P&T Committee Meeting Minutes
Medicaid
July 8, 2025

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair Amir Antonious, Pharm.D. Leslie Astleford, Pharm.D. Kristen Bender, Pharm.D. Jeremy Bennett, MD Angela Bolesta, Pharm.D. Kim Castelnovo, RPh Kimberly Clark, Pharm.D. Michael Dubartell, MD Kelly Faust, Pharm.D. Jason Howay, Pharm.D. Emily Jacobson, Pharm.D. Dennis Janosczyk, Pharm.D. Alexandra Kempf-Malys, MSW, BSc Kerry Ann Kilkenny, MD Philip Krebs, R.EEG T Briana LeBeau, Pharm.D. Ted Marines, Pharm.D. Lisa Mazonkey, RPh Tyreese McCrea, Pharm.D. Perry Meadows, MD Jamie Miller, RPh Mark Mowery, Pharm.D. Andrei Nemoianu, MD Austin Paisley, Pharm.D. Lauren Pheasant, Pharm.D. Kimberly Reichard, Pharm.D. Melissa Sartori, Pharm.D. Kristen Scheib, Pharm.D. Michael Shepherd, MD Kirsten Smith, Pharm.D. Todd Sponenberg, Pharm.D. Jill Stone, Pharm.D. Kevin Szczecina, RPh Amanda Taylor, MD Ariana Wendoloski, Pharm.D. Brandon Whiteash, Pharm.D. Margaret Whiteash, Pharm.D. Abigail Chua, DO (non-voting participant) Jeremy Garris (non-voting participant) Jilu Jacob, Pharm.D. (pharmacy resident, non-voting participant)	Emily Bednarz, Pharm.D. Bhargavi Degapudi, MD Keri Donaldson, MD, MSCE Tricia Heitzman, Pharm.D. Nichole Hossler, MD Keith Hunsicker, Pharm.D. Kelli Hunsicker, Pharm.D. Jonas Pearson, RPh Aubrielle Smith-Masri, Pharm.D. Michael Spishock, RPh Luke Sullivan, DO

Ashley Mayes, Pharm.D. (pharmacy resident, non-voting participant) Morgan McIntyre, Pharm.D. (pharmacy resident, non-voting participant) Grace O'Toole, Pharm.D. (pharmacy resident, non-voting participant) Makenzie White (pharmacy student) Xintian Xu (pharmacy student)	

Call to Order: Dr. Bret Yarczower called the meeting to order at 1:01 p.m., Tuesday July 8, 2025.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the May 13, 2025 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Emrelis (telisotuzumab vedotin-tllv)

Review: Emrelis is a c-Met-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression (≥ 50% of tumor cells with strong [3+] staining), as determined by an FDA-approved test, who have received a prior systemic therapy. Emrelis is the first and only c-Met targeted antibody-drug conjugate.

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

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

Outcome: Emrelis will be a medical benefit managed by GHP. The following prior authorization criteria will apply:
• Medical record documentation of an age greater than or equal to 18 AND
• Medical record documentation that Emrelis is being prescribed by or in consultation with a hematologist or oncologist AND
• Medical record documentation of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) AND
• Medical record documentation of high c-MET protein overexpression (defined as ≥50% of tumor cells with strong [3+] staining), as determined by an FDA-approved test AND
• Medical record documentation that the tumor is *EGFR* wild-type AND
• Medical record documentation that the patient has received one prior systemic therapy in the advanced/metastatic setting AND
• Medical record documentation that Emrelis will be administered as monotherapy

Reauthorization Criteria (ALL LOB): Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

GPI Level: GPI-12

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.

Epysqli (eculizumab-aagh)

Review: Epysqli is a Soliris biosimilar approved for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis, atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy, and generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AchR) antibody positive.

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

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

Outcome: Epysqli will process as a medical benefit for GHP Family and will be managed by GHP. The following additional prior authorization criteria should be added to Medical Benefit Policy 54.0 with the following changes:

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

AND
• For Soliris: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a preferred eculizumab biosimilar*

AUTHORIZATION DURATION: Approval will be given for **6 months**. Additional coverage will only be provided when documentation of the following is provided:
• Member requires fewer transfusions or has stabilization of Hb levels **AND**
• Reduction in intravascular hemolysis as evidenced reduction in elevated LDH levels from baseline **AND**
• No recurrent infections

2. Atypical Hemolytic Uremic Syndrome (aHUS)
• Medical record documentation of a diagnosis of atypical hemolytic uremic syndrome (aHUS) **AND**
• For Soliris: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a preferred eculizumab biosimilar*

(Soliris is used to inhibit complement-mediated thrombotic microangiopathy)

AUTHORIZATION DURATION: Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **6 months** 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.

3. Generalized Myasthenia Gravis (gMG)

• Medical record documentation supporting a confirmed diagnosis of Generalized Myasthenia Gravis AND
• Medical record documentation that member is anti-acetylcholine receptor (AchR) antibody positive **AND**
• Prescribed by or in consultation with a neuromuscular specialist AND
• Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IV **AND***
• Medical record documentation Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of 6 or more at baseline **AND****
• Medical record documentation of age > 18 years **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) **AND**
• For Soliris: Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a preferred eculizumab biosimilar*

AUTHORIZATION DURATION: Initial approval will be given 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 **AND**
• Medical record documentation that the member is responding positively to therapy as evidenced by a 3-point reduction in MG-ADL total score**;

The medication will no longer be covered if patient experiences toxicity or worsening of disease.
**Note: Class I Myasthenia gravis is indicated by any eye muscle weakness, possible ptosis (drooping or falling of the upper eyelid) and no other evidence of muscle weakness elsewhere, Class II to IV include muscle weakness in areas of the body beyond the eye.*
Note: Corticosteroids: betamethasone, dexamethasone, methylprednisolone, prednisone
Cholinesterase inhibitors: pyridostigmine, neostigmine
Immunosuppressants: azathioprine, mycophenolate, cyclosporine, Rituxan
Note: Dosing for MG is 900 mg IV every 7 days for the first 4 weeks, followed by a single dose of 1,200 mg 7 days after the fourth dose, and then 1,200 mg every 2 weeks thereafter. Max dosage is 1,200 mg per dose.

MG Activities of Daily Living (MG-ADL)**

Grade	0	1	2	3	Score
Talking	Normal	Intermittent slurring or nasal speech	Constant slurring or nasal, but can be understood	Difficult to understand speech	
Chewing	Normal	Fatigue with solid food	Fatigue with soft food	Gastric tube	
Swallowing	Normal	Rare episode of choking	Frequent choking necessitating changes in diet	Gastric tube	
Breathing	Normal	Shortness of breath with exertion	Shortness of breath at rest	Ventilator dependence	
Impairment of ability to brush teeth or comb hair	None	Extra effort, but no rest periods needed	Rest periods needed	Cannot do one of these functions	
Impairment of ability to arise from a chair	None	Mild, sometimes uses arms	Moderate, always uses arms	Severe, requires assistance	
Double vision	None	Occurs, but not daily	Daily, but not constant	Constant	
Eyelid droop	None	Occurs, but not daily	Daily, but not constant	Constant	

Total score _____

4. Neuromyelitis Optica Spectrum Disorder (NMOSD) (SOLIRIS ONLY)
• Prescribed by or in consultation with a neurologist
• Medical record documentation that member is 18 years or older AND
• Medical record documentation of diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) AND
• Medical record documentation that member is anti-Aquaporin-4 (AQP4) antibody positive **AND**
• Medical record documentation of failure on intolerance to, or contraindication to rituximab or rituximab biosimilar **AND**
• Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Enspryng.

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

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

Journavx (suzetrigine)

Review: Journavx is a sodium channel blocker indicated for the treatment of moderate to severe acute pain in adults. Journavx is a first-in-class non-opioid pain medication, the first new class of pain medications approved in over 20 years. It works by selective blocking of NaV1.8 voltage-gated sodium channel. NaV1.8 is expressed in peripheral sensory neurons where it transmits pain signals. By inhibiting NaV1.8 channels, Journavx and its major active metabolite, M6-SUZ, inhibit transmission of pain signals to the spinal cord and brain.

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

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

Outcome: Journavx is a pharmacy benefit that will be managed by GHP and should not be added to the GHP Family formulary. The following prior authorization criteria should apply:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of moderate to severe acute pain **AND**
- Medical record documentation that Journavx will not be used in combination with opioid products **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on three formulary alternatives

Medispan Authorization Level: GPI-12

Authorization Duration: 14 days

RPH Signoff Required: No, Rph Signoff will not be required.

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

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Niktimvo (axatilimab)

Review: Niktimvo is a colony stimulating factor-1 receptor (CSF-1R)-blocking antibody indicated for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg. The recommended dose, for patients weighing at least 40kg, of Niktimvo is 0.3 mg per kg given intravenously over 30 minutes, with a maximum dose of 35mg, every 2 weeks until disease progression or unacceptable toxicity.

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

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

Outcome: Niktimvo is a medical benefit requiring prior authorization that is GHP managed. The following additional prior authorization criteria will apply.

•Medical record documentation that Niktimvo is prescribed by a hematologist, oncologist, or transplant specialist **AND**

•Medical record documentation of chronic graft-versus-host disease (cGVHD) **AND**

•Medical record documentation that the patient weighs greater than or equal to 40kg **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 that Niktimvo will not be used in combination with any of the following: ruxolitinib (Jakafi), ibrutinib (Imbruvica), belumosudil (Rezurock), rituximab **AND**
•Medical record documentation of therapeutic failure on, contraindication to, or intolerance to one (1) preferred oral glucocorticoid **AND**
•Medical record documentation of contraindication to, intolerance to, or therapeutic failure on three (3) of the following: ruxolitinib (Jakafi), ibrutinib (Imbruvica), belumosudil (Rezurock), rituximab

Medispan Authorization Level: GPI-12

Quantity Limits: Maximum of two 22mg/0.44mL vials OR four 9mg/0.18mL vials per 14 days. Note: the FDA approved maximum dose is 35mg per 14 days.

Authorization Duration: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 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**.**

RPH Signoff Required: Yes

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

FAST FACTS

UPDATES

Rebyota Update

Update: As of January 31, 2025, Merck has discontinued production of Zinplava. Zinplava was used to reduce recurrence of *C. difficile* infection (CDI) in adults and pediatric patients $\geq$ 1 year of age who were receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence. For Commercial, Exchange, CHIP, and Medicaid lines of business for Rebyota, members are required to step through Zinplava to qualify for Rebyota. This step is due to cost. Since Zinplava is no longer available, the criteria point requiring a step through Zinplava in MBP 280.0 Rebyota should be removed.

Recommendations: The criteria point for MBP 280.0 Rebyota requiring a step through Zinplava will be removed.

Result: 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.

Medical Benefit Policy Update

Anjeso Update

Recommendation: It is recommended to retire the medical benefit policy for Anjeso MBP 261.0 Anjeso (meloxicam injection). Anjeso was withdrawn from the market on 10/5/2023.

Ameluz Update

Recommendations: It is recommended to update the quantity limit for the medical benefit policy for Ameluz MBP 149.0 Ameluz (aminolevulinic acid).

QUANTITY LIMIT: 6 2 grams per application (3 1 tubes = 6 2 grams)

Result: 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 6, 2025, to June 19, 2025. Responses were received from 29 members (out of 49 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.

Opdivo

Updated Indication: Opdivo had updates made to the indications for Colorectal Cancer and Hepatocellular Carcinoma and is now FDA approved for:

- Adult and pediatric (12 years and older) patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC) in combination with ipilimumab.
- Adult patients with unresectable or metastatic hepatocellular carcinoma (HCC), as a first-line treatment in combination with ipilimumab.

Recommendation: It is recommended to change the prior authorization criteria for MBP 126.0

7. *Colorectal Cancer*
   - Prescription written by a hematologist/oncologist **AND**
   - Medical record documentation that patient is ≥ 12 years of age **AND**
   - Medical record documentation of a diagnosis of ~~metastatic~~ colorectal cancer **AND**
   - Medical record documentation of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease **AND**
   - Medical record documentation of one of the following:
     - Medical record documentation that Opdivo will be used in combination with ipilimumab (Yervoy) **AND**
     - Medical record documentation that the disease is unresectable or metastatic

     OR
     - Medical record documentation that Opdivo is being used as a single agent ~~or in combination with ipilimumab (Yervoy)~~ **AND**
     - Medical record documentation that the disease is metastatic **AND**

- Medical record documentation of progression following treatment with a fluoropyrimidine, oxaliplatin, or irinotecan

8. *Hepatocellular Carcinoma (HCC)*
   - Prescription written by a hematologist/oncologist **AND**
   - Medical record documentation of a diagnosis of unresectable or metastatic hepatocellular carcinoma **AND**
   - Medical record documentation that Opdivo will be used in combination with ipilimumab (Yervoy) **AND**
   - Medical record documentation of one of the following:
     - Medical record documentation that the regimen is being given as first-line treatment

     OR
     - Medical record documentation of a therapeutic failure on or intolerance to sorafenib (Nexavar) ~~**AND**~~
     - ~~Medical record documentation that Opdivo will be used as a single-agent or in combination with ipilimumab (Yervoy)~~

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

Rezdiffra Update

Discussion: Current guidelines for monitoring Rezdiffra from AASLD recommend evaluating efficacy every 12 months.

Safety and efficacy assessments at baseline and during 12 months of treatment with resmetirom

	Safety/Efficacy assessments	Safety assessments		Efficacy assessments	
Timeframe	**Hepatic function panel[a]**	**Thyroid function[b]**	**Lipid profile[c]**	**Noninvasive measurement of liver stiffness[d]**	**MRI-PDFF[e]**
Before treatment initiation	✓	✓	✓	✓	Consider
3 months	✓				
6 months	✓	✓	✓		
12 months	✓	✓	✓	Repeat if imaging NILDA was used at baseline	Consider repeating if baseline data are available

Hepatology81(1):312-320, January 2025.

Recommendation: Based on the guidelines noted above and feedback from Sara Gaines, PharmD it is recommended that the Committee approve updating the authorization duration as noted below.

Authorization Duration: Initial authorization will be for 12 months. Subsequent approvals will be for an additional 12 months and will require:

- Medical record documentation of continued disease improvement or lack of disease progression 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

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

Medical Benefit Policy Updates

Discussion: On PARP review, it was recommended to GHP to closely align policy criteria with the FDA approved indication.

Recommendations: It is recommended to update the reauthorization criteria for botulinum toxins to allow for review of dose and dosing sites with each authorization request.

MBP 11.0 Botulinum Toxin

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 the following:

- Medical record documentation of continued disease improvement or lack of disease progression** **AND**
- Medical record documentation that the proposed injection sites and dosage regimen are consistent with Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature for the requested indication **AND**
- Medical record documentation of one of the following:
    - Repeated administrations are not being given more frequently than once every 12 weeks **OR**
    - Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing more frequently than every 12 weeks.

  AND

- For Chronic Migraines:
    - Medical record documentation of continued or sustained reduction in migraine or headache frequency or has experienced a decrease in severity or duration of migraine **AND**
    - Medical record documentation that Botox will not be used in combination with a CGRP antagonist **OR**
    - If the request is for use in combination with a CGRP antagonist, all of the following must be met:
        - Medical record documentation of a therapeutic failure on a minimum 3 month trial of at least one CGRP antagonists without the concomitant use of Botox **AND**
        - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of a CGRP antagonist

***Note: The requested medication will no longer be covered if the patient fails to present clinical benefit after two sequential therapies using maximum doses.*

Discussion: On PARP review, it was recommended to GHP to closely align policy criteria with the FDA approved indication.

Recommendations: It is recommended to update the prior authorization criteria of MBP 313.0 Rezzayo to align with the FDA approved indication.

MBP 313.0 Rezzayo (rezafungin)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of ~~a non-neutropenic patient with~~ a diagnosis of candidemia or invasive candidiasis (other than endocarditis, osteomyelitis, or meningitis) **AND**
- Medical record documentation that Rezzayo is prescribed by an infectious disease specialist **AND**
- Medical record documentation that member has limited or no alternative treatment options

Discussion: On PARP review, it was recommended to GHP to closely align policy criteria with the FDA approved prescribing information.

Recommendations: It is recommended to update the prior authorization criteria of MBP 198.0 Gamifant to align with the FDA approved prescribing information

MBP 198.0 Gamifant (emapalumab-lzsg)

- Prescription written by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of primary hemophagocytic lymphohistiocytosis (HLH) based on one of the following:
    - A molecular diagnosis (HLH gene mutations) **OR**
    - A family history consistent with primary HLH (X-linked lymphoproliferative syndrome) **OR**
    - 5 out of the following 8 criteria fulfilled:
        - Fever ≥ 38.5ºC
        - Splenomegaly
        - Cytopenias affecting 2 of 3 lineages in the peripheral blood; hemoglobin <9 g/dL (<10 g/dL for infants aged less than 4 weeks old), platelets <100 x 10^9/L, neutrophils <1 x 10^9/L
        - Hypertriglyceridemia (fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL) and/or hypofibrinogenemia (≤1.5 g/L)
        - Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy
        - Low or absent NK-cell activity
        - Ferritin ≥ 500 mcg/L
        - Soluble CD25 level (i.e. soluble IL-2 receptor) of ≥ 2,400 U/mL or two standard deviations above age-adjusted laboratory-specific norms

AND

- Medical record documentation of refractory, recurrent or progressive disease or intolerance with conventional HLH therapy (e.g. etoposide, dexamethasone, cyclosporine A, intrathecal methotrexate)

Discussion: On PARP review, it was recommended to GHP to closely align policy criteria with the newly FDA approved indication.

Recommendations: It is recommended to update the prior authorization criteria of MBP 213.0 Sarclisa to align with the newly FDA approved indication.

MBP 213.0 Sarclisa (isatuximab-irfc)

- Medical record documentation that Sarclisa is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of diagnosis of newly diagnosed multiple myeloma **AND** both of the following:
        - Medical record documentation that the member is not eligible for stem-cell transplantation **AND**
        - Medical record documentation that Sarclisa will be given in combination with bortezomib, lenalidomide and dexamethasone

      OR

    - Medical record documentation of diagnosis of relapsed or refractory multiple myeloma AND both of the following:
        - Medical record documentation that Sarclisa will be used in combination with carfilzomib (Kyprolis)* and dexamethasone **AND**
        - Medical record documentation of prior treatment with one to three lines of therapy

      OR

    - Medical record documentation of diagnosis of multiple myeloma AND both of the following:
        - Medical record documentation that Sarclisa will be used in combination with pomalidomide (Pomalyst) and dexamethasone **AND**
        - Medical record documentation of prior treatment with at least two lines of therapy, which included lenalidomide (Revlimid) AND a proteasome inhibitor (including but not limited to Velcade (bortezomib)*, Kyprolis (carfilzomib)*, or Ninlaro (ixazomib))

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

June 2025 GHP Family Update

Discussion: During review of the Miplyffa policy DHS responded with the following comment: *"Preservation of any functional status and slowing of disease progression is of benefit to the member with NPC. Please delete."*

Recommendation: It is recommended that the committee approve the update made below.

- Medical record documentation of age ≥2 years of age **AND**
- Medical record documentation of weight ≥ 8 kg and dose is weight appropriate **AND**
- Medical record documentation that medication is being prescribed by or in collaboration with a physician who specializes in the treatment of Niemann-Pick disease type C (NPC) or related disorders **AND**
- Medical record documentation of a diagnosis of NPC1 or NPC2, confirmed by genetic testing demonstrating one of the following:
    - Mutations in both alleles of NPC1 or NPC2 OR
    - Mutation in one allele AND either a positive filipin-staining or elevated cholestane triol/oxysterols (>2× ULN) **AND**
- Medical record documentation of at least one neurological sign of NPC (e.g., loss of fine motor skills, swallowing, speech, ambulation) **AND**
- ~~Medical record documentation of ability to walk independently or with assistance **AND**~~

- Medical record documentation that member has completed the NPC Clinical Severity Scale (NPCCSS) assessment to determine baseline score of disease severity (note: higher score indicates greater impairment) **AND**
- Medical record documentation that member is currently receiving miglustat and Miplyffa will be used in combination with miglustat **AND**
- Medical record documentation that member is NOT using Miplyffa in combination with Aqneursa **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

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

Meeting adjourned at 2:40 PM

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held September 7, 2025.

Meetings will be held virtually via phone/Microsoft Teams