit. No additional prior authorization criteria based on cost will apply.

- Medical record documentation of a diagnosis of late-onset Pompe disease supported by:
    - Acid alpha-glucosidase (GAA) assay performed on dried blood spots, skin fibroblasts or muscle biopsy AND
    - Genetic testing showing a mutation in the GAA gene

AND

- Medical record documentation of a consultation with a metabolic specialist and/or biochemical geneticist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of baseline percent-predicted forced vital capacity (% FVC) and 6-minute walk test (6MWT) AND
- Medical record documentation of member weight ≥ 40 kg AND
- Medical record documentation that Opfolda and Pombiliti will be used in combination AND
- Medical record documentation that member is currently receiving enzyme replacement therapy (e.g. Lumizyme, Nexviazyme) and is not experiencing improvement AND
- Medical record documentation that Pombiliti and Opfolda will not be used concurrently with other enzyme replacement therapy (e.g. Lumizyme, Nexviazyme)

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

- Medical record documentation of improvement or stabilization in percent-predicted forced vital capacity (% FVC) and/or 6-minute walk test (6MWT) AND
- Medical record documentation of member weight ≥ 40 kg AND
- Medical record documentation that Opfolda and Pombiliti will be used in combination AND
- Medical record documentation that Pombiliti and Opfolda will not be used concurrently with other enzyme replacement therapy (e.g. Lumizyme, Nexviazyme)

GPI Level: GPI-12

Require RPH Sign off: Yes. Rph Signoff will be required to ensure appropriate utilization.

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

Penbraya (Meningococcal Serotypes A,B,C,W and Y Vaccine iptacopan)

Review: Penbraya (Meningococcal Serotype A,B,C,W,Y) vaccine was FDA approved in 2023 and is indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroups A, B, C, W, and Y. Penbraya is approved for use in individuals 10 through 25 years of age who would generally be indicated to receive 2 different Meningococcal vaccines (Men B (Trumenba and Bexsero) and MenACWY(Menveo and Menquadfi) at the same clinic visit

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

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

Outcome: Anktiva will be a medical benefit managed by GHP and the following prior authorization criteria will apply:

- Medical record documentation of an age greater than or equal to 18 AND
- Medical record documentation that Anktiva is being prescribed by or in consultation with a hematologist, oncologist, or urologist AND
- Medical record documentation of Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors AND
- Medical record documentation that BCG will be administered with each dose of Anktiva AND
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Authorization Duration: Initial approval will be for **6 months** (to cover 2 potential induction courses) 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.

- Authorization of Anktiva should not exceed the approved treatment duration of 30 doses if 1 induction course **OR** 36 doses if 2 induction courses

For requests exceeding the above limits, 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

Require 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.

Imdelltra (tarlatamab-dlle)

Review: Imdelltra (tarlatamab-dlle) is a bispecific delta-like ligand 3 (DLL3)-directed CD3 T-cell engager indicated for the treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy. Imdelltra is a first-in-class immunotherapy that binds to both DLL3 on tumor cells and CD3 on T cells, activating T cells to kill DLL3-expressing SCLC cells. This results in the formation of a cytolytic synapse with lysis of the cancer cell. DLL3 is a protein that is expressed on the surface of SCLC cells in approximately 85%–96% of patients with SCLC but is minimally expressed on healthy cells. Imdelltra was approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication is contingent upon verification and description of clinical benefit in confirmatory trials.

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

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

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

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Imdelltra is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of extensive-stage small cell lung cancer (ES-SCLC) (ES-SCLC is classified as SCLC that is Stage IV (T any, N any, M 1a/b/c), or Stages 1-3 with T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan). **AND**
- Medical record documentation of disease progression on or after treatment with platinum-based chemotherapy.

GPI Level: GPI-12

AUTHORIZATION DURATION: Initial approval will be for **6 months**. Subsequent approvals will be for an **additional 6 months** and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Require 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.

Lantidra (donislecel-jujn)

Review: Lantidra is an allogeneic pancreatic islet cellular therapy indicated for the treatment of adults with Type 1 diabetes who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. It is used in conjunction with concomitant immunosuppression. When considering the risks associated with the infusion procedure and long-term immunosuppression, there is no evidence to show a benefit of administration of Lantidra patients whose diabetes is well-controlled with insulin therapy or patients with hypoglycemic unawareness who are able to prevent current repeated severe hypoglycemic events (neuroglycopenia requiring active intervention from a third party) using intensive diabetes management (including insulin, devices, and education). Repeated intraportal islet infusions are not recommended in patients who have experienced prior portal thrombosis unless the thrombosis was limited to second- or third-order portal vein branches. There is no evidence to support the safe and effective use of Lantidra in patients with liver disease, renal failure, or who have received a renal transplant.

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

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

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

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Lantidra is prescribed by or in consultation with an endocrinologist **AND**
- Medical record documentation of a diagnosis of Type I diabetes mellitus for at least 5 years **AND**
- Medical record documentation of failure to achieve target HbA1c with current treatment regimens **AND**
- Medical record documentation of intensive diabetes management and education, including all of the following
    - Documentation of use of greater than or equal to three daily injections of prandial and/or basal insulin or continuous subcutaneous insulin through an insulin pump **AND**
    - Documentation of use of a continuous glucose monitor **OR** both of the following:
        - Documentation of reason why a continuous glucose monitor cannot be used **AND**
        - Documentation of daily monitoring of blood glucose levels

AND

- Documentation that member has received education on insulin administration and dosing and dietary management **AND**

- Medical record documentation of repeated severe uncontrolled hypoglycemia including BOTH of the following:
    - At least one episode of severe hypoglycemia in the past 3 years defined as an event with symptoms compatible with hypoglycemia in which the subject required the assistance of another person, and which was associated with either a blood glucose level < 50 mg/dL (2.8 mmol/L) or prompt recovery after oral carbohydrate, intravenous glucose, or glucagon administration **AND**
    - Reduced awareness of hypoglycemia, as defined by the absence of adequate autonomic symptoms at capillary glucose levels of < 54 mg/dL (3 mmol/L) as reported by the subject

AND

- Medical record documentation that Lantidra will be used in conjunction with concomitant immunosuppression

GPI Level:GPI-12
Authorization Duration: Initial authorization will be for one (1) infusion of Lantidra
Reauthorization info: Reauthorization for Lantidra will be for one (1) additional infusion up to three (3) infusions per lifetime and will require all of the following:

- Medical record documentation that member has not achieved exogenous insulin independence within one year following the first or second Lantidra infusion (islet transplantation) OR within one year after losing independence from exogenous insulin after a previous infusion AND
- Medical record documentation that member has not exceeded the maximum of three (3) infusion per lifetime

Require RPH Sign off: Yes. Rph Sign off 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.

Zoryve Foam (roflumilast)

Review: Zoryve (roflumilast) 0.3% topical foam is a phosphodiesterase-4 (PDE4) inhibitor indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

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

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

Outcome: Zoryve foam is a pharmacy benefit and should not be added to the GHP family pharmacy formulary. The following prior authorization criteria should apply:

- Medical record documentation that Zoryve topical foam is prescribed by or in consultation with a dermatologist **AND**

- Medical record documentation of age greater than or equal to 9 years **AND**
- Medical record documentation of a diagnosis of seborrheic dermatitis **AND**
- Medical record documentation of therapeutic failure, intolerance, or contraindication to:
    - At least one low- to high-potency topical corticosteroid **AND**
    - At least one topical antifungal

GPI Level: GPI-12

Formulary Alternatives: per Statewide PDL

Quantity Limits: 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 clinical improvement based on signs and symptoms of seborrheic dermatitis

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

Class Review

Fast Facts

Updates

Medical Policies Update

Recommendation: It is recommended that the Committee approve the following updates.

The following policies were modified following PARP review:

Policy	DHS Identified Issue	Changes to Policy
MBP 234.0 Oxlumo (lumasiran)	Labeling updated to include dosing recommendations for patients on hemodialysis.	Removed kidney function criteria.

MBP 234.0 was updated to reflect the following changes:

- Prescription written by or in consultation with an appropriate specialist (including but not limited to a nephrologist, urologist, geneticist, or hepatologist) **AND**
- Medical Record documentation of primary hyperoxaluria type 1 (PH1) as confirmed by ONE of the following:
    - Molecular genetic testing that confirms a mutation of alanin:glyoxylate aminotransferase (AGXT) gene* **OR**
    - A liver biopsy to confirm absent or significantly reduced alanin:glyoxylate aminotransferase (AGT)

AND

- Medical record documentation of metabolic screening that demonstrates ONE of the following:
    - Markedly increased urinary oxalate excretion (i.e. generally greater than 0.7 mmol/1.73 m^2 per day or greater than the upper limit of normal) **OR**
    - Increased urinary oxalate to creatinine ratio (i.e. greater than the age-specific upper limit of normal)

~~**AND**~~

- ~~Medical record documentation of sufficient kidney function as defined by ONE of the following:~~
    - ~~Medical record documentation patient has an eGFR ≥30 mL/min/1.73m^2~~ ~~**OR**~~
    - ~~If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range~~

AND

- Medical record documentation that the patient does not have a history of liver transplant.

*****Note: AGXT genotypes include but are not limited to: PR/RR, PR/M, PR/N, M/M, M/N, N/N

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 twelve (12) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- ~~Sufficient kidney function as defined by ONE of the following:~~
    - ~~Medical record documentation patient has an eGFR ≥30 mL/min/1.73m^2~~ ~~**OR**~~
    - ~~If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range~~

~~**AND**~~

- Medical record documentation that the patient does not have a history of liver transplant.

Ongoing subsequent approvals will be for a **duration of twelve (12) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- ~~Sufficient kidney function as defined by ONE of the following:~~
  - ~~Medical record documentation patient has an eGFR ≥30 mL/min/1.73m^2~~ **~~OR~~**
  - ~~If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range~~

~~AND~~

- Medical record documentation that the patient does not have a history of liver transplant.

MBP 300.0 Medical Benefit Drug Optimization Program

I. Policy:

Medical Benefit Drug Optimization Program

II. Purpose/Objective:

To provide a policy of coverage regarding certain complex, rare disease, and specialty drugs, which are required to be obtained from and billed by a Specialty Pharmacy and are not eligible for direct reimbursement to a provider or facility. This policy applies to these medications:

1. Atezolizumab (Tecentriq) [effective 8/12/24]
2. Avelumab (Bavencio) [effective 8/12/24]
3. Cemiplimab (Libtayo) [effective 8/12/24]
4. Dostarlimab (Jemperli) [effective 8/12/24]
5. Durvalumab (Imfinzi) [effective 8/12/24]
6. Enfortumab Vedotin (Padcev) [effective 8/12/24]
7. Ipilimumab (Yervoy) [effective 8/12/24]
8. Nivolumab (Opdivo) [effective 8/12/24]
9. Pembrolizumab (Keytruda)
10. Relatlimab and nivolumab (Opdualag) [effective 8/12/24]
11. Retifanlimab (Zynyz) [effective 8/12/24]
12. Tislelizumab (Tevimbra) [effective 8/12/24]
13. Toripalimab (Loqtorzi) [effective 8/12/24]
14. Tremelimumab (Imjudo) [effective 8/12/24]

III. Responsibility:

A. Medical Directors

B. Medical Management

C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Health Plan – Shall refer to Geisinger Health Plan and Geisinger Indemnity Insurance Company collectively.
6. Revised – the date of every revision to the policy, including typographical and grammatical changes.
7. Reviewed – the date documenting the annual review if the policy has no revisions necessary.
8. Specialty Medication – high-cost prescriptions used to treat and manage complex and chronic conditions. Specialty medications sometimes require special handling and administration, typically injection or infusion.
9. Specialty Pharmacy – a closed door pharmacy that is trained to dispense specialty medications.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;

b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;

c. in accordance with current standards good medical treatment practiced by the general medical community;

d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and

e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:

Specific intravenous and injectable drugs must meet applicable medical necessity criteria for coverage. If these

criteria are met, this coverage policy will be used to define which medications must be obtained through a Specialty Pharmacy. The Specialty Pharmacy will distribute the patient specific medication directly to the providers office or facility where the medication will be prepared and administered to the patient. This policy is effective for the ~~Medicaid~~, exchange, commercial, and ASO lines of business, excluding PEBTF and medical benefit only ASOs.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

This policy lists medications that are suitable for distribution from a specialty pharmacy to a prescribing provider or facility to administer.

Prescribing providers or facilities

The prescribing provider must order a specialty medication from a contracted preferred Specialty pharmacy. The prescribing provider or facility will be responsible for a well-trained staff to admix and administer the medication safely to the patient. The specialty pharmacy will be able to answer any questions they may have regarding the specialty medication. The prescribing provider or facility can bill for the administration of the medication only. The prescribing provider or facility may not bill for the full cost of the medication because they did not purchase it or dispense from their own supply (as would be the practice of buy and bill).

If prior authorization is needed, the prescribing provider must submit the prior authorization request including relevant chart information to the health plan for review.

Specialty Pharmacy

The specialty pharmacy will dispense the member specific medication and bill Geisinger Health Plan. The specialty pharmacy will then dispense (ship out/deliver) the medication directly to the provider's office or facility for administration.

Medications are subject to cost-sharing and utilization management, as outlined in formulary and/or benefit documentation.

The specialty pharmacy will dispense (ship out/deliver) the prescribed medication to the administering provider or facility with patient-specific labeling (after prior authorization is approved, if applicable). The specialty pharmacy must package the drug for delivery to ensure product integrity and temperature control of the medications in transit. The drug shipment will not include the IV bags, lines, and other administrative supplies. These will need to be issued/supplied by the administering provider or facility.

To mitigate wastage, the specialty pharmacy will need to do the following two steps when dispensing:

1. If the drug is to be admixed or compounded, it is their responsibility to send out a dosage that is the smallest amount possible above the prescribed amount. This will be monitored and addressed with the specialty pharmacies if wastage discrepancies are noticed.
2. Verify the date of administration with the member and provider or facility, as the claim will be processed at the time of dispense (not the date of administration). The drug will not be able to be returned after it is dispensed, if not used for that specific member.

The specialty pharmacy is responsible for delivering the medication to the administering facility or provider's office in time for the patient's administration appointment. In the case of same day treatment changes, a provider's office or facility may request a one-time emergency reimbursement from the health plan by contacting the customer call center so that the member may obtain their infusion and there is no delay in therapy. The one-time authorization is only valid the same day as the treatment change and the request for the emergency authorization. If approved, the drug would be reimbursed to the office or facility at the contracted rate of the specialty pharmacy.

LIMITATIONS:

- If the above conditions are not met, but the administration location is determined by the Health Plan to be a least costly administration site, the provider may be approved for direct reimbursement of the administered medication.
- Home infusion companies administering the intravenous or injectable drug in a home or suite setting may opt, but are not required, to supply the administered drug via specialty pharmacy.

LINE OF BUSINESS:

This policy does not apply to the Medicare, Medicaid, CHIP, PEBTF, or medical benefit only ASO lines of business. Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

Outcome: 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.

June ELECTRONIC VOTE

An electronic vote was held from June 14, 2024, to June 19, 2024. Responses were received from 26 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.

Zilbrysq (zilucoplan)

Review: Zilbrysq is a complement inhibitor indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. Zilbrysq is the first self-administered complement inhibitor in gMG. Zilbrysq binds complement protein C5, inhibiting its cleavage to C5a and C5b and preventing the generation of C5b-9. The precise mechanism of Zilbrysq in gMG is unknown but is thought to involve reduction of C5b-9 deposition at the neuromuscular junction.

Recommendation: Zilbrysq will be managed by GHP and should not be added to the GHP Family formulary. The following additional prior authorization criteria should apply:

- Medical record documentation of age 18 years or older AND
- Medical record documentation that Zilbrysq is prescribed by or in consultation with a neurologist AND
- Medical record documentation of a diagnosis of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) positive AND
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IV AND
- Medical record documentation of a baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) score greater than or equal to 6 AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids AND
- Medical record documentation of therapeutic failure on intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies OR has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) AND
- Medical record documentation of failure on, intolerance to, or contraindication to intravenous immunoglobulin (IVIG).

Authorization Duration: 6 months
Reauthorization Info: Subsequent approvals will be for an additional 6 months and will require:
• Medical record documentation of continued disease improvement or lack of disease progression AND
• Medical record documentation that the member is responding positively to therapy as evidenced by an improvement of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score from baseline.

Formulary Alternatives:
Corticosteroids: dexamethasone, methylprednisolone, prednisone
Cholinesterase inhibitors: pyridostigmine
Immunosuppressants: azathioprine, mycophenolate, cyclosporine, Rituxan

GPI Level: GPI-12

Require RPH Sign off: Yes. RPh Signoff will be required to ensure appropriate utilization.

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

Abecma

Updated Indication: Abecma has an updated indication for relapsed or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Previously Abecma was indicated following four prior lines of therapy.

Recommendation: Make the following update to the Abecma policy:

- Medical record documentation that Abecma is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of relapsed or refractory multiple myeloma AND
- Medical record documentation of at least ~~four~~ two prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

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

Avycaz

Updated Age: The age has been updated now to include the pediatric population from birth (at least 31 weeks gestational age) to less than 3 months of age for the treatment of susceptible Gram-negative microorganisms in Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole, Complicated Urinary Tract Infections (cUTI), including pyelonephritis and Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP).

Recommendation: Make the following update to the Avycaz policy:
Avycaz (cetfazidime/avibactam) is a combination cephalosporin/beta-lactamase inhibitor indicated in combination with metronidazole, for the treatment of complicated intra-abdominal infections (cIAI) caused by the following susceptible microorganisms: Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Enterobacter cloacae, Klebsiella oxytoca, Citrobacter freundii complex and Pseudomonas aeruginosa in patients ~~3 months or older~~. adult and pediatric patients ≥31 weeks gestational age.

Avycaz is also indicated for the treatment of complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Citrobacter freundii complex, Proteus mirabilis, and Pseudomonas aeruginosa in patients ~~3 months or older.~~ adult and pediatric patients ≥31 weeks gestational age.

Avycaz is also indicated for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by the following susceptible microorganisms: Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa and, Serratia marcescens in adult and pediatric patients ≥31 weeks gestational age.

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 now has the following new indications:

- adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least 2 prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s)
- adult patients with relapsed or refractory follicular lymphoma (FL) who have received 2 or more prior lines of systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s)
- adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor

Recommendation: It is recommended that the following prior authorization be added to MBP 228.0 to incorporate the new indications:

CLL/SLL

- 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 chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) **AND**
- Medical record documentation of at least 2 prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.

FL

- 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 follicular lymphoma (FL) **AND**
- Medical record documentation of at least 2 prior lines of systemic therapy

MCL

- 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 mantle cell lymphoma (MCL) **AND**
- Medical record documentation of at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor.

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

Carvykti

Updated Indication: Carvykti is now indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 1 prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide. Previously, this was indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

Recommendation: Make the following update to the Carvykti policy:

- Medical record documentation that Carvykti is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of relapsed or refractory multiple myeloma AND
- Medical record documentation of at least ~~four~~ one prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and ~~an anti-CD38 monoclonal antibody~~ are refractory to lenalidomide **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

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

Enhertu

Updated Indication: Enhertu is now indicated for the:

- treatment of adult patients with unresectable or metastatic HER2-positive (IHC 3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options.
    - This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Recommendation: Make the following update to the Enhertu policy:
Breast Cancer

- Prescription written by a hematologist or oncologist AND
- Medical record documentation of patient age greater than or equal to 18 years AND
- Medical record documentation of unresectable or metastatic HER2-positive (IHC 3+ or ISH positive) breast cancer AND
- Medical record documentation of one of the following:
    - Documentation of a prior anti-HER2 based therapy in the metastatic setting OR
    - Documentation of a prior anti-HER2 based therapy in the neoadjuvant or adjuvant setting AND documentation of disease recurrence during or within 6 months of completing therapy

OR

- Prescription written by a hematologist or oncologist AND
- Medical record documentation of patient age greater than or equal to 18 years AND
- Medical record documentation of unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer, as detected by an Food and Drug Administration (FDA)-approved test AND
- Medical record documentation that Enhertu will be used as a single agent AND

- Medical record documentation of one of the following:
    - Documentation of a prior chemotherapy in the metastatic setting OR
    - Documentation of disease recurrence during or within 6 months of completing adjuvant chemotherapy

Gastric Cancer

- Medical record documentation that Enhertu is written by a hematologist/oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of locally advanced or metastatic HER2-positive (IHC 3+ or IHC 2+/ISH positive) gastric or gastroesophageal junction (GEJ) adenocarcinoma AND
- Medical record documentation of one or more prior trastuzumab-based therapies

Non-Small Cell Lung Cancer

- Medical record documentation that Enhertu is written by a hematologist/oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of unresectable or metastatic non-small cell lung cancer (NSCLC) AND
- Medical record documentation of tumors that have activating HER2 (ERBB2) mutations, as detected by an FDA-approved test AND
- Medical record documentation that Enhertu will be used as a single agent AND
- Medical record documentation of a prior systemic therapy

HER2-Positive Solid Tumors

- Medical record documentation that Enhertu is written by a hematologist/oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of unresectable or metastatic HER2-positive (IHC 3+) solid tumors AND
- Medical record documentation of prior systemic treatment and have no satisfactory alternative treatment options

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

Onivyde

Updated Indication: Onivyde is now indicated, in combination with oxaliplatin, fluorouracil and leucovorin for the first line treatment of adult patients with metastatic pancreatic adenocarcinoma. Previously, Onivyde was indicated in combination with fluorouracil and leucovorin, for the treatment of adult patients with metastatic pancreatic adenocarcinoma after disease progression following gemcitabine-based therapy.

Recommendation: Make the following update to the Onivyde policy:

- Must be prescribed by an oncologist **AND**
- Medical record documentation of the patient being ≥18 years of age **AND**
- Medical record documentation of a diagnosis of metastatic adenocarcinoma of the pancreas **AND**

- Medical record documentation of one of the following:
    - Medical record documentation that Onivyde is being prescribed in combination with fluorouracil and leucovorin for disease progression following gemcitabine-based therapy **OR**
    - Medical record documentation that Onivyde is being prescribed in combination with oxaliplatin, fluorouracil and leucovorin for first line treatment

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

Xdemvy and Oxervate Update

Recommendation: It is recommended to update the polices to allow optometrists to prescribe Xdemvy and Oxervate

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

Syfovre and Izervay Update

Recommendation: As part of Eye Disorder CarePath discussions, updates to the Syfovre and Izervay policy were recommended. Among the topics discussed were to delete the criteria point regarding CNV, change the authorization duration to allow for closer monitoring, and add criteria points regarding best corrected visual acuity and safety.

<u>Syfovre</u>

- Medical record documentation of the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) **AND**
- Medical record documentation of a confirmed diagnosis of geographic atrophy (GA) using imagining modalities, including but not limited to fundus autofluorescence (FAF), fundus photography, or optical coherence tomography (OCT) **AND**
- Medical record documentation of a current (within 3 months) best corrected visual acuity (BCVA) of 20/320 or better (for example 20/200, 20/80, 20/70, etc) in the eye(s) to be treated with Syfovre
- ~~For new starts only: Medical record documentation of the absence of active, or history of, choroidal neovascularization* (CNV) in the eye(s) to be treated with Syfovre.~~

~~*Note: Age-related macular degeneration (AMD) with CNV is often referred to as exudative AMD (eAMD), neovascular AMD (nAMD), or wet AMD (wAMD).~~

AUTHORIZATION DURATION: ~~Approvals will be given for a lifetime duration.~~ Initial approval will be for **12 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for **12 months** or less if the reviewing provider feels it is medically appropriate and will require the following criteria:

- Medical record documentation of a current (within 3 months) best corrected visual acuity (BCVA) of better than 20/320 (for example 20/200, 20/80, 20/70, etc.) in the eye(s) being treated with Syfovre **AND**
- Medical record documentation of the absence, or resolution, of Retinal Vasculitis, Retinal Vascular Occlusion, and/or active Intraocular Inflammation (including but not limited to: vitritis, vitreal cells, iridocyclitis, uveitis, anterior chamber cells, iritis, and anterior chamber flare)

AND

- One of the following:
  - Medical record documentation of the absence of active choroidal neovascularization (CNV), or neovascular (wet) Age Related Macular Degeneration (nAMD) in the Syfovre-treated eye(s) **OR**
  - Medical record documentation that the member's active CNV, or nAMD is NOT worsening **OR**
  - Medical record documentation of rationale for continued use in the setting of worsening CNV, or nAMD (eg. The benefits of Syfovre outweigh the risks of Syfovre administration)

Izervay

- Medical record documentation of the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) **AND**
- Medical record documentation of a confirmed diagnosis of GA using imagining modalities, including but not limited to fundus autofluorescence (FAF), fundus photography, or optical coherence tomography (OCT) **AND**
- Medical record documentation of a current (within 3 months) best corrected visual acuity (BCVA) of 20/320 or better (for example 20/200, 20/80, 20/70, etc) in the eye(s) to be treated with Syfovre **AND**
- ~~For new starts only: Medical record documentation of the absence of active, or history of, choroidal neovascularization* (CNV) in the eye(s) to be treated with Izervay **AND**~~
- Medical record documentation that Izervay will not be administered concurrently with other complement inhibitors for the treatment of geographic atrophy secondary to age-related macular degeneration (AMD) (i.e.. Syfovre)

AUTHORIZATION DURATION: ~~12 months~~ Initial approval will be for **12 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for **12 months** or less if the reviewing provider feels it is medically appropriate and will require the following criteria:

- Medical record documentation of a current (within 3 months) best corrected visual acuity (BCVA) of better than 20/320 (for example 20/200, 20/80, 20/70, etc.) in the eye(s) being treated with Izervay

AND

- One of the following:
  - Medical record documentation of the absence of active choroidal neovascularization (CNV), or neovascular (wet) Age Related Macular Degeneration (nAMD) in the Izervay-treated eye(s) **OR**
  - Medical record documentation that the member's active CNV, or nAMD is NOT worsening **OR**
  - Medical record documentation of rationale for continued use in the setting of worsening CNV, or nAMD (eg. The benefits of Izervay outweigh the risks of Izervay administration)

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

GHP Family Update

Recommendation: It is recommended the following updates be approved:

Strensiq

During the annual formulary review DHS requested we consider reference ranges used by the lab that conducted the test, not necessarily the table we had provided.

- Must be prescribed by an endocrinologist or metabolic specialist **AND**
- Medical record documentation of a diagnosis of perinatal/infantile- or juvenile-onset hypophosphatasia (HPP) **AND**
- Medical record documentation of low total serum alkaline phosphatase activity ~~(see chart below for typical lowest normal reference values)~~ as determined by the lab that conducted the test **AND**
- Medical record documentation that member will receive a weight and diagnosis appropriate dosing regimen.

Benlysta SQ

During the annual formulary review DHS requested we make the following updates to align with the package insert and clarify the reauthorization criteria.

Systemic Lupus Erythematosus:

- Medical record documentation of age ≥ 18 years
- 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 CNS involvement **AND**
- Prescribed by 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 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
- 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: Benlysta has not been studied in combination with other biologics. ~~Use of Benlysta is not recommended in these situations~~ Caution should be exercised if Benlysta is administered in combination with other biologic therapies.

Authorization Duration: Each authorization will be for a period of 12 months. Re-review is required every 12 months using the following criteria:.~~with medical record documentation showing a clinical benefit of one of the following:~~

Systemic Lupus Erythematosus

- Improvement in functional impairment
  OR
- Decrease in the number of exacerbations since the start of Benlysta
  OR
- Decrease in the daily required dose of oral corticosteroids such as Prednisone

- **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

Insulin Pens

It was discovered that there are no insulin pens on formulary for GHP Family so the recommendation is to add the following to the Brand Tier of the formulary.

Device Name	Device NDC
NovoPen Echo DEVICE	00169185459
Autopen DEVICE	08470380001
Autopen DEVICE	08470381001

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

Meeting adjourned at 3:39 pm

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held on September 17, 2024 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams