P&T Committee Meeting Minutes
Medicaid
November 19, 2024

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	
Amir Antonius, Pharm.D.	Benjamin Andrick, Pharm.D. (non-voting participant)
Leslie Astleford, PharmD.	
Emily Bednarz, Pharm.D.	Marika Bergenstock, DO (non-voting participant)
Kristen Bender, Pharm.D.	
Jeremy Bennett, MD	Birju Bhatt, MD (non-voting participant)
Kim Castelnovo, RPh	Alyssa Cilia, RPh
Kimberly Clark, Pharm.D.	Alfred Denio, MD (non-voting participant)
Bhargavi Degapudi, MD	Michael Evans, RPh
Keri Jon Donaldson	Jason Howay, Pharm.D.
Michael Dubartell, MD	Nichole Hossler, MD
Kelly Faust, Pharm.D.	Lisa Mazonkey, RPh
Tricia Heitzman, Pharm.D.	Mark Mowery, Pharm.D.
Keith Hunsicker, Pharm.D.	Andrei Nemoianu, MD (non-voting participant)
Kelli Hunsicker, Pharm.D.	
Emily Jacobson, Pharm.D.	William Seavey, Pharm.D.
Dennis Janosczyk, Pharm.D.	Michael Shepherd, MD
Alexandra Kempf-Malys	
Kerry Ann Kilkenny, MD	
Philip Krebs, R.EEG T	
Briana LeBeau, Pharm.D.	
Ted Marines, Pharm.D.	
Tyreese McCrea, Pharm.D.	
Perry Meadows, MD	
Jamie Miller, RPh	
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	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
Luke Sullivan, DO	
Kevin Szczecina, RPh	
Amanda Taylor, MD	
Ariana Wendoloski, Pharm.D.	
Brandon Whiteash, Pharm.D.	
Margaret Whiteash, Pharm.D.	
Jeremy Garris, Pharm.D. (non-voting participant)	
Nicole Hawk (pharmacy student)	

Edward Liu (medical student) Adrienne Maximin (pharmacy student)	

Call to Order: Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday November 19, 2024.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the September 17, 2024 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Capaxive (Pneumococcal 21-valent conjugate vaccine)

Review: Capvaxive was approved in June of 2024 and is a Pneumococcal 21-valent conjugate vaccine indicated for the prevention of invasive disease cause by streptococcus pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older. It is also indicated for prevention of pneumonia caused by S. pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 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: Capaxive is a medical or pharmacy benefit and will be covered for members over the age of 19. It should not require prior authorization. The following quantity and age limits should apply:

GPI Level: GPI-12
Quantity Limits: 0.5 mL per lifetime
Authorization Duration: n/a
Reauthorization info: None needed
Require RPH Sign off: no
Age: 19 and older

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

Sofdra (Sofpironium)

Review: Sofdra (Sofpironium) is FDA approved for the treatment of primary axillary hyperhidrosis in patients 9 years or older. Sofdra (Sofpironium) is an anticholinergic product that works by inhibiting the acetylcholine receptors in peripheral tissue sweat glands thus decreasing the amount of sweat produced in the axilla. Current initial treatments for primary focal axillary hyperhidrosis as outlined by the International Hyperhidrosis Society (IHS) include topical antiperspirant therapy (Aluminum and Zirconium Salts) or Glycopyrronium cloths (Qbrexza). If results are not satisfactory with initial treatments, other treatments can include Botulinum Toxin A injections, microwave thermolysis or oral systemic therapies such as anticholinergics, propranolol, clonidine, and diltiazem. Currently, the IHS guidelines have not been updated to include, Sofdra (Sofpironium), but based on its mechanism of action and current recommended products by the IHS, Sofdra (Sofpironium) can be an alternative or optional product to Glycopyrronium cloths (Qbrexza).

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

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

Outcome: Sofdra is a pharmacy benefit and will be managed by GHP. Sofdra will not be added to the Medicaid formulary as the labeler is non-rebate able. If/when the labeler participates in DHS Medicaid rebates, then the medication will be non-formulary and will require the following prior authorization criteria:

- Medical record documentation of age greater than or equal to 9 years AND
- Medical record documentation of a diagnosis of primary axillary hyperhidrosis
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication

to at least 2 alternatives which must include prescription antiperspirant (aluminum chloride hexahydrate 6.25% [Xerac AC], 20% [Drysol]) and Qbrexza

GPI Level: GPI-12

Formulary alternatives: Drysol 20%, Xerac AC 6.25%, glycopyrrolate, oxybutynin, propranolol, clonidine

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

Tevimbra (tislelizumab-jsgr)

Review: Tevimbra (tislelizumab-jsgr) is a humanized immunoglobulin G4 (IgG4), monoclonal antibody, programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor. Tevimbra is designed to minimize binding to Fc-gamma receptors on macrophages, aiding the body's immune cells in detecting and fighting tumors.

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

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

Outcome: Tevimbra 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 Tevimbra is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of unresectable or metastatic esophageal squamous cell carcinoma (ESCC) **AND**
- Medical record documentation of disease progression after one or more prior lines of systemic chemotherapy that did not include a PD-(L) 1 inhibitor.

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.

GPI Level: GPI-12

Require RPh sign off: no

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

Beqvez (fidanacogene elaparvovec-dzkt)

Review: Beqvez is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with moderate to severe hemophilia B (congenital factor IX deficiency) who:

- Currently use factor IX prophylaxis therapy or
- Have current or historical life-threatening hemorrhage or
- Have repeated serious spontaneous bleeding episodes and
- Do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA approved test

Beqvez introduces transduced cells with a functional copy of the factor IX gene encoding a high-activity FIX variant. Beqvez is developed with recombinant DNA technology that consists of a recombinant viral capsid (AAVRh74var) derived from a naturally occurring AAV serotype (Rh74) vector containing the human coagulation factor IX (FIX) transgene modified to a high-specific factor IX activity variant known as FIX-R338L. Single intravenous infusion of Beqvez results in cell transduction and increase in circulating factor IX activity in patients with hemophilia B.

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

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

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

- Prescription written by or in consultation with a hematologist AND
- Medical record documentation that the member is a male based on assigned sex at birth and age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of moderate or severe hemophilia B with Factor IX level < 2 IU/dL or ≤ 2% of normal AND
- Medical record documentation of one of the following:
    - Member has current use of Factor IX prophylaxis therapy for at least 6 months with ≥ 50 exposure days^ of treatment with Factor IX protein
    - Member has current or historical life-threatening hemorrhage
    - Member has repeated, serious spontaneous bleeding episodes

AND

- Medical record documentation that member does not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test*
- Medical record documentation that the member has a recent negative inhibitor status to Factor IX prior to administration of Beqvez AND

- Medical record documentation that the member does not have an active hepatitis B or hepatitis C infection** assessed within the last 6 months AND
- Medical record documentation that the member does not have uncontrolled HIV*** assessed within the last 6 months AND
- Medical record documentation that the member does not have evidence of advanced cirrhosis**** assessed within the last 6 months AND
- Medical record documentation that the member has not received any previous gene therapy for hemophilia B AND
- Medical record documentation that Beqvez is being dosed according to the Food and Drug Administration approved labeling***** AND
- Medical record documentation of the frequency of bleeds within the previous 12 months

*The FDA approved test for AAVRh74var capsid neutralizing antibodies is nAbCyte Anti-AAVRh74var HB-FE Assay (Labcorp Drug Development)

**The BENEGENE-2 trial excluded patients currently on antiviral therapy for hepatitis B or C, hepatitis B surface antigen, hepatitis B virus deoxyribonucleic acid positivity, or hepatitis C ribonucleic positivity

***The BENEGENE-2 trial excluded patients with serological evidence of HIV1 or HIV2 infection with either CD4+ cell count <=200 mm3 and/or a viral load >20 copies/mL.
****The BENEGENE-2 trial excluded patients with history of chronic infection or other chronic disease, clinically significant major disease or condition unsuitable for participation and/or may interfere with the interpretation of study results, current unstable liver or biliary disease, or significant liver fibrosis and disease.

*****Beqvez is a single IV infusion. The recommended dosage is based on body weight in kg/m^2

Patient's BMI	Patient's Dose Weight
$\leq 30\ kg/m^2$	Dose Weight = Actual body weight
$>30\ kg/m^2$	Determine using the following calculation: Dose Weight (kg) = $30\ kg/m^2 \times [\text{Height (m)}]^2$

Beqvez dose (mL)= Beqvez dose weight (kg) / 20 = dose in mL

Authorization Duration: One (1) time approval per lifetime; Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

RPh Signoff: RPh Signoff will be required to ensure appropriate utilization given the complexity of the prior authorization criteria

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

MRsevia (Respiratory Syncytial Virus Vaccine)

Review: MResvia is indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older. MResvia induces an immune response against RSV pre-F protein that protects against LRTD caused by RSV. Each 0.5 ml dose of MResvia contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F protein). MResvia is the first mRNA vaccine for the prevention of RSV. The CDC and ACIP currently recommend only a single dose of RSV vaccine for all adults aged 75 years and older and for adults ages 60-74 with increased risk of severe RSV disease. Individuals at increased risk include persons with certain chronic medical conditions (chronic cardiovascular disease, chronic lung disease or respiratory disease, end-stage renal disease, diabetes, neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness, chronic liver disease, chronic hematologic conditions, and severe obesity), persons with moderate or severe immune compromise, and persons living in nursing homes. Adults who have previously received the RSV vaccine should not receive another dose.

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

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

Outcome: MRsevia will be medical or pharmacy benefit and should be added to the GHP Family formulary. MResvia will not require a prior authorization for members 60 years of age and older but will have the following limits:

- **Age Limit:** 60 years to 999 years
- **Quantity Limit:** 0.5 mL / 999 years

- For members under 60 years of age, the following prior authorization criteria will apply:
  - Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by administering to an individual with an age under the FDA-approved age
    - **Quantity Limit:** 0.5 mL / 999 years
- For members under 19 years of age, Mresvia will not be covered as these members are required to receive the vaccine from their MD through the VFC program

GPI Level: GPI-12
Require Rph Sign Off: No

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

Duvyzat (givinostat)

Review: Duvyzat is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older. Although the exact mechanism of Duvyzat in the treatment of DMD is unknown, Duvyzat contains a histone deacetylase inhibitor which activate repair mechanisms and may aid in prevention of muscle degeneration and reduction of inflammation. Other treatment options for improvement of muscle function in DMD include corticosteroids, such as prednisone, Emflaza, or Agamree. Other therapies focus on restoring dystrophin function and include gene-based therapies, such as Exondys 51, Vyondys 53, Viltepso, Amondys 45, and Elevidys.

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

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

Outcome: Duvyzat is a pharmacy benefit and will be managed by the GHP and should not be added to the formulary. The following criteria will apply:

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

GPI-Level: GPI-12

RPh Signoff: 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.

FAST FACTS

Rybrevant

Updated Indication: Rybrevant is now indicated in combination with carboplatin and pemetrexed for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor. Rybrevant is also indicated in combination with lazertinib for the first line-treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, as determined by and FDA-approved test. Previous indications include Rybrevant in combination with carboplatin + pemetrexed for first-line treatment of NSCLC with EGFR exons 20 insertion mutations, and as a single agent for previously treated NSCLC with EGFR exon 20 insertion mutations.

Recommendation: No changes are recommended to the formulary placement and authorization duration of Rybrevant.

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- Medical record documentation that Rybrevant is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of with locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND**
- **One of the following:**

- Medical record documentation of epidermal growth factor receptor (EGFR) exon 20 insertion mutations as determined by an FDA approved test* **AND** one of the following:
  - Medical record documentation of disease progression on or following prior treatment with a platinum-based chemotherapy AND that Rybrevant will be used as a single agent **OR**
  - Medical record documentation that Rybrevant is being used as first line treatment AND that Rybrevant will be used in combination with carboplatin and pemetrexed

OR

- Medical record documentation of epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations as determined by an FDA-approved test **AND** one of the following:
  - Medical record documentation that Rybrevant is being used as first-line treatment AND Rybrevant will be used in combination with Lazcluze (Lazertinib)

  OR

  - Medical record documentation of disease progression on or following treatment with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor AND Rybrevant will be used in combination with carboplatin and pemetrexed

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.

***NOTE:** The FDA approved test for Rybrevant to detect the presences of EGFR exon 20 insertion mutations is the Guardant360® CDx

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.

Elevidys

Updated Indication: Elevidys is an adeno-associated virus vector-based gene therapy that was previously indicated in patients at least 4 years of age but no older than 5 years of age, in patients who are ambulatory and have a confirmed mutation in the Duchenne muscular dystrophy (DMD) gene. Elevidys is now indicated for all individuals at least 4 years of age with a mutation in the DMD gene, for both ambulatory and non-ambulatory patients. The indication for non-ambulatory patients was approved under accelerated approval based on expression of Elevidys micro-dystrophin in skeletal muscle and continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Per IPD Analytics, the label expansion goes beyond the patient population for which data from randomized control trials is available. In a press release the FDA stated the expanded approval is based on the “totality of the evidence, including the potential risks associated with the product, the life-threatening and debilitating nature of the disease, and the urgent unmet medical need.”

Recommendation: There are no changes recommended to the formulary placement of Elevidys. It is recommended to update the following criteria as a result of the new indication:

MBP 307.0 Elevidys (delandistrogene moxeparvovec-rokl)

Elevidys (delandistrogene moxeparvovec-rokl) will be considered medically necessary for ALL lines of business when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of Duchenne Muscular Dystrophy confirmed by a genetic mutation in the Duchenne Muscular Dystrophy gene **AND**
- One of the following:
    - Medical record documentation that the member is a male based on assigned sex at birth

    OR

    - Medical record documentation that the member is a female based on assigned sex at birth AND
    - Medical record documentation that the member has a confirmed X-inactivation of the unmutated X-chromosome OR confirmed biallelic variants in the *DMD* gene (cytogenetic or molecular) alteration involving the Xp21 locus

    AND

- Medical record documentation of patient age of at least 4 ~~but no older than 5,~~ years of age **AND**
- Medical record documentation that the patient does NOT have a deletion in exon 8 and/or exon 9 in the Duchenne Muscular Dystrophy gene **AND**
- Medical record documentation that the patient has anti-adeno-associated virus serotype rh74 (anti-AAVrh74) antibody titers <1:400 **AND**
- Medical record documentation of provider attestation that the member is ambulatory (e.g., able to walk with or without assistance, not wheelchair dependent) OR non-ambulatory **AND**
- Medical record documentation that Elevidys is prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation that patient has been initiated on corticosteroids for Duchenne muscular dystrophy one day prior to Elevidys infusion and medical documentation that patient will continue the regimen after for 60 days* **AND**
- Medical record documentation that the patient is on the appropriate weight-based dose **AND**
- Medical record documentation that the patient has never received Elevidys treatment in their lifetime **AND**
- Medical record documentation that the member has not received any previous gene therapy for Duchenne muscular dystrophy **AND**
- Medical record documentation that the patient will not receive exon-skipping therapies for Duchenne Muscular Dystrophy [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)] concomitantly with Elevidys treatment. (Note: Any current authorizations for exon-skipping therapy will be terminated upon Elevidys approval.)

***** Deflazacort is <u>not</u> recommended for use as a peri-Elevidys infusion corticosteroid

AUTHORIZATION DURATION: One (1) time approval (auth duration: 2 months) per lifetime. Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

Note to Reviewer: Based on the Elevidys prescribing information, patients with deletions in the DMD gene in exons 1 to 17 and /or exons 59 to 71 may be at risk for severe immune-mediated myositis reaction.

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.

UPDATES

Strensiq

Discussion: Due to the complexity of the disease being treated by Strensiq, and the financial considerations of Strensiq, a re-review of policy criteria was completed. Areas of opportunity to clearly define diagnosis and dose were identified.

Recommendation: Update policy as noted below:

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

- 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 disease onset prior to the age of 18 years (note: If member is 18 years or older at the time of request, documentation must be provided that member began experiencing symptoms prior to 18 years old) **AND**
- ~~Medical record documentation of low total serum alkaline phosphatase activity as determined by the lab that conducted the test **AND**~~
- Medical record documentation of the following:
    - A pathological mutation in the alkaline phosphatase (ALPL) gene as determined by molecular genetic testing

    OR

    - Low total serum alkaline phosphatase activity as determined by the lab conducting the test **AND**
    - One of the following:
        - Radiographic evidence* supporting the diagnosis of hypophosphatasia **OR**
        - An elevated substrate of tissue non-specific alkaline phosphatase (TNSALP), including but not limited to pyridoxal-5´-phosphate (PLP), inorganic pyrophosphate (PPi), or phosphoethanolamine (PEA) in serum, tissues, or urine **AND**
- Medical record documentation that member will receive a weight and diagnosis appropriate dosing regimen **AND**
- Medical record documentation that the member will receive the appropriate vials, as stated in the prescribing information, for the dose that is being prescribed

Note:

- *Radiographic evidence

    - In clinical trials this included but was not limited to osteopenia, rachitic chest/deformed ribs, metaphyseal fraying/flaring/tongues, physeal widening, long bone bowing, thin gracile bones, sclerosis, bony spurs, fracture (non-union), or absence of some/all bones
- Perinatal/Infantile-Onset HPP
    - Recommended dosage regimen is 2 mg/kg administered subcutaneously three times per week, or 1 mg/kg administered six times per week. Injection site reactions may limit the tolerability of the six times per week regimen.
    - The dose may be increased to 3 mg/kg three times per week for insufficient efficacy.
- Juvenile-Onset HPP
    - Recommended dosage regimen is 2 mg/kg administered subcutaneously three times per week, or 1 mg/kg administered six times per week. Injection site reactions may limit the tolerability of the six times per week regimen.
- Preparation and Weight-Based Dosing Tables
    - Patient weights should be rounded to the nearest kilogram when determining dose. Use the following tables based on the frequency per week and the indication.

Authorization Duration: Initial approval will be for a period of 3 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.~~

- Medical record documentation that Strensiq is prescribed by an endocrinologist or metabolic specialist **AND**
- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation that member will receive a weight and diagnosis appropriate dosing regimen **AND**
- Medical record documentation that the member will receive the appropriate vials, as stated in the prescribing information, for the dose that is being prescribed

Table 1: Weight-Based Dosing for Administration of 2 mg/kg Three Times per Week

Body Weight (kg)*	Dose to Inject	Volume to Inject	Vial Configuration
3	6 mg	0.15 mL	18 mg/0.45 mL
4	8 mg	0.2 mL	18 mg/0.45 mL
5	10 mg	0.25 mL	18 mg/0.45 mL
6	12 mg	0.3 mL	18 mg/0.45 mL
7	14 mg	0.35 mL	18 mg/0.45 mL
8	16 mg	0.4 mL	18 mg/0.45 mL
9	18 mg	0.45 mL	18 mg/0.45 mL
10	20 mg	0.5 mL	28 mg/0.7 mL
15	30 mg	0.75 mL	40 mg/1 mL
20	40 mg	1 mL	40 mg/1 mL
25	50 mg	1.25 mL	Two 28 mg/0.7 mL vials
30	60 mg	1.5 mL	Two 40 mg/1 mL vials
35	70 mg	1.75 mL	Two 40 mg/1 mL vials
40	80 mg	0.8 mL	80 mg/0.8 mL
50	100 mg	1 mL	Two 80 mg/0.8 mL vials
60	120 mg	1.2 mL**	Two 80 mg/0.8 mL vials
70	140 mg	1.4 mL**	Two 80 mg/0.8 mL vials
80	160 mg	1.6 mL**	Two 80 mg/0.8 mL vials

* Do not use the 80 mg/0.8 mL vial of STRENSIQ in pediatric patients weighing less than 40 kg *[see Clinical Pharmacology (12.3)]*.

** When preparing a volume for injection greater than 1 mL, split the volume equally between two syringes, and administer two injections. When administering the two injections, use two separate injection sites.

Table 2: Weight-Based Dosing for Administration of 1 mg/kg Six Times per Week

Body Weight (kg)*	Dose to Inject	Volume to Inject	Vial Configuration
3	3 mg	0.08 mL	18 mg/0.45 mL
4	4 mg	0.1 mL	18 mg/0.45 mL
5	5 mg	0.13 mL	18 mg/0.45 mL
6	6 mg	0.15 mL	18 mg/0.45 mL
7	7 mg	0.18 mL	18 mg/0.45 mL
8	8 mg	0.2 mL	18 mg/0.45 mL
9	9 mg	0.23 mL	18 mg/0.45 mL
10	10 mg	0.25 mL	18 mg/0.45 mL
15	15 mg	0.38 mL	18 mg/0.45 mL
20	20 mg	0.5 mL	28 mg/0.7 mL
25	25 mg	0.63 mL	28 mg/0.7 mL
30	30 mg	0.75 mL	40 mg/1 mL
35	35 mg	0.88 mL	40 mg/1 mL
40	40 mg	1 mL	40 mg/1 mL
50	50 mg	0.5 mL	80 mg/0.8 mL
60	60 mg	0.6 mL	80 mg/0.8 mL
70	70 mg	0.7 mL	80 mg/0.8 mL
80	80 mg	0.8 mL	80 mg/0.8 mL
90	90 mg	0.9 mL	Two 80 mg/0.8 mL vials
100	100 mg	1 mL	Two 80 mg/0.8 mL vials

* Do not use the 80 mg/0.8 mL vial of STRENSIQ in pediatric patients weighing less than 40 kg *[see Clinical Pharmacology (12.3)]*.

Table 3: Weight-Based Dosing for Administration of 3 mg/kg Three Times per Week – Only for Perinatal/Infantile-Onset HPP*

Body Weight (kg)**	Dose to Inject	Volume to Inject	Vial Configuration
3	9 mg	0.23 mL	18 mg/0.45 mL
4	12 mg	0.3 mL	18 mg/0.45 mL
5	15 mg	0.38 mL	18 mg/0.45 mL
6	18 mg	0.45 mL	18 mg/0.45 mL
7	21 mg	0.53 mL	28 mg/0.7 mL
8	24 mg	0.6 mL	28 mg/0.7 mL
9	27 mg	0.68 mL	28 mg/0.7 mL
10	30 mg	0.75 mL	40 mg/1 mL
15	45 mg	1.13 mL***	Two 28 mg/0.7 mL vials
20	60 mg	1.5 mL***	Two 40 mg/1 mL vials
25	75 mg	1.88 mL***	Two 40 mg/1 mL vials

* A regimen of 3 mg/kg three times per week is recommended only for patients with perinatal/infantile-onset HPP *[see Dosage and Administration (2.2)]*
** Do not use the 80 mg/0.8 mL vial of STRENSIQ in pediatric patients weighing less than 40 kg *[see Clinical Pharmacology (12.3)]*.
*** When preparing a volume for injection greater than 1 mL, split the volume equally between two syringes, and administer two injections. When administering the two injections, use two separate injection sites.

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.

Medical Benefit Policy Updates

Discussion: It is recommended that the following updates be approved by the Committee.

Recommendation:

Tecelra Update

Recommendations: It is recommended that the "and" be changed to an "or" in the HLA-A criteria point, per package labeling.

MBP 327.0 Tecelra (afamitresgene autoleucel)

- Medical record documentation that Tecelra 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 unresectable or metastatic synovial sarcoma **AND**
- Medical record documentation of at least one (1) prior chemotherapy treatment **AND**
- Medical record documentation that member is HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, ~~and~~ or HLA-A*02:06P allele–positive* **AND**
- Medical record documentation that the member has not had a prior allogeneic hematopoietic stem cell transplant **AND**
- Medical record documentation of tumor expression of melanoma-associated antigen A4 (MAGE-A4)

*****Tecelra is contraindicated for patients who are heterozygous or homozygous for HLA-A*02:05P based on an alloreactivity screen which indicated in vitro alloreactivity against HLA-A*02:05

MBP 177.0 Prevymis IV (letermovir)

Kidney Transplant

- Medical record documentation that Prevymis is prescribed by or in consultation with a transplant or infectious disease specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that member is a recipient of a kidney transplant **AND**
- Medical record documentation that member is at high risk of CMV [defined as CMV seropositive donor and CMV seronegative recipient (D+/R-)] **AND**
- Medical record documentation that Prevymis is being used for cytomegalovirus (CMV) prophylaxis **AND**
- Medical record documentation that Prevymis is being initiated between Day 0 and Day 7 post-transplantation **AND**
- Medical record documentation that Prevymis is not being used in combination with pimozide, ergot alkaloids (ergotamine and dihydroergotamine), and/or pitavastatin and simvastatin (if co-administered with cyclosporine) **AND**
- Medical record documentation of intolerance to or contraindication to Prevymis tablets.

MBP 132.0 Avycaz (cetfazidime/avibactam)

- Prescribed by or in consultation with an infectious disease specialist **AND**
- Medical record documentation of one of the following:
    - A diagnosis of complicated intra-abdominal infection caused by caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Enterobacter cloacae, Klebsiella oxytoca, Citrobacter freundii* complex *and Pseudomonas aeruginosa* **OR**
    - A diagnosis 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* **OR**
    - A diagnosis of Hospital-acquired Bacterial Pneumonia ~~and~~ or 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*

AND

- Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity

MBP 325.0 Adzynma (ADAMTS13, recombinant-krhn)

- If being used for prophylactic treatment: Medical record documentation that member is currently receiving prophylactic therapy OR medical record documentation of at least one thrombotic thrombocytopenia purpura (TTP) event

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.

October ELECTRONIC VOTE
An electronic vote was held from October 11, 2024, to October 18, 2024. Responses were received from 27 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.

Lenmeldy (atidarsagene autotemcel)

Lenmeldy is an autologous stem cell-based gene therapy indicated for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD).

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

Pre-symptomatic Late Infantile Metachromatic Leukodystrophy (PSLI MDL)

- Prescription written by a hematologist, oncologist, and/or stem cell transplant specialist AND
- Medical record documentation of two out of three of the following:
    - Age at onset of symptoms in older sibling(s) ≤ 30 months
    - Presence of two null (0) mutant arylsulfatase A (ARSA) alleles
    - Peripheral neuropathy as determined by electroneurographic study

AND

- Medical record documentation that the patient does not have disease-related symptoms (motor or cognitive symptoms)* AND
- Medical record documentation of ARSA activity below the normal range in peripheral blood mononuclear cells or fibroblasts (normal activity is approximately 60 nmol/h/mg) AND
- Medical record documentation of the presence of sulfatides in a 24-hour urine collection AND
- Medical record documentation that the member has a negative serology test for Human Immunodeficiency Virus (HIV), Hepatitis B, and Hepatitis C AND
- Medical record documentation that the member has not had a prior hematopoietic stem cell transplant or hematopoietic stem-cell based gene therapy

*Note to Reviewer: In the clinical trial, pre-symptomatic was defined as patients without neurological impairment (disease-related symptoms) with or without signs of the disease revealed by instrumental evaluations (electroneurographic and brain MRI)

Pre-symptomatic Early Juvenile Metachromatic Leukodystrophy (PSEJ MLD)

- Prescription written by a hematologist, oncologist, and/or stem cell transplant specialist AND
- Medical record documentation of two out of three of the following:
    - Age at onset of symptoms (in the patient or in an older sibling) between 30 months and 6 years (has not celebrated 7th birthday)
    - Presence of one null (0) and one residual (R) mutant arylsulfatase A (ARSA) alleles
    - Peripheral neuropathy as determined by electroneurographic study

AND

- Medical record documentation that the patient does not have disease-related symptoms (motor or cognitive symptoms)* AND
- Medical record documentation of ARSA activity below the normal range in peripheral blood mononuclear cells or fibroblasts (normal activity is approximately 60 nmol/h/mg) AND
- Medical record documentation of the presence of sulfatides in a 24-hour urine collection AND
- Medical record documentation that the member has a negative serology test for Human Immunodeficiency Virus (HIV), Hepatitis B virus, and Hepatitis C virus AND
- Medical record documentation that the member has not had a prior hematopoietic stem cell transplant or hematopoietic stem-cell based gene therapy

*Note to Reviewer: In the clinical trial, pre-symptomatic was defined as patients without neurological impairment (disease-related symptoms) with or without signs of the disease revealed by instrumental evaluations (electroneurographic and brain MRI)

Early Symptomatic Early Juvenile Metachromatic Leukodystrophy (ESEJ MLD)

- Prescription written by a hematologist, oncologist, and/or stem cell transplant specialist AND
- Medical record documentation of <u>two</u> out of <u>three</u> of the following:
    - Age at onset of symptoms (in the patient or in an older sibling) between 30 months and 6 years (has not celebrated 7th birthday)
    - Presence of one null (0) and one residual (R) mutant arylsulfatase A (ARSA) alleles
    - Peripheral neuropathy as determined by electroneurographic study

AND

- Medical record documentation that the patient has been diagnosed with ESEJ MLD within 6 months of the first reported symptoms (i.e., cognitive symptoms: intelligence quotient ≥ 70 and motor symptoms: the ability to walk independently for ≥ 10 steps) AND
- Medical record documentation of ARSA activity below the normal range in peripheral blood mononuclear cells or fibroblasts (normal activity is approximately 60 nmol/h/mg) AND
- Medical record documentation of the presence of sulfatides in a 24-hour urine collection AND
- Medical record documentation that the member has a negative serology test for Human Immunodeficiency Virus (HIV), Hepatitis B virus, and Hepatitis C virus AND
- Medical record documentation that the member has not had a prior hematopoietic stem cell transplant or hematopoietic stem-cell based gene therapy

Note to Reviewer: In the clinical trial, early symptomatic was initially defined as a patient identified within 6 months from the first reported symptoms. Subsequently, ESEJ patients were defined as meeting both criteria: intelligence quotient ≥ 70 and the ability to walk independently for ≥ 10 steps).

Authorization Duration: 2 months, a one (1) time approval per lifetime; Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

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.

Arexvy

Updated Indication: Arexvy is now approved for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV. Its original indication remains - active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older.

Recommendation: No changes recommended to the formulary placement of Arexvy at this time. It is recommended that Arexvy will continue to not require prior authorization for those 60 and older. It is recommended that the following prior authorization criteria will apply:

- Medical record documentation that the member is 50 to 59 years of age AND
- Medical record documentation of a diagnosis of chronic pulmonary disease, chronic cardiovascular disease, diabetes, chronic kidney disease, or chronic liver disease AND
- Medical record documentation that the member is at an increased risk of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)

Quantity limit: 1 each per lifetime

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

Benlysta Autoinjector

Updated Indication: Benlysta Autoinjectors are now indicated for the treatment of Systemic Lupus Erythematosus (SLE) in pediatric patients age 5 to less than 18 years of age

Recommendation: No changes to formulary placement are recommended. It is recommended to update the prior authorization criteria.

- 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 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

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

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

Cresemba

Updated Indication: Cresemba VIAL is now approved for pediatric patients 1 year of age and older.

Recommendation: It is recommended that the following update be made to the Cresemba IV policy:
• Medical record documentation that the patient is 1 year of age or older AND
o Medical record documentation that Cresemba is being used for the treatment of invasive aspergillosis OR for the treatment of invasive mucormycosis OR
•Medical record documentation that the patient is 18 years of age or older AND
o Medical record documentation that Cresemba is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider AND
o Medical record documentation of use for prophylaxis of invasive Aspergillus or Candida infections in patients at high risk of developing these infections due to being severely immunocompromised AND
o Medical record documentation that member requires treatment with an anti-cancer medication that interacts with posaconazole

AUTHORIZATION DURATION: Authorization duration should be for a length of 3 months.
Reauthorization will be based on the following criteria:
• Medical record documentation of a culture and sensitivity showing the isolates are susceptible to Cresemba AND
• Medical record documentation that the appropriate dose is being prescribed (1 vial/day)

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

Infinzi

Updated Indication: Imfinzi is now indicated in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by Imfinzi as a single agent as adjuvant treated after surgery, for the treatment of adult patients with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements..

Recommendation: Make the following update to the Imfinzi policy:
Neoadjuvant/Adjuvant Non-Small Cell Lung Cancer

- Medical record documentation that Imfinzi is prescribed by a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) AND

Medical record documentation that Imfinzi is being used in the neoadjuvant setting in combination with platinum containing chemotherapy then continued as a single agent in the adjuvant setting following surgery AND

- Medical record documentation of no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

AUTHORIZATION DURATION:
Neoadjuvant/Adjuvant NSCLC: One approval for **18 months** or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Imfinzi for the neoadjuvant/adjuvant treatment of NSCLC should not exceed the FDA-approved treatment duration of 4 cycles of neoadjuvant treatment prior to surgery and 12 cycles of adjuvant treatment following surgery. 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.

Stage III NSCLC: One approval for **12 months** or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Imfinzi for the treatment of non-small cell lung cancer should not exceed the FDA-approved treatment duration of 1 year (12 months). For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

All Other Indications: Initial approval will be for **6 months**. Subsequent approvals will be for an additional **12 months** and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

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

Jemperli

Updated Indication: Jemperli (dostarlimab) is now approved in combination with carboplatin and paclitaxel, followed by Jemperli as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial cancer.

Endometrial Cancer

- Medical record documentation that Jemperli 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 <u>one</u> of the following:
    - Medical record documentation of a diagnosis of recurrent or advanced endometrial cancer **AND**
    - Medical record documentation of mismatch repair deficient (dMMR) as determined by an FDA approved test **AND**
    - Medical record documentation of disease progression on or following prior treatment with a platinum-containing regimen **AND**
    - Medical record documentation that member is not a candidate for curative surgery or radiation

OR

    - Medical record documentation of primary advanced or recurrent endometrial cancer **AND**
    - Medical record documentation that Jemperli will be used in combination with carboplatin and paclitaxel for 6 doses, followed by Jemperli as a single agent **AND**
    - Medical record documentation of mismatch repair deficient (dMMR) as determined by an FDA approved test OR microsatellite instability-high (MSI-H)

Solid Tumors

- Medical record documentation that Jemperli is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of recurrent or advanced solid tumors **AND**
- Medical record documentation of mismatch repair deficient (dMMR) as determined by an FDA approved test **AND**
- Medical record documentation of disease progression on or following at least one prior treatment **AND**
- Medical record documentation of no satisfactory alternative treatment options

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.

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

Keytruda

Updated Indication: Keytruda is now indicated in combination with pemetrexed and platinum chemotherapy as first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma (MPM). Keytruda also received full approval with changes to the indication for hepatocellular carcinoma (HCC) which was previously approved under accelerated approval. Previously Keytruda was approved for HCC who have been previously treated with sorafenib. The new indication is for treatment of patients with HCC secondary to hepatitis B who have received prior systemic therapy other than a PD-1/PD-L1-containing regimen.

Recommendation: Make the following update to the Keytruda policy:
Malignant Pleural Mesothelioma (MPM)

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is ≥ 18 years of age AND
- Medical record documentation of unresectable advanced or metastatic malignant pleural mesothelioma (MPM) AND
- Medical record documentation that Keytruda is being used as first-line treatment in combination with pemetrexed and platinum chemotherapy.

11. Hepatocellular Carcinoma (HCC)

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is ≥ 18 years of age AND
- Medical record documentation of a diagnosis of hepatocellular carcinoma (HCC) secondary to Hepatitis B AND
- Medical record documentation ~~of a therapeutic failure on or intolerance to sorafenib (Nexavar)~~ of at least one (1) prior systemic therapy other than a PD-1 and PD-L1 containing regimen

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

Lutathera

Updated Indication: Lutathera is a radiolabeled somatostatin analog now indicated for the treatment of adult and pediatric patients 12 years of age and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors. Previously Lutathera was indicated in adult patients only.

Recommendation: Make the following update to the Lutathera policy:

- Prescribed by a hematologist/oncologist AND
- Patient is ~~18 years of age or older~~ 12 years and older **AND**
- Medical record documentation of a diagnosis of gastroenteropancreatic neuroendocrine tumor (GEP-NET) (including foregut, midgut, and hindgut tumors) **AND**
- Medical record documentation of presence of somatostatin receptors on all lesions (somatostatin receptor positive disease) **AND**
- Medical record documentation that long-acting somatostatin analogs have been (or will be) discontinued at least 4 weeks prior to initiation of treatment with Lutathera
-

Note: Per the package labeling, short-acting somatostatin analogs may be used within 4 weeks of treatment with Lutathera but must be discontinued 24 hours prior to Lutathera treatment. Long-acting somatostatin analogs may be given between 4 and 24 hours after each Lutathera dose provided that it is again discontinued 4-weeks prior to retreatment with Lutathera. After completing Lutathera treatment, long-acting somatostatin analogs may be restarted for 18 months.

AUTHORIZATION DURATION: Approval will be for a one-time authorization of **4 visits (7 months)** of therapy. 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 labeling.

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

Vyvgart Hytrulo

Updated Indication: Vyvgart Hytrulo is a combination of efgartigimod alfa, a neonatal Fc receptor blocker, and hyaluronidase, an endoglycosidase, indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive. Vyvgart Hytrulo is now also indicated for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP).

Recommendation: Make the following update to the Vyvgart Hytrulo and Vyvgart policy:
Generalized Myasthenia Gravis (gMG)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that ~~Vyvgart~~ the medication 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) antibody 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 of 5 or more **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)

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the medication is prescribed by or in consultation with a neurologist **AND**
- Documented evidence of focal or symmetric neurologic deficits that are slowly progressive or relapsing over 2 months or longer **AND**
- Physician provided documentation of EMG abnormalities consistent with the diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy with the presence of at least ONE of the following:
    - Motor distal latency prolongation ≥ 50% above upper limit of normal (ULN) in two nerves (excluding median neuropathy at the wrist from carpal tunnel syndrome) **OR**
    - Reduction of motor conduction velocity ≥ 30% below lower limit of normal (LLN) in two nerves **OR**
    - Prolongation of F-wave latency ≥ 20% above ULN in two nerves (> 50% if amplitude of distal negative peak compound muscle action potential (CMAP) <80% of LLN values) **OR**
    - Absence of F-waves in two nerves if these nerves have distal negative peak CMAP amplitudes ≥ 20% of LLN + ≥ 1 other demyelinating parameter in ≥ 1 other nerve **OR**
    - Partial motor conduction block: ≥ 30% amplitude reduction of the proximal negative peak CMAP relative to distal, if distal negative peak CMAP ≥ 20% of LLN, in two nerves, or in one nerve + ≥1 other demyelinating parameter in ≥ 1 other nerve **OR**
    - Abnormal temporal dispersion (>30% duration increase between the proximal and distal negative peak CMAP) in ≥ 2 nerves **OR**
    - Distal CMAP duration (interval between onset of the first negative peak and return to baseline of the last negative peak) increase in ≥ 1 nerve (median ≥ 6.6 ms, ulnar ≥ 6.7 ms, peroneal ≥ 7.6 ms, tibial ≥ 8.8 ms) + ≥ 1 other demyelinating parameter in ≥ 1 other nerve

  AND

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one (1) intravenous or subcutaneous immune globulin (IVIG/SCIG) therapy, one (1) corticosteroid therapy, OR plasma exchange (PLEX) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one (1) non-steroidal immunosuppressive therapy (can include but is not limited to azathioprine, cyclophosphamide, cyclosporine, methotrexate, mycophenolate) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab

AUTHORIZATION DURATION:

Generalized Myasthenia Gravis (gMG)

Initial approval will be for 6 months. Subsequent approvals will be for 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 2-point reduction from baseline in Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score**

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

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

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

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

GHP Family Update

Recommendation: During the review of the GHP Family Furosix policy DHS requested we update the renewal criteria as noted below to align with its updated indication. It is recommended the Committee approve the update.

- Medical record documentation that Furoscix is prescribed by or in consultation with a cardiologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of ~~New York Heart Association (NYHA) Class II or Class III~~ chronic heart failure AND
- Medical record documentation of congestion due to fluid overload AND
- Medical record documentation that member is stable on background loop diuretic therapy AND
- Medical record documentation of provider attestation that member will use Furoscix for short-term use only and will be transitioned to oral diuretics as soon as practical.

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

DUR/Adherence Update

The GHP Family DURs were presented to the Committee for review.

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

Meeting adjourned at 3:40 pm

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held in January 2025.

Meetings will be held virtually via phone/Microsoft Teams