P&T Committee Meeting Minutes
Medicaid
September 8, 2026

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Leslie Astleford, Pharm.D.
Amir Antonious, Pharm.D.	Bhargavi Degapudi, MD
Emily Bednarz, Pharm.D.	Keri Donaldson, MD, MSCE
Kristen Bender, Pharm.D.	Kelly Faust, Pharm.D.
Jeremy Bennett, MD	Nichole Hossler, MD
Angela Bolesta, Pharm.D.	Jason Howay, Pharm.D.
Kim Castelnovo, RPh	Briana LeBeau, Pharm.D.
Kimberly Clark, Pharm.D.	Jonas Pearson, RPh
Thomas Ciccarelli, Pharm.D.	Michael Spishock, RPh
Destiny Cragle, Pharm.D.	Luke Sullivan, DO
Michael Dubartell, MD	Amanda Taylor, MD
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	
Lauren Lesh, Pharm.D.	
Lisa Manoski, 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	
Kara Pabst, Pharm.D.	
Austin Paisley, 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.	
Emily Snitzer, Pharm.D.	

Todd Sponenberg, Pharm.D. Jill Stone, Pharm.D. Kevin Szczecina, RPh Ariana Wendoloski, Pharm.D. Brandon Whiteash, Pharm.D. Margaret Whiteash, Pharm.D. Sherry Beagle (non-voting participant) Jeremy Garris (non-voting participant) Simran Kaur, Pharm.D. (non-voting participant) Tiffany O'Hagan (non-voting participant)	

Call to Order: Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday September 8, 2026.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: The July 14, 2026, minutes were unanimously approved.

DRUG REVIEWS

Avlayah (tividenofusp alfa-eknm)

Review: Avlayah is indicated for the treatment of neurologic manifestations of mucopolysaccharidosis type II (MPS II), also known as Hunter syndrome, when initiated in presymptomatic or symptomatic pediatric patients weighing ≥ 5 kg prior to advanced neurologic impairment. This was approved under accelerated approval based on reduction of cerebrospinal fluid heparan sulfate observed in patients treated with Avlayah. It is not recommended for use in combination with other enzyme replacement therapies for the treatment of Hunter syndrome

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

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

Outcome: Avlayah will be a medical benefit. Avlayah will require a prior authorization with the following criteria.

- 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
    - 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, 7.5 mg/kg once weekly weeks 5 to 8, 15 mg/kg once weekly for week 9 and beyond as long as tolerated

Authorization Duration: 6 months initial and 12 months subsequent

Re-authorization criteria:

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

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

Rapiblyk (landiolol)

Review: Rapiblyk is indicated for the treatment of adults with supraventricular tachycardia including atrial fibrillation and atrial flutter. Additionally, since its initial approval Rapiblyk has also been approved for the treatment of pediatric patients with supraventricular tachycardia. Rapiblyk is administered as a continuous intravenous infusion in a monitored setting.

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

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

Outcome: Rapiblyk is a medical benefit for Medicaid It is anticipated that this drug will only be used in an inpatient and/or emergent setting. No outpatient medical benefit prior authorization criteria are required at this time.

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

Ivtisma (onasemnogene abeparvovec-brve)

Review: Itvisma is indicated for the treatment of spinal muscular atrophy (SMA) in adult and pediatric patients 2 years of age and older with confirmed mutation in survival motor neuron 1 (SMN1) gene. It is an adeno-associated virus (AAV) vector-based gene therapy and is a more concentrated formulation of Zolgensma that delivers a functional copy of the SMN1 gene as a one-time, fixed-dose intrathecal injection to a broader population than Zolgensma which is indicated in pediatric patients less than 2 years of age.

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

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

Outcome: Itvisma will be covered as a medical benefit requiring prior authorization.

- Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
    - Homozygous exon 7 gene deletion OR
    - Homozygous exon 7 conversion mutation OR
    - Compound heterozygous exon 7 mutation OR
    - Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies

AND

- Prescription is being prescribed by a neurologist or pediatric neurologist AND
- Medical record documentation of age greater than or equal to 2 years to less than 18 years AND
- Medical record documentation that patient does not have anti-AAV9 antibody titers >1:50 as determined by ELISA (within two weeks of the anticipated infusion date) AND
- Medical record documentation that patient is not permanently ventilator-dependent AND
- Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Spinraza, Evrysdi) with Itvisma (Note: Any current authorizations for SMN modifying therapy will be terminated upon Itvisma approval)
- Medical record documentation the patient has not received prior gene therapy for the treatment of SMA (e.g. Zogensma) or a prior dose of Itvisma

AUTHORIZATION DURATION: 30 days (to receive the one-time infusion) or the date equivalent to the patient age of 18 years (whichever is less).

Note: Itvisma must be administered prior to 18 years of age. If the medication is not administered during this initial month, re-review should occur to ensure patient is still eligible for the medication, particularly the anti-AAV9 antibody titers and ventilator dependence.

QUANTITY LIMIT: One (1) Itvisma infusion per lifetime

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

FASTFACTS

Trodelvy

Updated Indication: Trodelvy is now indicated as a single agent for the first-line treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer (TNBC) who are

not candidates for PD-1 or PD-L1 inhibitor-based therapy OR in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for the first-line treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 (CPS ≥ 10) as determined by an FDA-authorized test.

Discussion: The committee unanimously voted to accept the recommendations.

Outcome: No changes are recommended to the formulary placement of Trodelvy. The following changes should be made to Medical Benefit Policy 216.0 to incorporate the new indications.

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).

Unresectable Locally Advanced or Metastatic HR Positive, HER2 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 hormone receptor (HR)positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer **AND**
- Medical record documentation of previously receiving endocrine-based therapy **AND**
- Medical record documentation of previously receiving at least two additional systemic therapies in the metastatic setting

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

Other Recommendations: In addition to the Trodelvy policy, Medical Benefit Policy 119.0 Keytruda and Medical Benefit Policy 357.0 Keytruda Qlex policies should be updated as follows to include the new indications. No changes are needed to the Part D Policy 425.0 D for Keytruda and Part D Policy 1179.0D for Keytruda Qlex.

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 sacituzumab govitecan-hziy (Trodelvy)

    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.

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

Pluvicto

Updated Indication: Pluvicto is now approved in combination with androgen receptor pathway inhibitor (ARPI) therapy for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer.

Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Pluvicto will remain a medical benefit and prior authorization criteria for the new indication will be added to MBP 263.0 Pluvicto. There are no changes recommended to the authorization duration or quantity limit. The new criteria are highlighted in green and removals are stricken.

Pluvicto (lutetium Lu 177 vipivotide tetraxetan) will be considered medically necessary when all of the following criteria are met:

1. **Metastatic Androgen-Pathway Modulation-Resistant (mAPMR) Prostate Cancer**
   - 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 androgen pathway modulation-resistant (mAPMR) prostate cancer ~~castration-resistant prostate cancer (mCRPC)~~ **AND**
   - Medical record documentation that a gonadotropin-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

2. **Metastatic Androgen Pathway Modulation-Naïve or -Sensitive (mAPMN/S) Prostate Cancer**
   - 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 androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer (mCRPC) **AND**
   - Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently OR member has had bilateral orchiectomy **AND**
   - Medical record documentation that Pluvicto will be used in combination with an androgen receptor pathway inhibitor

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.

Note:
Examples of androgen-receptor pathway inhibitors include but are not limited to: abiraterone (Zytriga), enzalutamide (Xtandi), apalutamide (Erleada), darolutamide (Nubeqa)
Examples of gonadotropin-releasing hormone (GnRH) analogs include but are not limited to: leuprolide (Lupron Depot, Eligard), goserelin (Zoladex), histrelin (Vantas), triptorelin (Trelstar)

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

Kerendia

Updated Indication: Kerendia is now indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) ≥ 40%.

Discussion: The committee unanimously voted to accept the recommendations.

Outcome: For GHP Family, Kerendia 40 mg tablets will remain non-formulary to match the placement of Kerendia 10 mg and 20 mg.

Chronic Kidney disease associated with type 2 Diabetes

- Medical record documentation of a diagnosis of chronic kidney disease associated with type 2 diabetes **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of serum potassium ≤ 5.0 mEq/L or ≤ 5.5 mEq/L if previously established on therapy **AND**
- Medical record documentation of persistent albuminuria (albumin to creatinine ratio consistently greater than 30 mg/g) despite treatment with both of the following:
    - Maximally tolerated angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) OR medical record documentation of contraindication or intolerance to one angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB AND
    - One sodium-glucose co-transporter 2 (SGLT-2) inhibitor with proven kidney or cardiovascular benefit OR medical record documentation of contraindication or intolerance to one sodium-glucose co-transporter 2 (SGLT-2) inhibitor with proven kidney or cardiovascular benefit

Heart Failure with LVEF ≥ 40%

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of New York Heart Association [NYHA] class II–IV heart failure AND
- Medical record documentation of left ventricular ejection fraction (LVEF) greater than or equal to 40% AND
- Medical record documentation that Kerendia is prescribed by or in consultation with a cardiologist AND
- Medical record documentation of one of the following:
    - Serum Potassium ≤ 5.0 MEQ/L OR
    - Serum Potassium ≤ 5.5 MEQ/L if already established on therapy

AND

- Medical record documentation that member is inadequately controlled with a sodium glucose co-transporter-2 (SGLT-2) inhibitor OR has an intolerance to or contraindication to SGLT-2 inhibitor therapy.

Authorization duration: not applicable

Alternatives: per Statewide PDL (Hypoglycemics, SGLT2 Inhibitors and Angiotensin Modulators)

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

Imcivree

Updated Indication: Imcivree is now indicated to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients 4 years and older with acquired hypothalamic obesity (HO).

Discussion: The committee unanimously voted to accept the recommendations.

Outcome: No changes are recommended to the formulary placement of Imcivree. The following prior authorization criteria should be added to GHP Family Policy 1560.0F.

Obesity due to acquired hypothalamic obesity (HO)

- Medical record documentation of age greater than or equal to 4 years AND
- Medical record documentation of acquired hypothalamic obesity due to hypothalamic injury or dysfunction AND
- Medical record documentation of one of the following:
  - For patients 18 years and older: Medical record documentation of body mass index (BMI) of greater than or equal to 30kg/m^2
  - For patients 4 years to less than 18 years: Medical record documentation of weight greater than or equal to 95th percentile using growth chart assessments
- 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

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

UPDATES

Filspari

Recommendation It is recommended to add the following criterion to the "IgA nephropathy" section of the policy:

- Medical record documentation that the prescribed dosing is appropriate for member's weight

Discussion: The committee unanimously voted to accept the recommendation.

Outcome: The recommended update will be made to the GHP Family Filspari policy.

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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Medical Benefit Policy Update

Kresladi Update

Recommendations: It is recommended to update the age requirement per clinical trial treatment population and per PARP recommendation. It is also recommended to update the PNMs level per clinical trial inclusion criteria and per PARP recommendation.

MBP 364.0 Kresladi (marnetegragene autotemcel)

- Medical record documentation of an age greater than or equal to ~~3~~ 9 months and less than 18 years of age **AND**
- Medical record documentation that Kresladi is being prescribed by or in consultation with an immunologist, hematologist, oncologist, infectious disease specialist, or other providers with expertise in the diagnosis and treatment of leukocyte adhesion deficiency-I (LAD-I) **AND**
- Medical record documentation of a confirmed diagnosis of severe LAD-I demonstrated by **ONE** of the following:
    - Flow cytometry indicating CD18 expression on < 2% neutrophils (polymorphonuclear neutrophils [PMNs]) **OR**
    - For patients in which CD18+ PMNs are ≥2%, all of the following:
        - <2% CD11a or CD11b expressing PMNs **AND**
        - Documented *ITGB2* mutation **AND**
        - Clinical history consistent with LAD-I **OR** documented known family history of LAD-I **AND**

Gazyva Update

Recommendations: It is recommended to update the authorization duration per FDA approved labeling and per PARP recommendation.

MBP 113.0 Gazyva (obinutuzumab)

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.

Synagis and Lumoxiti Update

Discussion: Synagis was withdrawn from the market on 12/31/25 per an AAP publication on 8/12/25. AAP also no longer routinely recommends use of Synagis and instead recommends Beyfortus or Enflonsia be used.

Lumoxiti was permanently discontinued in July of 2023 per a letter from AstraZeneca to the FDA on 11/18/22. In the letter, it states that Lumoxiti was not removed from the market due to safety or efficacy, but rather because of very low clinical uptake. Per the letter, providers are not to initiate new treatment with Lumoxiti and supply of the medication is not available after August 2023.

Recommendations: It is recommended to retire MBP 2.0 Synagis and MBP 189.0 Lumoxiti.

Discussion: The committee unanimously voted to accept the recommendation.

Outcome: the recommended updates were adopted.

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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August ELECTRONIC VOTE

An electronic vote was held from August 6, 2026, to August 12, 2026. Responses were received from 30 members (out of 50 members) and all voted to approve. Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Lasix ONYU

Review: Lasix ONYU (furosemide injection) is a loop diuretic indicated for the treatment of edema in adult patients with chronic heart failure. Lasix ONYU is a subcutaneous injection available as an 80 mg per 2.67 mL single-dose prefilled cartridge co-packaged with a single-use Disposable Unit of the Infusor.

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

- Medical record documentation of age 18 years or older **AND**
- Medical record documentation of diagnosis of chronic heart failure **AND**
- Medical record documentation of treatment of edema **AND**
- Medical record documentation that Lasix ONYU is prescribed by or in consultation with a cardiologist **AND**
- Medical record documentation that member is established on background loop diuretic therapy **AND**
- Medical record documentation of provider attestation that member will use Lasix ONYU for short-term use only and will be transitioned to oral diuretics as soon as practical **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

NOTE: The Reusable Unit will be billed under DME.
Formulary Alternatives: N/A
Authorization Duration: one month
Quantity Limit: N/A
GPI Level: GPI-14

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

Otarmeni

Review: Otarmeni is an adeno-associated virus vector-based gene therapy indicated for the treatment of pediatric and adult patients with severe-to-profound and profound sensorineural hearing loss (any frequency > 90 dB HL) associated with molecularly confirmed biallelic variants in the *OTOF* gene, preserved outer hair cell function, and no prior cochlear implant in the same ear.

- Recommendation: Otarmeni will be a Medical Benefit drug that will not be added to any Geisinger formularies. Otarmeni is offered at no cost (drug only) by Regeneron via the OnPath program (Regeneron assesses eligibility). Otarmeni is not eligible to be billed to the third-party payer and is not coverable. If approved by Regeneron's OnPath program, GHP will be billed for any associated non-drug costs. Otarmeni will be coded within the system as non-covered, and a clinical policy is not necessary.

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

Arexvy

Updated Indication: The expanded indication now includes individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.

Recommendation: Update the age in Policy 1592.0F to 19 to 59 years of age

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

Bizengri

Updated Indication: Bizengri is now indicated in adult patients with advanced, unresectable or metastatic cholangiocarcinoma harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy.

Recommendation: No changes are recommended for the formulary placement of Bizengri. The following changes are recommended to formulary placement, quantity limits, or authorization duration for Bizengri. The following changes are recommended to Medical Benefit Policy 338.0 to incorporate the new indications.

Medical Benefit Policy 338.0

- 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

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.

QUANTITY LIMIT: 75 milliliters (4 vials) per 28 days

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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Enhertu

Updated Dosing: Enhertu is now indicated in early breast cancer as neoadjuvant treatment of adult patients with HER2-positive (IHC 3+ or ISH+) Stage II or III breast cancer, as determined by an FDA authorized test followed by a taxane, trastuzumab, and pertuzumab (THP) and as adjuvant treatment of adult patients with HER2-positive (IHC 3+ or ISH+) breast cancer who have residual invasive disease following neoadjuvant trastuzumab (with or without pertuzumab) and taxane based treatment.

Recommendation: No changes are recommended to the formulary placement of Enhertu. The following additional criteria and updated auth duration should be added to Medical Benefit Policy 208.0 for Enhertu.

Neoadjuvant treatment of early breast cancer: One approval for 6 months or less if the reviewing provider feels it is medically appropriate.

- Authorization of Enhertu for the neoadjuvant treatment of early breast cancer should not exceed the FDA-approved treatment duration of every 3 weeks for 4 cycles followed by 4 cycles of THP.

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

Adjuvant treatment of early breast cancer: One approval for 12 months or less if the reviewing provider feels it is medically appropriate.

- Authorization of Enhertu for the adjuvant treatment of early breast cancer should not exceed the FDA-approved treatment duration of every 3 weeks for 14 cycles

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

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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Filspari

Updated Indication: Filspari is now approved for Focal segmental glomerulosclerosis, without nephrotic syndrome in adults and children ages 8 years and older

Recommendation: No changes to formulary placement are recommended. The following prior authorization criteria are recommended to be added to pharmacy benefit policy 1570.0F Filspari to account for the new indication.

For focal segmental glomerulosclerosis, without nephrotic syndrome:

- Medical record documentation of Focal segmental glomerulosclerosis, without nephrotic syndrome age **AND**
- Medical record documentation that member is 8 years of age or older **AND**
- Medical record documentation that the medication is prescribed by or in consultation with a nephrologist **AND**
- Medical record documentation that patient is at high risk of disease progression, defined as urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g or proteinuria ≥ 1g/day **AND**
- Medical record documentation that patient has received ≥ 90 days of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification **AND**
- Medical record documentation of eGFR ≥ 30 mL/min/1.73 m2 **AND**
- Medical record documentation that patient has received a stable dose of a RAS Inhibitor (ACE inhibitor or ARB) at a maximally tolerated dose for ≥ 90 days **AND**
- Medical record documentation that RAS inhibitor (ACE inhibitor or ARB) will be discontinued prior to initiation of treatment with Filspari **AND**
- Medical record documentation that Filspari will NOT be used in combination with any RAS inhibitors (ACE inhibitor or ARB), endothelin receptor antagonists, or aliskiren **AND**
- Medical record documentation that Filspari is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

Authorization Duration: Initial approval will be for nine (9) months and subsequent approvals will be for twelve (12) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of continued disease improvement or lack of disease progression according to prescriber (i.e. decreased levels of proteinuria from baseline or decreased UPCR from baseline) **AND**
- Medical record documentation that Filspari will NOT be used in combination with any RAS inhibitors (ACE inhibitor or ARB), endothelin receptor antagonists, or aliskiren **AND**
- Medical record documentation that Filspari is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

NOTE: For patients weighing 50 kg or Less

1) Initial dosage: 200 mg orally once daily for 14 days then increase to a target dose of 400 mg once daily, as tolerated
2) Resuming treatment following interruption: Consider repeating initial dose titration, beginning with 200 mg once daily

For patients weighing greater than 50 kg

1) Initial dosage: 400 mg orally once daily for 14 days then increase to a target dose of 800 mg once daily, as tolerated
2) Resuming treatment following interruption: Consider repeating initial dose titration, beginning with 400 mg once daily

***If approving for patients weighing greater than 50 kg, allow quantity limit of two tablets per day to achieve target dose of 800mg daily**

Days supply per fill: 30 days
Formulary Alternative: Not applicable
GPI Level: GPI-12

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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Inqovi

Updated Indication: Inqovi is now indicated for use in combination with venetoclax for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

Recommendation: It is recommended that the following changes to the prior authorization criteria for GHP Family policy 1532.0F for the new indication for Inqovi.

OR

• Medical record documentation that Inqovi is prescribed by or in consultation with an oncologist or hematologist AND
• Medical record documentation of age greater than or equal to 75 years AND
• Medical record documentation that Inqovi is being used in combination with venetoclax for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

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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Palynziq

Updated Indication: Palynziq (pegvaliase-pqpz) is now indicated to reduce blood phenylalanine concentrations in adult and pediatric patients 12 years of age and older with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management. Previously, Palynziq was only indicated for use adult patients for the same indication.
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Recommendation: There are no changes recommended to formulary placement of Palynziq at this time. However, it is recommended to update the prior authorization criteria in the current policy to match the expanded age indication, as well as to update the formulary alternative section to remove brand Kuvan and add generic sapropterin.

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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Spinraza

Updated Indication: Spinraza has been approved in a new high dose regimen for the treatment of spinal muscular atrophy (SMA). The high dose regimen allows for an accelerated loading phase with two 50mg doses administered 14 days apart followed by 28mg maintenance dose injections every four months thereafter.

Recommendation: The following changes are recommended to policy MBP 151.0: Spinraza

1. Prescription is being prescribed by a neurologist or pediatric neurologist AND
2. Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
    a. Homozygous exon 7 gene deletion OR
    b. Homozygous exon 7 conversion mutation OR
    c. Compound heterozygous exon 7 mutation OR
    d. Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies. AND
3. Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Zolgensma)* AND
4. Medical record documentation of testing and documented results of at least one of the following:
    a. CHOP-INTEND (Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders)
    b. HFMSE (Hammersmith Functional Motor Scale Expanded) and RULM (Revised Upper Limb Module)
    c. RULM (Revised Upper Limb Module)
    d. 6-Minute Walk Test (^MWT) AND
5. Medical record documentation that treatment with standard-dose Spinraza that is now requiring high-dose Spinraza as evidenced by ongoing functional impairment, plateaued response, caregiver/physician-documented unmet treatment need, or provider attestation supporting escalation OR clinical rationale for initiating high-dose therapy without a standard-dose trial* AND

6. Medical record documentation that Spinraza is not being used in combination with Evrysdi.

*Note: Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis. Additionally, requests for high dose Spinraza prior to use of low dose Spinraza will be reviewed on a case by case basis.

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

1. Medical record documentation that member is compliant with prescribed nusinersen regimen AND
2. Medical record documentation that the patient has not received prior treatment with gene therapy (Zolgensma) AND
3. Provider attestation that Spinraza is still medically necessary to continue AND
4. Medical record documentation of repeat testing and documented results of at least one of the following:
    a. CHOP-INTEND (Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders)
    b. HFMSE (Hammersmith Functional Motor Scale Expanded) and RULM (Revised Upper Limb Module)
    c. RULM (Revised Upper Limb Module)
    d. 6-Minute Walk Test (6MWT)

QUANTITY LIMIT:

For Low Dose Spinraza

Initial approval: One (1) injection (5ml) per fill with an RX count of 6 for a 12-month authorization duration.

Subsequent approvals: One (1) injection (5ml) per fill with an RX count of 3 for a 12-month authorization duration. Max quantity supply: 5; Max Day Supply: 365; Min Day Supply: 120

For High Dose Spinraza

Initial approval: One (1) injection (5ml) per fill with an RX count of 4 for a 12-month authorization duration.

Subsequent approvals: One (1) injection (5ml) per fill with an RX count of 3 for a 12-month authorization duration. Max quantity supply: 5; Max Day Supply: 365; Min Day Supply: 120

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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Tecentriq

Updated Indication: Tecentriq is now indicated as adjuvant treatment of adult patients with MIBC after cystectomy who have circulating tumor DNA molecular residual disease (ctDNA MRD) as determined by an FDA-authorized test

Recommendation: There are no recommendations for changes to the formulary placement. The following prior authorization criteria and updates to the authorization duration should be added to Medical Benefit Policy 144.0 to incorporate the new indication

Muscle Invasive Bladder Cancer (MIBC)

- Prescription written by an oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of muscle invasive bladder cancer (MIBC) AND
- Medical record documentation that Tecentriq will be used for adjuvant treatment following a cystectomy AND
- Medical record documentation of circulating tumor DNA molecular residual disease (ctDNA MRD) as determined by an FDA-authorized test.

AUTHORIZATION DURATION:

For adjuvant treatment of stage II to IIIA non-small cell lung cancer (NSCLC) following resection and platinum-based chemotherapy OR adjuvant treatment of MIBC with ctDNA MRD following cystectomy: One approval will be given for 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Tecentriq for adjuvant treatment of stage II to IIIA non-small cell lung cancer (NSCLC) following resection and platinum-based chemotherapy OR adjuvant treatment of MIBC with ctDNA MRD following cystectomy should not exceed the FDA-approved treatment duration of 1 year (12 months) in patients. For requests exceeding the above limit, medical record documentation of the following is required:

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

For all other indications: 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.

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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Evrysdi Update

Discussion: The Spinraza policy was recently updated to now include baseline monitoring parameters to allow for assessment of disease progression upon renewal. The Evrysdi policy currently lacks these criteria.

Recommendation: To create consistency across these policies, it is recommended to update Evrysdi policy 1536.0F (GHP Family).

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

- Medical record documentation that Evrysdi is prescribed by a neurologist or pediatric neurologist AND
- Medical record documentation that Evrysdi is prescribed with 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 of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
    - Homozygous exon 7 gene deletion OR
    - Homozygous exon 7 conversion mutation OR
    - Compound heterozygous exon 7 mutation

  OR
    - Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies AND
    - Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Zolgensma)*

- Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Spinraza) AND
- Medical record documentation of testing and documented results of at least one of the following:
    - CHOP-INTEND (Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders)
    - HFMSE (Hammersmith Functional Motor Scale Expanded) and RULM (Revised Upper Limb Module)
    - RULM (Revised Upper Limb Module)
    - 6-Minute Walk Test (^MWT)

AUTHORIZATION DURATION: Evrysdi will be approved for an initial authorization duration of 12 months. Subsequent authorizations will be determined medically necessary and should be approved for an authorization duration of 12 months when the following criteria are met:

1. Medical record documentation that member is compliant with the prescribed risdiplam regimen AND
2. Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Zolgensma)* AND
3. Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Spinraza) AND
4. Provider attestation that Evrysdi is still medically necessary to continue AND
5. Medical record documentation of repeat testing and documented results of at least one of the following:
    e. CHOP-INTEND (Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders)
    f. HFMSE (Hammersmith Functional Motor Scale Expanded) and RULM (Revised Upper Limb Module)
    g. RULM (Revised Upper Limb Module)
    h. 6-Minute Walk Test (6MWT)

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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Zerbaxa Update

Discussion: Previously, Zerbaxa was approved only for adult patients with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia. The FDA indication has been updated to include pediatric and adult patients with either of the diagnoses, which is now consistent with all other indications.

Recommendation: It is recommended to remove the age criteria point from MBP 205 Zerbaxa.

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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GHP Family Update

Moviprep and Suprep: it is recommended to add an authorization duration of "1-month auth duration, Rx count 1" and approve as generic only.

The updates noted below were made at the request of DHS during the PARP review. It is recommended the Committee approve the changes**.**

Palynziq – it was noted that Palynziq is now indicated for pediatric patients 12 years of age and older. The policy was updated to reflect this.

Carglumic Acid – it was requested that the following update be made:

- Medical record documentation that Carglumic Acid is being prescribed as adjunctive treatment to standard of care (including such as but not limited to intravenous glucose, insulin, L-carnitine, protein restriction, and dialysis)

Annual DUR Survey – CMS FFY 2025 Managed Care Organization (MCO) Drug Utilization Review (DUR) Survey was submitted on June 11, 2026

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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Meeting adjourned at 3:31 PM

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held November 10, 2026.

Meetings will be held virtually via phone/Microsoft Teams