P&T Committee Meeting Minutes
Medicaid
September 9, 2025

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair Amir Antonious, Pharm.D. Kristen Bender, Pharm.D. Jeremy Bennett, MD Angela Bolesta, Pharm.D. Kim Castelnovo, RPh Kimberly Clark, Pharm.D. Kelly Faust, Pharm.D. Tricia Heitzman, Pharm.D. Keith Hunsicker, Pharm.D. Kelli Hunsicker, Pharm.D. Emily Jacobson, Pharm.D. Dennis Janosczyk, Pharm.D. Alexandra Kempf-Malys, MSW, BSc Kerry Ann Kilkenny, MD Philip Krebs, R.EEG T Briana LeBeau, Pharm.D. Ted Marines, Pharm.D. Lisa Mazonkey, RPh Tyreese McCrea, Pharm.D. Perry Meadows, MD 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. Aubrielle Smith-Masri, Pharm.D. Michael Spishock, RPh 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. Jeremy Garris, Pharm.D. (non-voting participant) Tiffany O'Hagan, Pharm.D., MBA (non-voting participant) Abigail Chua	Leslie Astleford, Pharm.D Emily Bednarz, Pharm.D. Alyssa Cilia, RPh Bhargavi Degapudi, MD Keri Donaldson, MD, MSCE Michael Dubartell, MD Michael Evans, RPh Nichole Hossler, MD Jason Howay, Pharm.D. Jonas Pearson, RPh Angela Scarantino Luke Sullivan, DO

Lacey Blauser – Pharmacy resident (non-voting)	

Call to Order: Dr. Bret Yarczower called the meeting to order at 1:03 p.m., Tuesday Septermber 9, 2025.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the July 8, 2025 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Encelto (revakinagene taroretcel-lwey)

Review: Encelto is an allogeneic encapsulated cell-based gene therapy indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel). Encelto is the first FDA-approved treatment for MacTel type 2. Encelto is a surgically implanted, allogeneic encapsulated cell-based gene therapy that continually delivers recombinant human ciliary neurotrophic factor (rhCNTF) to the retina to slow disease progression. Exogenous CNTF is thought to initially target Muller glia to trigger a cascade of signaling events that may promote photoreceptor survival; however, the mechanism of action for Encelto is not completely understood.

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

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

Outcome: Encelto will be a medical benefit. The following prior authorization criteria will apply.

- Medical record documentation that Encelto is prescribed by an ophthalmologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of idiopathic macular telangiectasia type 2 (MacTel) type 2 as evident by the following:
    - Evidence of fluorescein leakage and one of the following AND
        - Hyperpigmentation outside a 500-micron radius from the fovea center,
        - Retinal opacification,
        - Crystalline deposits,
        - Right-angle vessels,
        - Or inner/outer lamellar cavities AND
- Medical record documentation that the patient has not previously received an Encelto implant in the requested eye AND
- Medical record documentation of photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm^2 AND
- Medical record documentation of best corrected visual acuity (BCVA) of 54-letter score or better (20/80 or better) AND
- Medical record documentation that the member does NOT have neovascular MacTel type 2

Authorization Duration: One (1) time approval per eye 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 Required: Yes

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

Hemiclor (chlorthalidone)

Review: On March 17, 2025, the United States Food and Drug Administration (FDA) approved Hemiclor (chlorthalidone), an oral thiazide-like diuretic, for the treatment of hypertension in adults. This is a line extension of chlorthalidone, offering a new low dose 12.5mg strength.

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

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

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

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to 3 thiazide and/or thiazide-like diuretic formulary alternatives, one of which must be generic chlorthalidone

Formulary Alternatives: chlorthalidone, Diuril, hydrochlorothiazide, indapamide, metolazone

Authorization Duration: Open-ended
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.

Enflonsia (clesrovimab-cfor)

Review: Enflonsia is a respiratory syncytial virus (RSV) F protein-directed fusion inhibitor indicated for the prevention of RSV lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season. Enflonsia is a monoclonal antibody with anti-RSV activity.

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

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

Outcome: Enflonsia is not listed as a medication on the Vaccine for Children (VFC) program, however GHP anticipates it to be added. If added to the VFC Program, Enflonsia will not be eligible for reimbursement, and will be provided by the VFC Program. If Enflonsia is not added to the VFC Program, it is recommended to have an age and quantity limit. The following limits will apply if Enflonsia is not added to the VFC Program:
Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee

Medical Benefit:

- Age limit: younger than 8 months (<8 months old)
- Quantity limit: 1 injection per lifetime

Other Recommendations

Beyfortus Update

Discussion: A review of the U.S. Center for Disease Control and Prevention's (CDC's) article titled RSV Immunization Guidance for Infants and Young Children was completed. It was found that the CDC firmly recommends administration of RSV antibody during October through March. The article states: "Administration of infant RSV antibody is recommended during October through March in most of the U.S. The optimal timing for infant RSV antibody administration is shortly before the RSV season begins (e.g., October–November), or within a baby's first week of life if born October through March (ideally during the birth hospitalization.)"

In addition, the American Academy of Pediatrics (AAP) also released a publication on 8/19/25 with a statement that RSV immunization may be administered from October through the end of March. The AAP went on to define "high risk" with new criteria compared to previous publications.

Recommendations: It is recommended to update the authorization duration of MBP 297.0 Beyfortus to more closely align with CDC and AAP's recommendations to allow administration of Beyfortus starting in the month of October. It is also recommended to update the high risk criteria to more closely align with AAP's definition.

MBP 297.0 Beyfortus (nirsevimab-alip)

For the commercial, exchange, CHIP, and Medicare lines of business, Beyfortus (nirsevimab-alip) will not require prior authorization for patients less than 8 months of age. Beyfortus (nirsevimab-alip) will be considered medically necessary for patients 8 months of age or greater but less than 24 months of age when ALL of the following criteria are met:

- For Children 8 through 19 months of age, medical record documentation of:
  - Chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) at any time during the 6-month period before the start of the second RSV season **OR**
  - Severe immunocompromise **OR**
  - Cystic fibrosis, with either:
    - Manifestations of severe lung disease, denied as previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable **OR**
    - Weight-for-length that is less than the 10th percentile **OR**
  - American Indian or Alaska Native children

AND

- Medical record documentation that member has not received Synagis during the current RSV season

- ~~Infants ≤ 12 months of age, and born before < 29 weeks gestation at the onset of RSV season **OR**~~
- ~~Infants < 12 months of age, who have a diagnosis of a congenital abnormality of the airway or a diagnosis of a neuromuscular condition that compromises handling of respiratory secretions **OR**~~
- ~~Infants and children < 24 months of age who will be profoundly immunocompromised during the RSV~~

season (e.g., severe combined immunodeficiency or severe acquired immunodeficiency syndrome) **OR**

- Infants < 12 months of age, born at < 32 weeks gestation, with chronic lung disease of prematurity, defined as > 21% oxygen for at least 28 days after birth **OR**
- Infants and children < 24 months of age with chronic lung disease (CLD) who have required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic steroid use, bronchodilator use or diuretic use) **OR**
- Infants < 12 months of age with hemodynamically significant acyanotic heart disease who:
  - are receiving medication to control congestive heart failure; or
  - have moderate to severe pulmonary hypertension

OR

- Infants < 12 months of age with cyanotic heart disease who have been evaluated and recommended for treatment by a cardiologist **OR**
- Infants or children who have been receiving prophylaxis and undergo cardiopulmonary bypass during RSV season should receive an additional dose of Beyfortus post-operatively as soon as possible after procedure (even if sooner than a month from previous dose) when medically stable (serum concentrations decrease by a mean of 58% following by-pass) **OR**
- Children less than two years of age who undergo cardiac transplantation during the RSV season **OR**
- Infants in the first year of life with CF and clinical evidence of CLD and/or nutritional compromise **OR**
- Infants in the second year of life with CF and who have severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or whose weight for length is less than the 10th percentile.

AUTHORIZATION DURATION: Prophylaxis of 1 dose should be initiated on or after October 1 ~~on November 1~~ (prior to RSV season). Listed indications would need to be met on October 1 ~~November 1~~ of the calendar year that prophylaxis is initiated. Members born after October 1 ~~November 1~~ during RSV season who meet criteria will receive one dose of prophylaxis.

In the event of an atypical RSV season (i.e. unpredicted, early, or late, high rates of RSV circulation), prophylaxis of 1 dose should be initiated on dates deemed appropriate by Geisinger Health Plan in conjunction with guidance from the American Academy of Pediatrics (AAP) and other applicable clinical resources. Members born after the start of the atypical RSV season who meet criteria will receive 1 dose on the date deemed appropriate by Geisinger Health Plan in conjunction with guidance from the American Academy of Pediatrics (AAP) and other applicable clinical resources.

Dosing beyond 1 dose will be reviewed on a case-by case basis based on CDC surveillance reports, state/local health department recommendations, and other current medical literature.

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

Vykat XR (diazoxide choline)

Review: Vykat XR (diazoxide choline extended-release) is a new FDA-approved therapy indicated for the treatment of hyperphagia in adults and pediatric patients aged 4 years and older with Prader-Willi Syndrome (PWS). Approved in March 2025, Vykat XR represents a significant therapeutic advancement as the first and only medication approved for hyperphagia associated with PWS—a rare, complex neurodevelopmental disorder characterized by neurobehavioral, endocrine, and metabolic abnormalities. This review is being conducted as a new

drug evaluation of diazoxide, which has historically been used in its immediate-release formulation for the treatment of hyperinsulinemic hypoglycemia. The focus of this evaluation is to assess the clinical value, safety profile, and appropriate place in therapy for the newly approved extended-release formulation, which represents both a new dosage form and a new therapeutic indication.

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

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

Outcome: Vykat XR should be added to the Brand tier for the Geisinger Family formulary. The following prior authorization criteria should apply.

- Medical record documentation of age greater than or equal to 4 years **AND**
- Medical record documentation of a diagnosis of hyperphagia in Prader Willi Syndrome **AND**
- Medical record documentation of diagnosis of Prader Willi Syndrome confirmed by genetic testing (such as DNA methylation analysis to detect deletion of the chromosome 15q11-q13 region, uniparental disomy in chromosome 15, or imprinting, translocation, or inversion mutations involving chromosome 15) **AND**
- Medical record documentation that VYKAT XR is being prescribed by or in collaboration with a neurologist, psychiatrist, endocrinologist, or physician with expertise in the treatment of PWS **AND**
- Medical record documentation that the patient and/or caregiver have been counseled on appropriate non-pharmacologic strategies, including dietary restriction, exercise, and behavioral modification **AND**
- Medical record documentation of HbA1c or glucose monitoring at baseline **AND**
- Medical record documentation that patient's dose will be titrated appropriately based on patient's weight **OR** that maintenance dose is appropriate based on patient's weight.

Vykat XR Dosing Chart

Weight (kg)	Starting Dosage	Titration Dosage	Titration Dosage	Target Maintenace Dosage
	Weeks 1 and 2	Weeks 3 and 4	Weeks 5 and 6	
20 to <30 kg	25 mg	50 mg	75 mg	100 mg
30 to <40 kg	75 mg	150 mg	150 mg	150 mg
40 to <65 kg	75 mg	150 mg	225 mg	225 mg
65 to <100 kg	150 mg	225 mg	300 mg	375 mg
100 to <135 kg	150 mg	300 mg	375 mg	450 mg
≥135 kg	150 mg	300 mg	450 mg	525 mg

Medispan Authorization Level: GPI-12
Quantity Limits: 28-day supply per fill.
Authorization Duration: 12 months
Reauthorization info:

- Medical record documentation of improvement of patient's hyperphagia symptoms (for example, but not limited to, decrease in food-seeking behaviors; decrease/maintenance in patient weight; etc.) **AND**
- Medical record documentation of appropriate dosing based on patient's weight **AND**
- Medical record documentation of HbA1c and/or glucose monitoring within the last 6 months.

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

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

Lynzofic (linvoseltamab-gcpt)

Review: Lynozyfic is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. This was based on response rate and durability of response.

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

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

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

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Lynozyfic is prescribed by a hematologist or oncologist AND
- Medical record documentation of relapsed or refractory multiple myeloma AND
- Medical record documentation of treatment with at least four (4) prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

Medispan Authorization Level: GPI-12

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 the member experiences unacceptable toxicity or worsening of disease

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

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FAST FACTS

Enhertu

Updated Indication: Enhertu is now approved for adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining) breast cancer, as determined by an FDA-approved test, that has progressed on one of more endocrine therapies in the metastatic setting. This new indication is added to the label that also includes other forms of breast cancer, non-small cell lung cancer, gastric or gastroesophageal junction cancer, and solid tumors.

Discussion: The committee unanimously voted to accept the recommendations.

Outcome: No changes recommended to the formulary placement or authorization duration of Enhertu at this time. However, it is recommended to update policy Medical Benefit Policy 208.0 to include the following highlighted changes.

Medical Benefit Policy 208 Enhertu (Breast Cancer Section Only):

Breast Cancer

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

OR

- Prescription written by a hematologist or oncologist AND
- Medical record documentation of patient age greater than or equal to 18 years AND
- Medical record documentation of unresectable or metastatic hormone-receptor (HR)-positive breast cancer AND
- Medical record documentation of one of the following:
    - Documentation that the tumor is HER2-low (IHC 1+ or IHC 2+/ISH-) as determined by an FDA-approved test OR
    - Documentation that the tumor is HER2-ultralow (IHC 0 with membrane staining) as determined by an FDA-approved test

  AND

- Medical record documentation that the patient has progressed on one or more endocrine therapies in the metastatic setting

OR

- Prescription written by a hematologist or oncologist AND
- Medical record documentation of patient age greater than or equal to 18 years AND
- Medical record documentation of unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer, as detected by a Food and Drug Administration (FDA)-approved test AND
- Medical record documentation that Enhertu will be used as a single agent AND
- Medical record documentation of one of the following:
    - Documentation of a prior chemotherapy in the metastatic setting OR
    - Documentation of disease recurrence during or within 6 months of completing adjuvant chemotherapy

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

UPDATES

09.2025 DUR Update

Update: The Sept 2025 P&T DUR/Adherence Update was 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.

August ELECTRONIC VOTE
An electronic vote was held from August 14, 2025, to August 19, 2025. Responses were received from 32 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.

Amvuttra

Updated Indication: Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visits.
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Recommendation: It is recommended to change the prior authorization criteria for MBP 268.0.

- Prescription written by or in consultation with a neurologist, cardiologist board-certified medical geneticist, or specialist with experience in the treatment of hereditary transthyretin-mediated amyloidosis (hATTR) **AND**
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of one of the following
    - For hereditary transthyretin-mediated amyloidosis
        - Medical record documentation of diagnosis of hereditary transthyretin-mediated amyloidosis as confirmed by genetic testing to confirm a pathogenic mutation in TTR AND one of the following:
            - Biopsy of tissue/organ to confirm amyloid presence OR
            - A clinical manifestation typical of hATTR (Neuropathy and/or CHF) without a better alternative explanation **AND**
        - Medical record documentation of Amvuttra being used to treat polyneuropathy **AND**
        - Medical record documentation of familial amyloid polyneuropathy (FAP) stage 1-2 and/or polyneuropathy disability score (PND) indicating the patient is not wheelchair bound or bedridden

          OR

        - Medical record documentation Amvuttra is being used for cardiomyopathy to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visits

    OR

    - For wild-type transthyretin-mediated amyloidosis
        - Medical record documentation of diagnosis of wild-type transthyretin-mediated amyloidosis as confirmed by genetic testing
        - Medical record documentation Amvuttra is being used for cardiomyopathy to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visits 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 **AND**
- Medical record documentation that Amvuttra will not be used in combination with other RNA interference treatment

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

Furoscix

Updated Indication Furoscix is indicated for the treatment of edema in adult patients with chronic heart failure or chronic kidney disease (CKD), including the nephrotic syndrome.

Recommendation: Make the following change to GHP Family policy 1575.0F to reflect the additional indication for Furoscix. Formulary status, auth duration would remain the same.

- 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 chronic heart failure AND
- Medical record documentation of congestion due to fluid overload OR
- Medical record documentation of chronic kidney disease (CKD), including the nephrotic syndrome 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.

Inzirqo

Discussion: Inzirqo oral suspension [10 mg/ml] is a thiazide diuretic indicated for the following:
(1) The treatment of hypertension in adult and pediatric patients alone or in combination with other antihypertensive agents.

(2) The treatment of edema associated with congestive heart failure, hepatic cirrhosis and renal disease including the nephrotic syndrome in adult and pediatric patients.

Recommendation: Inzirqo is a pharmacy benefit and recommendation is to not add this medication to the GHP Family formulary.

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 for the treatment of adult patients with resectable locally advanced HNSCC whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by an FDA-approved test, as a single agent as neoadjuvant treatment, continued as adjuvant treatment in combination with radiotherapy (RT) with or without cisplatin and then as a single agent. There was also an update to the population for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma used combination with fluoropyrimidine- and platinum-containing chemotherapy. This is now restricted to patients whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test to reflect the population with a favorable risk-benefit assessment.

Recommendation: No changes are needed for the formulary placement of Keytruda. The following changes are recommended for the authorization duration and prior authorization criteria in Medical Benefit Policy 119.0.

1. **Melanoma**
   - Prescription written by a hematologist/oncologist **AND**
   - Medical record documentation of one of the following:

   <u>Unresectable or metastatic melanoma:</u>

     - Medical record documentation that patient is ≥ 18 years of age **AND**
     - A diagnosis of unresectable or metastatic melanoma **AND**
     - Keytruda is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma.

OR

<u>Adjuvant treatment of completely resected melanoma</u>

- Medical record documentation that patient is ≥ 12 years of age **AND**
- A diagnosis of Stage IIB, IIC, or III melanoma, which has been completely resected **AND**
- Keytruda is being used in the adjuvant setting (following complete resection) **AND**
- Keytruda is being used as a single agent.

2. **Neoadjuvant or Adjuvant Treatment of Non-Small Cell Lung Cancer (NSCLC)**
   - Prescription written by a hematologist/oncologist **AND**
   - Medical record documentation that patient is ≥ 18 years of age **AND**
   - Medical record documentation of one of the following:
     - Medical record documentation of Stage IB (T2a ≥ 4 cm), II, or IIIa non-small cell lung cancer (NSCLC) **AND**
     - Keytruda is being used in the adjuvant setting following resection and platinum-based chemotherapy **AND**

- Keytruda is being used as a single agent

OR

- Medical record documentation of resectable (Tumors ≥ 4 cm or Node Positive) non-small cell lung cancer (NSCLC) **AND**
- Keytruda is being used in the neoadjuvant setting in combination with platinum containing chemotherapy then continued as a single agent in the adjuvant setting following resection

3. **Metastatic Non-Small Cell Lung Cancer (NSCLC)**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of metastatic NSCLC meeting one of the following situations:
  - Medical record documentation of stage III NSCLC, metastatic NSCLC, OR that the member is not a candidate for surgical resection or definitive chemoradiation **AND**
  - Medical record documentation that Keytruda is being used as first-line treatment **AND**
  - Medical record documentation that Keytruda is being given as monotherapy **AND**
  - Medical record documentation that tumors express PD-L1 (TPS) ≥1% as determined by an FDA-approved test AND
  - Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

OR

  - Medical record documentation that Keytruda is being given as monotherapy **AND**
  - Medical record documentation that tumors express PD-L1 (TPS) ≥1% as determined by an FDA-approved test **AND**
  - Medical record documentation of disease progression on or after platinum-containing chemotherapy **AND**
  - For patients with EGFR or ALK genomic tumor aberrations: medical record documentation of disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.

OR

  - Medical record documentation of metastatic nonsquamous NSCLC **AND**
  - Medical record documentation that Keytruda will be given in combination with pemetrexed AND either carboplatin or cisplatin **AND**
  - Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations

OR

  - Medical record documentation of metastatic squamous NSCLC **AND**
  - Medical record documentation that Keytruda will be given in combination with carboplatin AND either paclitaxel or nab-paclitaxel AND
  - Medical record documentation that Keytruda, carboplatin, and paclitaxel (or nab-paclitaxel) are being used as first-line treatment **AND**
  - ~~Medical record documentation that tumors do not have EGFR or ALK genomic tumor aberrations~~

4. **Head and Neck Squamous Cell Carcinoma**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of one of the following:

- A diagnosis of Head and Neck Squamous Cell Carcinoma that is recurrent or metastatic **AND**
- Disease progression on or after platinum-containing chemotherapy **AND**
- Keytruda is being used as a single agent.

OR

- A diagnosis of metastatic or unresectable, recurrent Head and Neck Squamous Cell Carcinoma **AND**
- Keytruda is being used as a first-line treatment **AND**
- Keytruda is being used as a single agent **AND**
- Tumors express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-approved test

OR

- A diagnosis of metastatic or unresectable, recurrent Head and Neck Squamous Cell Carcinoma **AND**
- Keytruda is being used as a first-line treatment **AND**
- Keytruda is being administered in combination with platinum chemotherapy and fluorouracil (FU)

OR

- A diagnosis of resectable locally advanced Head and Neck Squamous Cell Carcinoma **AND**
- Tumors express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-approved test
- Keytruda is being used as a single agent for neoadjuvant treatment, followed by adjuvant treatment in combination with radiotherapy (RT) with or without cisplatin and then as a single agent

5. Classical Hodgkin Lymphoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of Classical Hodgkin Lymphoma **AND**
- One of the following:
  a. Medical record documentation of a diagnosis of refractory Classical Hodgkin Lymphoma **OR**
  b. Medical record documentation of age greater than or equal to 18 years AND relapse following one (1) or more prior lines of therapy **OR**
  c. Medical record documentation of age less than 18 years AND relapse following two (2) or more prior lines of therapy

6. Microsatellite Instability-High Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors OR colorectal cancer

AND

- For solid tumors:
  - Medical record documentation of progression following prior treatment(s) **AND**
  - Medical record documentation of no satisfactory alternative treatment options

7. **Urothelial Carcinoma**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of locally advanced or metastatic urothelial carcinoma **AND**
- Medical record documentation of one of the following:
    - Disease progression during or following platinum-containing chemotherapy

OR

    - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

OR

    - Patient is not eligible for any platinum-containing chemotherapy

OR

    - Patient has high-risk, non-muscle invasive bladder cancer (NMIBC)** **AND**
    - Patient's disease is unresponsive to an adequate trial of Bacillus Calmette-Guerin (BCG) therapy** **AND**
    - Patient is ineligible for or has elected not to undergo cystectomy

OR

    - Keytruda is being used in combination with Padcev

**Note:

- BCG-unresponsive high-risk NMIBC is defined as persistent disease despite adequate BCG therapy, disease recurrence after an initial tumor-free state following adequate BCG therapy, or T1 disease following a single induction course of BCG.
- Adequate BCG therapy was defined as administration of at least five of six doses of an initial induction course plus either of: at least two of three doses of maintenance therapy or at least two of six doses of a second induction course.

8. **Gastric Cancer**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that Keytruda will be used as first-line treatment **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of a diagnosis of locally advanced unresectable or metastatic HER-2 positive gastric or gastroesophageal junction adenocarcinoma **AND**
    - Medical record documentation that tumors express PD-L1 (CPS≥1) as approved by an FDA approved test **AND**
    - Medical record documentation that Keytruda will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy

OR

    - Medical record documentation of locally advanced unresectable or metastatic HER-2 negative gastric or gastroesophageal junction (GEJ) adenocarcinoma **AND**

- Medical record documentation that tumors express PD-L1 (CPS≥1) as approved by an FDA approved test **AND**
- Medical record documentation that Keytruda will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

9. **Cervical Cancer**

- Prescription written by a hematologist/oncologist **AND**
- One of the following:
  - Medical record documentation of recurrent or metastatic cervical cancer **AND**
  - Medical record documentation that tumors express PD-L1 (CPS≥1) **AND**
  - Medical record documentation of disease progression after receiving at least one prior line of therapy

OR

  - Medical record documentation of persistent, recurrent or metastatic cervical cancer **AND**
  - Medical record documentation that tumors express PD-L1 (CPS≥1) **AND**
  - Medical record documentation that Keytruda will be used in combination with chemotherapy (paclitaxel, cisplatin or carboplatin), with or without bevacizumab

OR

  - Medical record documentation of FIGO 2014 Stage III-IVA cervical cancer **AND**
  - Medical record documentation that Keytruda will be used in combination with chemoradiotherapy (cisplatin and external beam radiation therapy [EBRT] followed by brachytherapy [BT])

*Note: FIGO 2014 Stage III-IVA includes patients with tumor involvement of the lower vagina with or without extension onto pelvic sidewall or hydronephrosis/non-functioning kidney or has spread to adjacent pelvic organs.

10. **Primary Mediastinal Large B-cell Lymphoma (PMBCL)**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of refractory primary mediastinal large B-cell lymphoma (PMBCL) **OR**
- Medical record documentation of relapse following two (2) prior lines of therapy

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 secondary to Hepatitis B **AND**
- Medical record documentation of at least one (1) prior systemic therapy other than a PD-1 and PD-L1 containing regimen

12. **Merkel Cell Carcinoma (MCC)**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of Merkel Cell Carcinoma **AND**
- Medical record documentation of metastatic and/or recurrent disease

13. Renal Cell Carcinoma (RCC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of one of the following:

Advanced Renal Cell Carcinoma

- Medical record documentation of a diagnosis of advanced renal cell carcinoma **AND**
- Medical record documentation that Keytruda is being used in combination with axitinib (Inlyta) OR lenvatinib (Lenvima) **AND**
- Medical record documentation that Keytruda in combination with axitinib (Inlyta) OR lenvatinib (Lenvima) is being used as first-line treatment for advanced disease

Note: In clinical trials, advanced disease included newly diagnosed or recurrent Stage IV renal cell carcinoma.

OR

Adjuvant treatment of Renal Cell Carcinoma

- A diagnosis of renal cell carcinoma **AND**
- Documentation of intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions **AND**
- Keytruda is being used in the adjuvant setting **AND**
- Keytruda is being used as a single agent

Note: In clinical trials, intermediate-high risk category included: pT2 with Grade 4 or sarcomatoid features; pT3, any Grade without nodal involvement (N0) or distant metastases (M0); and high risk included: pT4, any Grade N0 and M0; any pT, any Grade with nodal involvement and M0. The M1 no evidence of disease (NED) category includes patients with metastatic disease who had undergone complete resection of primary and metastatic lesions.

14. Esophageal Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- One of the following:
  - Medical record documentation of a diagnosis of locally advanced or metastatic squamous cell carcinoma of the esophagus or gastroesophageal junction (GEJ) **AND**
  - Medical record documentation that tumors express PD-L1 (CPS ≥10) as determined by an FDA-approved test **AND**
  - Medical record documentation of disease progression after one or more prior lines of systemic therapy for advanced disease.

- **OR**
    - Medical record documentation of a diagnosis of locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) carcinoma not amenable to surgical resection or definitive chemoradiation **AND**
    - Medical record documentation of use in combination with platinum (oxaliplatin or cisplatin) and fluoropyrimidine-based (fluorouracil or capecitabine) chemotherapy

15. Endometrial Carcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of a diagnosis of primary advanced or recurrent endometrial carcinoma **AND**
    - Medical record documentation that Keytruda will be used in combination with carboplatin and paclitaxel followed by Keytruda as a single agent

OR

    - Medical record documentation of a diagnosis of advanced endometrial carcinoma **AND**
    - Medical record documentation of disease progression following at least one prior systemic therapy **AND**
    - Medical record documentation that patient is not a candidate for curative surgery or radiation **AND**
    - Medical record documentation of one of the following:
        - Medical record documentation that tumors are **not** microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) **AND**
        - Medical record documentation that Keytruda will be given in combination with lenvatinib (Lenvima)

OR

        - Medical record documentation that Keytruda will be used as a single agent for treatment of tumors that are microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

16. Tumor Mutational Burden – High (TMB-H) Solid Tumors

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of unresectable or metastatic solid tumors **AND**
- Medical record documentation that tumors are tumor mutational burden-high (TMB-H), defined as greater than or equal to 10 mutations per megabase (≥10 mut/Mb), determined by an FDA-approved test **AND**
- Medical record documentation of progression following prior treatment(s) **AND**
- Medical record documentation of no satisfactory alternative treatment options

17. Cutaneous Squamous Cell Carcinoma (cSCC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of locally advanced, recurrent, OR metastatic cutaneous squamous cell carcinoma **AND**

- Medical record documentation that the patient's disease is not curable by surgery **AND**
- Medical record documentation that the patient's disease is not curable by radiation.

18. Triple Negative Breast Cancer

- Prescription written by a hematologist/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 locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) **AND** both of the following:
        - Medical record documentation that tumors express PD-L1 [Combined Positive Score (CPS) greater than or equal to 10] as determined by an FDA approved test **AND**
        - Medical record documentation that Keytruda will be given in combination with chemotherapy (paclitaxel, paclitaxel protein-bound, or gemcitabine and carboplatin).

    OR

    - Medical record documentation of high-risk, early-stage triple-negative breast cancer (TNBC) **AND**
    - Medical record documentation that Keytruda will be given in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery

LIMITATIONS: The treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.

18. Biliary Tract Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of locally advanced unresectable or metastatic biliary tract cancer **AND**
- Medical record documentation that Keytruda will be used in combination with gemcitabine and cisplatin

19. 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.

AUTHORIZATION DURATION:

For adjuvant treatment of metastatic melanoma (completely resected melanoma), neoadjuvant/adjuvant treatment of early-stage triple negative breast cancer, neoadjuvant/adjuvant treatment of non-small cell lung cancer, and adjuvant treatment of renal cell carcinoma:

Initial approval will be for 6 months. One subsequent approval will be for an additional 6 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

- Authorization of Keytruda for the adjuvant treatment of metastatic melanoma, of non-small cell lung cancer, and of renal cell carcinoma should not exceed the FDA-approved treatment duration of 1 year (12 months).
- Authorization of Keytruda for the treatment of early-stage triple negative breast cancer should not exceed the approved treatment duration of 24 weeks for neoadjuvant therapy and 27 weeks for adjuvant therapy.
- Authorization for the treatment of neoadjuvant/adjuvant treatment of non-small cell lung cancer should not exceed the approved treatment duration of 12 weeks of neoadjuvant treatment and 39 weeks of adjuvant therapy.

For requests exceeding the above limits, medical record documentation of the following is required:

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

For neoadjuvant/adjuvant treatment of head and neck squamous cell carcinoma:

Initial approval will be for 6 months. Additional approval will be for up to an additional 12 months or less if determined medically appropriate by the reviewing provider and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

- Authorization for the treatment of neoadjuvant/adjuvant treatment of head and neck squamous cell carcinoma should not exceed the approved treatment duration of 6 weeks of neoadjuvant treatment and 12 months of adjuvant treatment.

For requests exceeding the above limits, medical record documentation of the following is required:

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

For all other indications:

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

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

Monjuvi

Updated Indication: Monjuvi had an update to it indications section and is now also FDA approved in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma

(FL). A limitation of use was also added, which states Monjuvi is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma outside of controlled clinical trials.

Recommendation: There are no changes recommended to the formulary placement or authorization duration of Monjuvi. It is recommended to change the prior authorization criteria for MBP 221.0.

1. **Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)**
    - Medical record documentation of age greater than or equal to 18 years **AND**
    - Medical record documentation that Monjuvi is prescribed by a hematologist or oncologist **AND**
    - Medical record documentation of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma **AND**
    - Medical record documentation that the member is not eligible for autologous stem cell transplant (ASCT) **AND**
    - Medical record documentation that Monjuvi will be used in combination with Revlimid (lenalidomide)

2. **Relapsed or Refractory Follicular Lymphoma (FL)**
    - Medical record documentation of age greater than or equal to 18 years **AND**
    - Medical record documentation that Monjuvi is prescribed by a hematologist or oncologist **AND**
    - Medical record documentation of relapsed or refractory follicular lymphoma (FL) **AND**
    - Medical record documentation that Monjuvi will be used in combination with lenalidomide (Revlimid) and rituximab

AUTHORIZATION DURATION: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

Limitation of use: Monjuvi is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma outside of controlled clinical trials

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

Pluvicto

Updated Indication: The FDA expanded the indication for Pluvicto to include the treatment of adult patients with prostate-specific membrane antigen-positive (PSMA+) metastatic castrate-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibitor (ARPI) therapy and are considered appropriate to delay taxane-based chemotherapy.

Recommendation: The following updated prior authorization criteria will apply.

- Medical record documentation that Pluvicto 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 prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) AND
- Medical record documentation that a gonadotropic-releasing hormone (GnRH) analog will be used concurrently OR member has had bilateral orchiectomy AND

- Medical record documentation of prior treatment with an androgen-receptor pathway inhibitor AND
- One of the following:
    - Medical record documentation of prior treatment with taxane-based chemotherapy OR
    - Medical record documentation that the patient is considered appropriate to delay taxane-based chemotherapy

AUTHORIZATION DURATION: Approval will be for a one-time authorization of 6 visits (15 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.

Rivfloza

Updated Indication: Rivfloza (nedosiran) is now approved to lower urinary oxalate levels in children 2 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., eGFR ≥ 30 mL/min/1.73 m^2

Recommendation: Update the age in the Rivfloza policy to 2 years

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

Sivextro

Updated Indication: Sivextro is an oxazolidinone antibacterial now indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following gram-positive microorganisms: Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), and Enterococcus faecalis, in adult and pediatric patients (at least 26 weeks gestational age and weighing at least 1 kg).

Recommendation: There are no changes recommended to the formulary placement or authorization duration of Sivextro. It is recommended to make the following changes the prior authorization criteria.

MBP 122.0 Sivextro (tedizolid phosphate) IV

Sivextro (tedizolid phosphate) IV will be considered medically necessary for the commercial, exchange, CHIP, and Medicaid lines of business when all of the following criteria are met:

- ~~Medical record documentation that patient is ≥ 12 years of age **AND**~~
- Medical record documentation of a diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by: Staphylococcus aureus, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus, or Enterococcus faecalis which has been diagnosed and documented with Infectious Disease consultation **AND**

- Medical record documentation of a prescribed dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of a 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 **OR**
- If Sivextro was initiated during an inpatient stay, medical record documentation of a 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

AUTHORIZATION LIMIT: If approved, Sivextro IV will be authorized for a maximum of 6 daily doses.

(Facets RX Count: 200 (J3090 units) per dose)

Sivextro (tedizolid phosphate) IV will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

- ~~Medical record documentation that patient is ≥ 12 years of age **AND**~~
- Medical record documentation of a diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by: Staphylococcus aureus, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus, or Enterococcus faecalis which has been diagnosed and documented with Infectious Disease consultation **AND**
- Medical record documentation of a prescribed dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION LIMIT: If approved, Sivextro IV will be authorized for a maximum of 6 daily doses.

(Facets RX Count: 200 (J3090 units) per dose)

Pharmacy Medicaid Policy 1275.0F Sivextro Oral

- ~~Documentation of that patient is ≥ 12 years of age **AND**~~
- Medical record documentation of a diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by: *Staphylococcus aureus* (including methicillin-susceptible and methicillin-resistant strains), *Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus*, or *Enterococcus faecalis* which has been diagnosed and documented with Infectious Disease consultation **AND**
- Medical record documentation of a prescribed dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of a 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 **OR**
- If initiated during an inpatient say: Medical record documentation of a 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

Authorization Duration: one-time fill

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

Soliris

Updated Indication: Soliris was granted FDA approval for treatment of pediatric patients aged six (6) years and older with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor positive on March 10, 2025. Soliris became the first and only FDA approved therapy for pediatrics with gMG. Soliris is indicated for use as chronic immunosuppressive therapy in refractory anti-acetylcholine receptor antibody positive (AChR+) myasthenia gravis in select patients (eg, dependence on maintenance IVIG or plasma exchange or lack of response to at least one other immunosuppressant).

Recommendation: Soliris (eculizumab) will be considered medically necessary for the and Medicaid line of business when all of the following criteria are met per indication:

- 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 age ≥ 6 years **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IV **AND***
- For members 18 years of age or older: Medical record documentation Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of 6 or more at baseline **AND**
- For members under the age of 18 years: Medical record documentation of baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL), Quantitative Myasthenia Gravis (QMG) or Myasthenia Gravis Composite (MGC) score **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND**
- Medical record documentation of therapeutic failure on intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies **OR** has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) **AND**
- Medical record documentation of failure on intolerance to, or contraindication to intravenous immunoglobulin (IVIG)

AUTHORIZATION DURATION: 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**
- For members 18 years of age or older: 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.

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

Zynz

Updated Indication: The FDA approved Zynyz in combination with carboplatin and paclitaxel for the first-line treatment of adults with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC). The FDA also approved Zynyz as monotherapy for adults with locally recurrent or metastatic SCAC whose disease has progressed on or who are intolerant to platinum-based chemotherapy. There is no biomarker requirement for use in either setting. Zynyz was initially approved for only metastatic or recurrent locally advanced Merkel cell carcinoma.

Recommendation: Make the following update to the Zynz policy:

1. **Merkel Cell Carcinoma**

- Medical record documentation that Zynyz is written by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years of age **AND**
- Medical record documentation of a diagnosis of metastatic or recurrent locally advanced Merkel cell carcinoma

2. **Squamous Cell Carcinoma of the Anal Canal**

- Medical record documentation that Zynyz is written by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years of age **AND**
- Medical record documentation of a diagnosis of locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC) **AND**
- One of the following:
    - Medical record documentation of inoperable disease **AND**
    - Medical record documentation of use in the first-line setting **AND**
    - Medical record documentation of use in combination with carboplatin and paclitaxel

OR

- Medical record documentation that Zynyz will be used as a single agent **AND**
- Medical record documentation of disease progression on or intolerance to platinum-based chemotherapy

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 the patient experiences toxicity or worsening of disease.

QUANTITY LIMIT: 20mL per 28 days

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

Day Supply Updates

Discussion: Due to HB 1993, several specialty medications were removed from the specialty drug list since they no longer met the specialty definition. Once the specialty edit was removed from these medications, they would no longer have the specialty day supply limitation (i.e. 34 day supply). The day supply edits were added to the following medications to ensure the dispensing pharmacy submits an appropriate day supply.

Recommendation: The day supply edits were added to the following medications to ensure the dispensing pharmacy submits an appropriate day supply.

Medicaid:

Drug	**Day Supply**
Anagrelide	Max: 34 day supply
Droxidopa	Max: 34 day supply
Irinotecan	Max: 42 day supply
Penicillamine	Max: 34 day supply
Penicillamine	Max: 34 day supply
Penicillamine	Max: 34 day supply
Palonosetron	Max: 34 day supply
Palonosetron	Max: 34 day supply
Paragard	Max: 3650 day supply
Paragard	Max: 3650 day supply
Miudella	Max: 1095 day supply
Xatmep	Max: 34 day supply
acitretin	Max: 34 day supply
palforzia	Max: 34 day supply
Xdemvy	Max: 42 day supply
Ycanth	Max: 21 day supply
Zoladex	Max: 28 day supply

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

Medical Benefit Drug Updates

Discussion: Recently, GHP engaged with outside consulting. During this process the GHP medical benefit prior authorization (PAL) list was compared to that of three competitors. Discrepancies between GHP's PAL and at least 2 other competitors' lists were flagged by the consultant for GHP review. Based on GHP's review and leadership direction, the following changes are recommended.

Recommendations:

Drug	**Policy**	**Current PA Status**	**Proposed PA Status**	**Other Actions Required**

Xiaflex (Collagenase clostridium histolyticum)	MBP 80.0	PA=Yes	PA=No	Retire MBP 80.0, Remove Xiaflex from MBP 300.0
Zulresso (Brexanolone)	MBP 201.0	PA=Yes	PA=No	Retire MBP 201.0 (Note: this drug was removed from market)
Triptodur (triptorelin ER)	MBP 204.0	PA=Yes	PA=No	Retire MBP 204.0
Iluvien (fluocinolone acetonide)	MBP 129.0	PA=Yes	PA=No	Retire MBP 129.0
Clolar (clofarabine)	MBP 38.0	PA=Yes	PA=No	Retire MBP 38.0
Zaltrap (ziv-aflibercept)	MBP 101.0	PA=Yes	PA=No	Retire MBP 101.0
Somatuline Depot (lanreotide)	N/A	PA=No	PA=Yes	Create policy. See proposed criteria below.
Bendamustine (multiple generics and brands)	N/A	PA=No	PA=Yes (except generic Treanda)	Create policy. See proposed criteria below

Proposed criteria for lanreotide:

Acromegaly

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of acromegaly **AND**
- One of the following:
    - Medical record documentation that the patient has an insufficient response to surgery and/or radiotherapy **OR**
    - Medical record documentation that the patient is not a candidate for surgery and/or radiotherapy

Carcinoid Syndrome

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of histologically-confirmed neuroendocrine tumor **AND**
- Medical record documentation of carcinoid syndrome (flushing and/or diarrhea)

Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumor (GEP-NET) **AND**
- All of the following:
    - Medical record documentation that the tumor is unresectable **AND**
    - Medical record documentation that the tumor is non-functioning **AND**
    - Medical record documentation that the tumor is without hormone-related symptoms

AND

- Medical record documentation that the medication is being used to improve progression-free survival

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

Proposed criteria for bendamustine (see final page for cost and utilization information):

For all lines of business: Generic Treanda will not require prior authorization. Brand Treanda, Belrapzo (and its generics), Bendeka, and Vivimusta, will be considered medically necessary when ALL of the following criteria are met. Part B Step therapy will apply.

For a request for brand Treanda:

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

For Belrapzo (or its generics) and Bendeka requests:

- Medical record documentation of a therapeutic failure of, intolerance to, or contraindication to generic Treanda

For Vivimusta requests (Commercial/Exchange/CHIP/Medicaid):

- Medical record documentation of a therapeutic failure of, intolerance to, or contraindication to generic Treanda **AND**
- Medical record documentation of a therapeutic failure of, intolerance to, or contraindication to both of the following: Belrapzo (or its generics)* AND Bendeka*

For Vivimusta requests (Medicare ONLY):

- Medical record documentation of a therapeutic failure of, intolerance to, or contraindication to generic Treanda **AND**
- Medical record documentation of a therapeutic failure of, intolerance to, or contraindication to one of the following: Belrapzo (or its generics)* OR Bendeka*

*prior authorization required (note: generic Treanda is preferred and does not require prior authorization)

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.

Utilization Data from 7/1/2023 - 7/1/2025

Bendeka Utilization

Line of Business	Unique Members	Total Claims	Total Paid by Health Plan
Medicare	38	277	$535,576
Commercial/Exchange	10	68	$413,366
Medicaid	6	54	$132,710
Total	**54**	**399**	**$1,081,652**

*Note: Only Bendeka claims have been produced over the past 2 years, no other bendamustine products

Cost Effectiveness

Drug	ASP per unit* ($)	ASP per complete regimen* ($)	AWP per unit* ($)	AWP per complete regimen* ($)	Formulary Status Commercial/ Exchange	Formulary Status Medicare
Vivimusta (Azurity, J9056)	$28.06 per 1mg	**$67,344 - $107,750**	$3,928 per 100mg/4mL vial	**$94,272- $150,835**	Tier 3	NF
Bendeka (Teva, J9034)	$13.12 per 1mg	**$31,488 - $50,381**	$2,969 per 100mg/4mL vial	**$71,256- $114,010**	Tier 3	NF
Belrapzo (Eagle, J9036)	$11.99 per 1mg	**$28,776 - $46,042**	$3,120 per 100mg/4mL	**$74,880- $119,808**	Tier 3	NF
Bendamustine (Belrapzo generic, Apotex NDC 60505622800, J9036)	$11.99 per 1mg	$28,776 - $46,042	$3,909 per 100mg/4mL	$93,816 - $150,106	Tier 3	Tier 5
Bendamustine (Belrapzo generic, Baxter NDC 10019007901, J9036)	$11.99 per 1mg	$28,776 - $46,042	$2,808 per 100mg/4mL	$67,392 - $107,827	Tier 3	Tier 5
Treanda (Teva, J9033)	$1.85 per 1mg	**$4,440 - $7,104**	$3,566 per 100mg	**$85,584- $136,934**	NF	NF
Bendamustine (Treanda generic, Bluepoint, NDC 68001057241, J9033)	$1.85 per 1mg	$4,440 - $7,104	$1,920 per 100mg	$46,080 - $73,728	Tier 3	Tier 5
Bendamustine (Treanda generic, Accord, NDC	$1.85 per 1mg	$4,440 - $7,104	$1,920 per 100mg	$46,080 - $73,728	Tier 3	Tier 5

16729025105, J9033)						
Bendamustine (Treanda generic, Eugia, NDC 55150039201, J9033)	$1.85 per 1mg	$4,440 - $7,104	$660 per 100mg	$15,840 - $25,344	Tier 3	Tier 5
Bendamustine (Treanda generic, Meitheal, NDC 71288010320, J9033)	$1.85 per 1mg	$4,440 - $7,104	$420 per 100mg	$10,080 - $16,128	Tier 3	Tier 5
*based on 2.0 m^2 adult patient Note: Generic Belrapzo shows on Navitus as "solution", the other generic are under "Solution reconstituted" Dose: CLL: 100mg/m2 days 1 and 2, for 6 cycles, NHL: 120mg/m2 days 1 & 2, for 8 cycles						

Aliqopa & Arzerra Update
Recommendations: It is recommended to retire the medical benefit policy for Aliqopa MBP 161.0 Aliqopa (copanlisib) & Arzerra MBP 73.0 Arzerra (ofatumumab). Aliqopa was withdrawn from the market March 2024 and Arzerra was moved to a patient access program via manufacturer only on August 2020.

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

Meeting adjourned at 3:47 PM

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held November 11, 2025.

Meetings will be held virtually via phone/Microsoft Teams