"What's New" Medical Pharmaceutical Policy November 2026 Updates

Listed below are the recent changes made to policies and policy reviews within the Geisinger Health Plan Medical Benefit Pharmaceutical Policy Portfolio. New and revised policies will become effective December 15, 2026 (unless otherwise specified). The Plan uses medical policies as guidelines for coverage decisions made within members written benefit documents. Coverage may vary by line of business and providers and members are encouraged to verify benefit questions regarding eligibility before applying the terms of the policy.

The following policy updates and reviews apply to all GHP members (Commercial, Marketplace, TPA, Medicare and Medicaid):

MBP 374.0 Avlayah (tividenofusp alfa-eknm) – New Policy

- Medical record documentation that Avlayah is prescribed by or in consultation with a physician who specializes in the treatment of metabolic disease and/or lysosomal storage disorders **AND**
- Medical record documentation of diagnosis of mucopolysaccharidosis type II (MPS II), also known as Hunter syndrome, confirmed by one of the following:
    - Deficiency in IDS enzyme activity **OR**
    - Molecular genetic testing for deletion or mutations in the IDS gene **AND**
- Medical record documentation of member is a pediatric patient **AND**
- Medical record documentation that the patient weighs at least 5 kg **AND**
- Prescriber attestation of neurologic manifestations associated with MPS II, or the patient is presymptomatic and at risk for neurologic manifestations **AND**
- Prescriber attestation the patient does not have advanced neurologic impairment **AND**
- Medical record documentation that Avlayah will not be used in combination with another enzyme replace therapy for mucopolysaccharidosis type II (MPS II) **AND**
- Medical record documentation that the dosing is consistent with FDA approved labeling and patient weight*

*Avlayah is dosed at 3 mg/kg once weekly for 4 weeks, then 7.5 mg/kg once weekly weeks 5 to 8, then 15 mg/kg once weekly for week 9 and beyond as long as tolerated

AUTHORIZATION DURATION: If determined to be medically necessary, Avlayah should be approved for an initial authorization duration of 6 months. Subsequent authorizations of Avlayah should be approved for an authorization duration of 12 months when the following criteria are met:

- Prescriber attestation of continued disease improvement, stabilization, or lack of disease progression.

MBP 290.0 Epkinly (epcoritamab-bysp) – Updated Policy

DLBCL and High-grade B-cell Lymphoma

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Epkinly is written by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma **AND**
- Medical record documentation of prior therapy with at least two lines of systemic therapy

Follicular Lymphoma

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Epkinly is written by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of relapsed or refractory follicular lymphoma (FL) **AND**
- Medical record documentation of prior therapy with at least two lines of systemic therapy **OR**
- Medical record documentation that epcoritamab-bysp (Epkinly) is being used in combination with lenalidomide and rituximab

AUTHORIZATION DURATION:
For the treatment of FL in combination with lenalidomide and rituximab: 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 Epkinly for the treatment of FL in combination with lenalidomide and rituximab should not exceed the FDA-approved treatment duration of 1 year (12 months).

For all others: 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.

MBP 216.0 Trodelvy (sacituzumab govitecan-hziy) – Updated Policy

Unresectable Locally Advanced or Metastatic Triple-Negative Breast Cancer

- Medical record documentation that Trodelvy is written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of unresectable locally advanced or metastatic triple-negative breast cancer* **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of trial of at least two previous lines of systemic therapy, of which at least one was for metastatic disease **OR**
    - Medical record documentation that Trodelvy is administered first line treatment **AND**
        - Medical record documentation that Trodelvy will be administered in combination with pembrolizumab (Keytruda) or pembrolizumab-berahyaluronidase alfa-pmph (Keytruda Qlex) AND documentation of PD-L1 (CPS ≥ 10) tumor expression as determined by an FDA-authorized test

        OR
        - Medical record documentation that Trodelvy is administered as monotherapy AND documentation that member is not a candidate for PD-1 or PD-L1 therapy

***Note:** Triple negative breast cancer lacks expression of estrogen receptor (ER-negative), progesterone receptor (PR-negative) and human epidermal growth factor receptor 2 (HER2-negative).

MBP 113.0 Gazyva (obinutuzumab) – Updated Policy

2. Follicular Lymphoma

AUTHORIZATION DURATION for follicular lymphoma: Initial approval will be 6 months for this indication. The following criteria should apply to reauthorization requests for Gazyva:

- Medical record documentation that the patient achieved a complete response, partial response, or has stable disease after 6 cycles of Gazyva + bendamustine therapy OR after 6 cycles of Gazyva + chemotherapy (6 to 8 cycles if in combination with CVP) **AND**
- Documentation that Gazyva will be used as monotherapy.

Subsequent authorization duration should be 24 months as data does not extend past this point.

MBP 215 Recarbrio (imipenem/cilastatin/relebactam) – Updated Policy

- Prescription is written by or in consultation with Infectious Disease **AND**
- ~~Medical record documentation that the member is greater than or equal to 18 years of age **AND**~~
- Medical record documentation of one of the following:
    - Diagnosis of Complicated Urinary Tract Infection (including Pyelonephritis) (cUTI) caused by the following susceptible gram-negative microorganisms: *Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella pneumoniae, or Pseudomonas aeruginosa* **OR**
    - Diagnosis of Complicated Intra-abdominal Infection (cIAI) caused by the following susceptible gram-negative microorganisms*: Bacteroides caccae, Bacteroides fragilis, Bacteroides ovatus, Bacteroides stercoris, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Fusobacterium*

nucleatum, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Parabacteroides distasonis, or Pseudomonas aeruginosa **OR**

- Diagnosis of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, caused by the following susceptible gram-negative microorganisms: *Acinetobacter calcoaceticus-baumannii complex, Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Pseudomonas aeruginosa, or Serratia marcescens*

AND

- Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to preferred alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to three (3) preferred alternative antibiotics shown to be susceptible on the culture and sensitivity **AND**
- Medical record documentation of a therapeutic failure on imipenem/cilastatin OR medical rationale of why imipenem/cilastatin cannot be used.

MBP 273.0 Tecvayli (teclistamab-cqyv) – Updated Policy

- Medical record documentation that Tecvayli is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years old **AND**
- Medical record documentation of a diagnosis of relapsed or refractory multiple myeloma **AND**
- Medical record documentation of one of the following:
  - Medical record documentation ~~of~~ that Tecvayli is being used as monotherapy AND treatment with at least four (4) prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody **OR**
  - Medical record documentation that Tecvayli is being used in combination with daratumumab hyaluronidase-fihj (Darzalex Faspro) AND documentation of treatment with at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent

MBP 248.0 Nexviazyme (avalglucosidase alfa-ngpt) – Updated Policy

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

AND

- Medical record documentation of a consultation with a metabolic specialist and/or biochemical geneticist **AND**
- Medical record documentation of age greater than or equal to 1 year **AND**
- Medical record documentation of baseline pulmonary function testing and muscle strength evaluation (e.g. percent-predicted forced vital capacity (% FVC), 6-minute walk test (6MWT), GSGC (gait stairs, gower, chair)) **AND**
- ~~Medical record documentation of baseline percent-predicted forced vital capacity (% FVC) and 6-minute walk test (6MWT), if age appropriate **AND**~~
- Medical record documentation that the member is receiving an appropriate dose* based on patient's weight **AND**
- Medical record documentation that Nexviazyme will not be used in combination with other enzyme replacement therapy (e.g. Lumizyme) for Pompe disease.

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

- Medical record documentation of baseline pulmonary function testing and muscle strength evaluation (e.g. percent-predicted forced vital capacity (% FVC), 6-minute walk test (6MWT), GSGC (gait stairs, gower, chair)) **AND**
- ~~Medical record documentation of improvement or stabilization in percent-predicted forced vital capacity (% FVC) and/or 6-minute walk test (6MWT) **AND**~~

- Medical record documentation that the member is receiving an appropriate dose* based on patient's weight **AND**
- Medical record documentation that Nexviazyme will not be used in combination with other enzyme replacement therapy (e.g. Lumizyme) for Pompe disease.

MBP 338.0 Bizengri (zenocutuzumab-zbco) – Updated Policy

- Medical record documentation of an age greater than or equal to 18 years **AND**
- Medical record documentation that Bizengri is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a one of the following:
    - Documentation of a diagnosis of advanced, unresectable, or metastatic non-small cell lung cancer **OR**
    - Documentation of a diagnosis of advanced, unresectable, or metastatic pancreatic adenocarcinoma **OR**
    - Documentation of a diagnosis of advanced, unresectable, or metastatic cholangiocarcinoma

  AND
- Medical record documentation of the presence of neuregulin 1 (NRG1) gene fusion **AND**
- Medical record documentation of disease progression on or after at least one prior systemic therapy

MBP 83.0 Lumizyme (alglucosidase alfa) – Updated Policy

- Physician provided documentation of a diagnosis of late-onset (non-infantile) Pompe disease **OR** a diagnosis of infantile-onset Pompe disease supported by:
    - GAA assay performed on dried blood spots, skin fibroblasts or muscle biopsy **AND**
    - Baseline pulmonary function testing (PFT) and muscle strength evaluation (e.g. percent-predicted forced vital capacity (% FVC), 6-minute walk test (6MWT), GSGC (gait stairs, gower, chair) **AND**
    - For late-onset Pompe disease only – Genetic testing to identify the specific mutation to confirm the diagnosis of late-onset Pompe disease **AND**
- Physician provided documentation of a consultation with a metabolic specialist and/or biochemical geneticist **AND**
- Medical record documentation that the member is receiving an appropriate dose* based on patient's weight **AND**
- Medical record documentation that Lumizyme will not be used in combination with other enzyme replacement therapy (e.g. Nexviazyme) for Pompe disease.
- ~~Dosing calculation is based on the "Devine formula"[1,2] which is defined as:~~
    ~~Men: Ideal Body Weight (in kilograms) = 50 + 2.3 kg per inch over 5 feet.~~
    ~~Women: Ideal Body Weight (in kilograms) = 45.5 + 2.3 kg per inch over 5 feet.~~

~~[1] **Note:** Use of the Devine formula for dosing calculation is supported the Duke University Medical Center's Pompe Disease Clinic~~
~~[2] Genzyme acknowledges that some physicians dose Lumizyme based on ideal body weight although the trial that led to approval of Lumizyme used actual body weight. Additionally, Genzyme reports that at the 2012 American College of Medical Genetics conference, an abstract was presented in which the authors showed their research of dosing Lumizyme in a small population of overweight/obese patients with late-onset Pompe disease.~~

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

- Medical record documentation of improvement or stabilization in pulmonary function testing and/or muscle strength evaluation (e.g. percent-predicted forced vital capacity (% FVC), 6-minute walk test (6MWT), GSGC (gait stairs, gower, chair)) **AND**
- Medical record documentation that the member is receiving an appropriate dose* based on patient's weight **AND**

- Medical record documentation that Lumizyme will not be used in combination with other enzyme replacement therapy (e.g. Nexviazyme) for Pompe disease.

~~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 as evidenced by results of appropriate monitoring studies, including:~~

- ~~Upright and supine PFT's done at a minimum of 6 month intervals~~
- ~~Muscle strength evaluations~~
- ~~Echocardiograms~~

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

*Note to reviewing pharmacist: The recommended dose is 20 mg/kg intravenously every 2 weeks.

The following policies were reviewed with no changes:

- MBP 48.0 Rituxan, Truxima , Ruxience, and Riabni
- MBP 63.0 Ixempra
- MBP 79.0 Provenge
- MBP 93.0 Nulojix
- MBP 115.0 Cyramza
- MBP 132.0 Avycaz
- MBP 134.0 Cresemba IV
- MBP 143.0 Praxbind
- MBP 165.0 Rituxan Hycela
- MBP 174.0 Luxturna
- MBP 175.0 Mepsevii
- MBP 182.0 Crysvita
- MBP 194.0 Xerava
- MBP 200.0 Polivy
- MBP 203.0 Nuzyra
- MBP 206.0 Khapzory
- MBP 207.0 Xenleta IV
- MBP 214.0 Vyondys 53
- MBP 215.0 Recarbrio
- MBP 234.0 Oxlumo
- MBP 236.0 Jemperli
- MBP 237.0 Zynlonta
- MBP 238.0 Nulibry
- MBP 246.0 Tivdak
- MBP 247.0 Kimyrsa
- MBP 262.0 Fyarro
- MBP 277.0 Elahere
- MBP 282.0 Skysona
- MBP 285.0 Zynyz
- MBP 301.0 Elrexfio
- MBP 302.0 Talvey
- MBP 303.0 Adstiladrin
- MBP 305.0 Rystiggo
- MBP 315.0 Aphexda
- MBP 339.0 Datroway
- MBP 340.0 PiaSky
- MBP 352.0 Lynozyfic

The following policy updates and reviews apply to Commercial, Marketplace, TPA, and Medicare GHP members only:

MBP 155.0 Ocrevus (ocrelizumab) or Ocrevus Zunovo (ocrelizumab/hyaluronidase-ocsq) & 2027 Part B Step Therapy document – Updated Policy

- ~~Medical record documentation of age ≥ 18 years **AND**~~
- ~~Medical record documentation Ocrevus or Ocrevus Zunovo is prescribed by a neurologist **AND**~~
- ~~Medical record documentation of hepatitis B screening **AND**~~
- ~~One of the following:~~
  - ~~Medical record documentation of a diagnosis of primary progressive MS (PPMS) **OR**~~
  - ~~Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease~~

~~**AND**~~

- ~~For members with a diagnosis of a relapsing form of multiple sclerosis~~

- ~~Medical record documentation that member has failed, is intolerant to, or has a contraindication to a preferred rituximab product **AND**~~
- ~~If intolerant to the preferred rituximab product, documentation of previous history of severe or potentially life-threatening adverse event during or following administration and the adverse event cannot be managed using pre-medication(s) or adjusting the rate of infusion.~~

For ***adult members*** with a diagnosis of primary progressive multiple sclerosis:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of primary progressing MS (PPMS) **AND**
- Medical record documentation Ocrevus or Ocrevus Zunovo is prescribed by a neurologist **AND**
- Medical record documentation of hepatitis B screening **AND**
- Medical record documentation that the prescribed dose is consistent with FDA approved labeling

OR

For ***adult members*** with a diagnosis of a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease:

- Medical record documentation of age greater than or equal to 18 years of age **AND**
- Medical record documentation of a diagnosis of a relapsing form of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND**
- Medical record documentation Ocrevus or Ocrevus Zunovo is prescribed by a neurologist **AND**
- Medical record documentation of hepatitis B screening **AND**
- Medical record documentation that the prescribed dose is consistent with FDA approved labeling **AND**
- One of the following:
  - Medical record documentation that member has failed rituximab is defined as disease activity despite an adequate trial of rituximab as evidenced by clinical relapse, MRI progression, or disability progression as determined by the treating neurologist **OR**
  - Medical record documentation that member has a true contraindication to rituximab **OR**
  - Medical record documentation that member is intolerant to rituximab defined as a previous history of severe or potentially life-threatening adverse event during or following administration and the adverse event cannot be managed using pre-medication(s) or adjusting the rate of infusion

OR

For ***pediatric members*** with a diagnosis of relapsing remitting multiple sclerosis:

- Medical record documentation that Ocrevus IV is being prescribed for a pediatric member* **AND**
- Medical record documentation that the member is greater than or equal to 10 years of age but less than 18 years of age and weighs 25kg or more **AND**
- Medical record documentation of a diagnosis of relapsing-remitting MS (RRMS)** **AND**
- Medical record documentation that Ocrevus IV is prescribed by a neurologist **AND**
- Medical record documentation of hepatitis B screening **AND**
- Medical record documentation that the prescribed dose is consistent with FDA approved labeling **AND**
- One of the following:
  - Medical record documentation that member has failed rituximab is defined as disease activity despite an adequate trial of rituximab as evidenced by clinical relapse, MRI progression, or disability progression as determined by the treating neurologist OR

- Medical record documentation that member has a true contraindication to rituximab OR
- Medical record documentation that member is intolerant to rituximab defined as a previous history of severe or potentially life-threatening adverse event during or following administration and the adverse event cannot be managed using pre-medication(s) or adjusting the rate of infusion

*Ocrevus Zunovo is not approved for use in pediatric population
**Ocrevus IV is indicated for the treatment of relapsing-remitting MS ONLY in the pediatric population. In the pediatric population, Ocrevus IV is NOT indicated for clinically isolated syndrome, active secondary progressive disease, or primary progressive MS.

The following policies were reviewed with no changes:

- MBP 5.0 Remicade, Inflectra, Renflexis, Avsola
- MBP 49.0 Erythropoietin and Darbepoetin
- MBP 81.0 Prolia
- MBP 84.0 Berinert
- MBP 85.0 Cinryze
- MBP 130.0 Mircera
- MBP 341.0 Quzyttir
- MBP 361.0 Ryzneuta

The following policy updates and reviews apply to Commercial, Marketplace, TPA, and Medicaid GHP members only:

MBP 162.0 Yescarta (axicabtagene ciloleucel) – Updated Policy
Large B-Cell Lymphoma (third-line or beyond)

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

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

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

The following policy updates and reviews apply to Commercial, Marketplace, and TPA GHP members only:

MBP 89.0 Xgeva (denosumab) – Updated Policy

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 **AND**
- For members already established on Xgeva (denosumab) therapy: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to one (1) of the following: denosumab-bnht (Bomyntra), denosumab-bbdz (Wyost), and denosumab-bmwo (Osenvelt) OR
- For members naïve to Xgeva (denosumab) therapy: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) of the following: denosumab-bnht (Bomyntra), denosumab-bbdz (Wyost), and denosumab-bmwo (Osenvelt)

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