P&T Committee Meeting Minutes
Medicaid
September 20, 2022

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Kristen Bender, Pharm.D.
Amir Antonious, Pharm.D.	Holly Bones, Pharm.D.
Emily Antosh, Pharm.D.	Alyssa Cilia, RPh
Jeremy Bennett, MD	Michael Evans, RPh
Kim Castelnovo, RPh	Tricia Heitzman, Pharm.D.
Kimberly Clark, Pharm.D.	Nichole Hossler, MD
Rajneel Farley, Pharm.D.	Jason Howay, Pharm.D.
Kelly Faust Pharm.D.	Jamie Miller, RPh
Emily Hughes, Pharm.D.	Jonas Pearson, RPh
Keith Hunsicker, Pharm.D.	Michael Shepherd, MD
Kelli Hunsicker, Pharm.D.	Richard Silbert, MD
Derek Hunt, Pharm.D.	Todd Sponenberg, Pharm.D.
Kerry Ann Kilkenny, MD	Amanda Taylor, MD
Philip Krebs, R.EEG T	
Briana LeBeau, Pharm.D.	
Ted Marines, Pharm.D.	
Lisa Mazonkey, RPh	
Tyreese McCrea, Pharm.D.	
Perry Meadows, MD	
Mark Mowery, Pharm.D.	
Austin Paisley, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Melissa Renn, Pharm.D.	
Melissa Sartori, Pharm.D.	
Angela Scarantino	
Kristen Scheib, Pharm.D.	
William Seavey, Pharm.D.	
Leslie Shumlas, Pharm.D.	
Aubrielle Smith Pharm.D.	
Kirsten Smith, Pharm.D.	
Michael Spishock, RPh	
Jill Stone, Pharm.D.	
Robert Strony, MD MBA	
Kevin Szczecina, RPh	
Ariana Wendoloski, Pharm.D.	
Brandon Whiteash, Pharm.D.	
Margaret Whiteash, Pharm.D.	
Jeremy Garris (non-voting participant)	
Mallory Ellis, Pharm.D. (Pharmacy Resident)	
Jemimah Royer (Pharmacy Student)	

Call to Order:
Dr Yarczower called the meeting to order at 1:02 p.m., Tuesday, September 20, 2022.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Yarczower asked for a motion or approval to accept the July 19, 2022 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Soolantra (ivermectin 1% cream)

Review: Soolantra (ivermectin 1%) cream is a topical product indicated for the treatment of inflammatory lesions of rosacea in adult patients. Soolantra should be applied to the affected areas of the face one daily, using a pea sized amount and avoiding the eyes and lips. The efficacy of Soolantra was demonstrated in two randomized, double-blind vehicle-controlled trials with a total of 1371 subjects aged 18 years and older who were treated once daily for 12 weeks with either SOOLANTRA cream or vehicle cream. SOOLANTRA cream was more effective than vehicle cream based on the Investigator Global Assessment (IGA) scale looking at patients scored as "clear" or "almost clear" and in the absolute change from baseline in inflammatory lesion counts at Week 12. Soolantra was also demonstrated to be superior to twice daily metronidazole during an investigator blinded study of 962 patients with severe PPR Ivermectin showed a significantly higher percentage of patients with improvement in IGA score at week 16 to 'clear' or 'almost clear'. The most commonly noted adverse effects with Soolantra include localized reactions such as burning and skin irritation.

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

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

Outcome: Ivermectin 1% cream is a pharmacy benefit, managed by GHP, and should be added to the GHP Family formulary at the generic tier.

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

Radacava ORS (edaravone)

Review: Radicava and Radicava ORS are indicated for the treatment of amyotrophic lateral sclerosis (ALS). Radicava is available as a 30 mg/100 mL intravenous solution. Radicava ORS is available as a 105 mg/5mL oral suspension. The recommended dose of Radicava ORS is 105 mg (5 mL) taken orally or via feeding tube in the morning after overnight fasting. For both the oral suspension and IV infusion, Radicava is administered as an initial treatment cycle with daily dosing for 14 days, followed by a 14-day drug-free period. Subsequent cycles are daily dosing for 10 days out of 14-day periods, followed by a 14-day drug-free period. Food should not be consumed for 1 hour after administration except for water. If patients consume a high-fat meal (800-1,000 calories), they must fast 8 hours before administration of Radicava ORS. If patients consume a low-fat meal (400-500 calories), they must fast 4 hours before administration of Radicava ORS. If patients consume caloric supplement (250 calories), they must fast 2 hours before administration. Radicava ORS should be disposed after 15 days from opening the bottle or within 30 days from the shipment date on the pharmacy label, which ever happens first. When patients switch from Radicava to Radicava ORS, they should use the same dosing frequency. Once they switch to ORS, patients need to follow Radicava dosing recommendations with regards to food consumption.

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

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

Outcome: Radicava ORS will be a pharmacy benefit and will be added to the formulary on the brand tier. Radicava will require a prior authorization with the following criteria:.

- Prescription written by or in consultation with a neurologist AND
- Medical record documentation of a diagnosis of ALS (amyotrophic lateral sclerosis) AND
- Medical record documentation of baseline functional status (as evidenced by a scoring system such as ALSFRS-R, or by physician documentation of subjective reports on speech, motor function, pulmonary function, etc.) AND
- Medical record documentation that Radicava is being given in combination with riluzole OR intolerance or contraindication to riluzole 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

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 criteria.

- Medical record documentation that member is tolerating and compliant with prescribed edaravone regimen **AND**
- Medical record documentation of regular physician follow-up

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

Jemlyto (mitomycin)

Review:

FDA Approved Indication

- Jelmyto is an alkylating drug indicated for the treatment of adult patients with low-grade upper tract urothelial cancer.

Dosing/How Supplied

- Jelmyto is for pyelocaliceal use only and not for intravenous use, topical use, or oral administration.
- Administer 1.3 grams of sodium bicarbonate orally the evening prior to, the morning of, and 30 minutes prior to installation procedure (3.9 grams total).
- The dose of Jelmyto to be instilled is 4 mg per ml via ureteral catheter or nephrostomy tube, with total instillation volume based on volumetric measurements using pyelography, not to exceed 15 ml (60 mg of mitomycin).
- Instill Jelmyto once weekly for 6 weeks. For patients with a complete response 3 months after Jelmyto initiation, instillations may be administered once a month for a maximum of 11 additional instillations.
- Jelmyto for pyelocaliceal instillation is manufactured as a single-dose carton containing two 40 mg (each) single-dose vials of lyophilized mitomycin and one vial of 20 ml hydrogel for reconstitution.

Place in therapy

- Jelmyto is the first drug approved to treat cancer that grows in the upper portion of the urinary system known as upper tract urothelial cancer.

- Most urothelial cancers start in the bladder, but upper tract cancers start in the lining of the kidney or the ureter (the tube that connects the kidney to the bladder).
- In some people, upper tract cancers can block the ureter or kidney and cause problems including swelling, infection, and decrease in kidney effectiveness.
- These problems could lead to kidney and ureter removal.

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

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

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

- Documentation of age greater than or equal to 18 years AND
- Medical record documentation that Jelmyto is prescribed by or in consultation with a hematologist, oncologist or urologist AND
- Medical record documentation of a diagnosis of low-grade Upper Tract Urothelial Cancer (LG-UTUC) 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

Authorization Duration: Initial approval will be for 3 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less of the reviewing provider feels it is medically appropriate and will require medical record documentation of a complete response 3 months after Jelmyto initiation as evidenced by urine cytology and ureteroscopy. The medication will no longer be covered if patient experiences toxicity, worsening of disease, experiences a perforation of the bladder or upper urinary tract or if the patient has received 17 total instillations (maximum number of instillations per FDA approved labeling).

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

Camzyos (mavacamten)

Review: Camzyos is a first in its class cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (oHCM). By inhibiting myosin, mavacamten limits myosin's interaction with actin, resulting in limited cross-bridge formation and enhancing heart muscle relaxation. Mavacamten provides effective symptom relief and improves functional capacity in oHCM patients.
Hypertrophic cardiomyopathy (HCM) is a genetic condition with an estimated prevalence of 1 in every 500 people within the United States. The disease causes the heart muscles to uncontrollably contract and as a result, thicken, potentially leading to an array of symptoms and complications. Patients with HCM can be asymptomatic, especially early in the disease. However, HCM may cause shortness of breath, chest pain, fatigue, swollen ankles, legs, feet, abdomen, and neck veins, dizziness, lightheadedness, and syncope. Serious complications of HCM include fatal arrythmias or sudden cardiac death. HCM can be divided into two types: obstructive and nonobstructive. Obstructive HCM is more common, affecting two-thirds of HCM patients, and is denoted by left ventricular outflow

obstruction. Nonobstructive HCM similarly has cardiac hypertrophy present but does not cause left ventricle obstruction.
Current therapies for oHCM provide symptom relief. They do not treat the underlying cause of oHCM. First-line therapies include beta-blockers and non-dihydropyridine calcium channel blockers. Disopyramide and septal reduction therapy are second-line options if the patient continues to have symptoms despite use of first-line agents.

Camzyos is available as an oral capsule in 2.5 mg, 5 mg, 10 mg, and 15 mg strengths with the recommended starting dosage being 5 mg once daily. Once stabilized on this dose, dosage adjustments are made based on the patient's clinical status and electrocardiogram (ECG) results.

Camzyos causes reduced left ventricular ejection fraction (LVEF) and has a boxed warning for risk of heart failure. Because of this boxed warning, mavacamten is only available through a REMS program. Patients must have an ECG performed before initiation of mavacamten and at weeks 4, 8, 12, and every 12 weeks thereafter during treatment. Initiation of mavacamten in patients with a LVEF less than 55% is not recommended. The Camzyos REMS Program requires that prescribers, patients, and pharmacies be registered with the program for the patient to receive the drug. Contraindications to the use of mavacamten include the use of moderate to strong CYP2C19 inhibitors and inducers, moderate to strong CYP3A4 inducers, and strong CYP3A4 inhibitors due to the increased risk of heart failure when combined with mavacamten.

The most notable clinical trial for Camzyos is the EXPLORER-HCM trial, a double-blind, randomized, placebo-controlled, multicenter, international, parallel group trial. Patients enrolled in the trial had to be ≥18 years old and weigh ≥45 kg, have diagnosed oHCM according to ACC/AHA and ESC guidelines with LVEF ≥55% and NYHA class II or III oHCM, and an oxygen saturation ≥90% at screening. The study included 251 patients randomized 1:1 to receive mavacamten 5 mg daily or placebo.
The primary endpoint was either improvement of mixed peak oxygen consumption (pVO_2) by ≥1.5 mL/kg/min and ≥1 NYHA class reduction or a ≥3.0 mL/kg/min pVO_2 increase and no worsening of NYHA class. A significantly greater number of patients in the Camzyos arm achieved the primary endpoint at week 30 compared to placebo (37% vs. 17%, p=0.0005). Baseline LVEF and LVEF at week 38 after an eight-week drug washout period were compared and were similar among the groups. Syncope and dizziness were the most common adverse effects and occurred more frequently in the mavacamten group.
The safety and efficacy of Camzyos in certain populations and for extended time periods have not been evaluated. The safety and efficacy of Camzyos in pediatric patients has not been established. However, completed clinical trials have included patients who are 65 and older and have demonstrated similar safety and efficacy within this population. Trials regarding the long-term (≥1 year) safety and efficacy of Camzyos are currently lacking. The MAVA-LTE and DISCOVER-HCM trials plan to study mavacamten's long-term safety and efficacy.
Proposed criteria were presented to Geisinger Cardiology MTDM and the providers we consulted were in favor of decreasing the number of required alternatives.

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

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

Outcome: Camzyos is a pharmacy benefit and should be added to the brand tier with the following criteria:

- Medical record documentation that Camzyos is prescribed by a cardiologist **AND**
- Medical record documentation of age ≥18 years old **AND**
- Medical record documentation of diagnosis of NYHA class II-III obstructive hypertrophic cardiomyopathy **AND**
- Medical record documentation of left ventricular ejection fraction (LVEF) ≥55% **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two of the following: beta-blockers, non-dihydropyridine calcium channel blockers, or disopyramide **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

Authorization Duration: **Authorization Duration:** Initial approval will be for 6 months. Subsequent approvals are dependent upon the criteria listed below and will be allotted for 12 months.

Reauthorization Info:

- Medical record documentation of LVEF ≥50% **AND**
- Medical record documentation of clinical improvement or maintenance of condition.

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

COVID-19 CLASS REVIEW

COVID-19 Updates			
Brand Name	**Indication**	**Update**	**Manufacturer**
NEW APPROVALS			
Vaccines			
Novavax COVID-19 Vaccine, Adjuvanted	EUA ONLY For the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 12 years of age and older	-	Novavax, Inc.
UPDATES			
Vaccines			
Comirnaty	For active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.	FDA Full Approval for vaccination in individuals 12 years of age and older – Previously full approval was for 18 years and older EUA for individuals 6 months and older and for a single booster dose in individuals 12 years of age and older.	Pfizer, Inc.
Non-Vaccine Biologics			
Bebtelovimab	EUA ONLY For the treatment of mild-to-moderate COVID-19 in adults and pediatric patients	Purchasing of Bebtelovimab shifted to the private market beginning August	Eli Lilly and Company

	(12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.	15th, 2022 following depletion of 150,000 doses purchased by the US government in June 2022. Currently the only monoclonal antibody with an EUA effective against Omicron BA.5 subvariant.	
Olumiant	For the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive, or invasive mechanical ventilation, or ECMO	Received full FDA approval for adult patients EUA for pediatric patients 2 years to less than 18 years of age	Eli Lilly and Company
Lagevrio	EUA ONLY For the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.	Molnupiravir now under the brand name Lagevrio	Merck & Co, Inc.
Sotrovimab		Due to high frequency of Omicron BA.2 subvariant, not	GlaxoSmithKline LLC

		currently authorized in the US. Currently not available in Darwin which is consistent with the EUA status. No changes are needed at this time.	
Bamlanivimab/Etesevimab		Due to high frequency of Omicron variant, not currently authorized in the US. Currently not available in Darwin which is consistent with the EUA status. No changes are needed at this time.	Eli Lilly and Company
REGEN-COV, Casirivimab/imdevimab		Due to high frequency of Omicron variant, not currently authorized in the US. Currently not available in Darwin which is consistent with the EUA status. No changes are needed at this time.	Regeneron Pharmaceuticals, Inc.

Reccomentatons:

- Novavax COVID-19 Vaccine, Adjuvanted will be covered as a medical or pharmacy benefit and will not require a prior authorization
- Comirnaty is covered as a medical or pharmacy benefit and does not require a prior authorization.
- Bebtelovimab will be covered as a medical benefit and will be free to patients who qualify under the Emergency Use Authorization parameters issued by the FDA. It will not require a prior authorization.
- Lagevrio is a pharmacy benefit and is free to patients who qualify under the Emergency Use Authorization parameters issued by the FDA. It does not require a prior authorization and is currently on formulary to cover the cost of administration.
- The EUA for Olumiant is limited to inpatient use and Olumiant for the treatment of COVID-19 will be provided to inpatient pharmacies only by Lilly Authorized Specialty Distributors. Olumiant for the

treatment of COVID-19 will not be available at retail pharmacies and is not authorized for outpatient use. The following change is recommended to the note for the reviewer for the Commercial Policy 530.0 and the Part D Policy 686.0D for Olumiant: Note to Reviewer* If Olumiant is being prescribed for COVID-19, see the FDA website for the Olumiant Prescribing Information and Emergency Use Authorizations at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs for current FDA approved and EUA authorized use. At this time, Olumiant is authorized for inpatient use only for COVID-19 and would not be covered for outpatient use.

Outcome: The committee unanimously voted to accept the recommendations.

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

Updates

Rituximab

Recommendation: It is recommended to update the limitations under Rheumatoid Arthritis (RA) and the authorization duration under Chronic Immunothrombocytopenia (ITP) for Rituxan, Truxima, Ruxience and Riabni's policy (MBP 48.0) to accurately reflect dosing recommendations of the prescribing information and to align authorization durations across all indications for chronic use for rituximab. It is also recommended to update the alternatives section under Chronic Immunothrombocytopenia (ITP) for Rituxan, Truxima, Ruxience and Riabni's policy (MBP 48.0) for the Medicaid/Commercial/ Exchange/CHIP lines of business. Lastly it is recommended to update the alternatives section under Chronic Immunothrombocytopenia (ITP) for Rituxan as listed in the Medicare 2022 Part B Step Therapy policy to closely align with the American Society of Hematology guidelines for immune thrombocytopenia.

MBP 48.0 Rituxan (rituximab), Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), and Riabni (rituximab-arrx)

1. For Rheumatoid Arthritis:

   All of the following criteria must be met:

   - Physician documentation of a diagnosis of moderate to severe rheumatoid arthritis in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis; **AND**
   - At least 18 years of age or older; **AND**
   - Prescription written by a rheumatologist; **AND**
   - Medical record documentation that an effective dose of methotrexate will be continued during rituximab therapy; **AND**
   - Medical record documentation that Rituxan is not being used concurrently with a TNF blocker **AND**
   - Physician documentation of an inadequate response to 12 weeks of therapy with Humira*, Rinvoq*, OR Xeljanz*

   AND

   - For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

   ~~**LIMITATIONS:**~~

   ~~If criteria are met, approval will be limited to one course of therapy defined as two infusions, one given on day 1 and another on day 15.~~

~~Additional courses may be considered medically necessary if the following criteria are met:~~
- ~~At least 6 months has elapsed since the previous treatment course; **AND**~~
- ~~Physician documentation of improvement or lack or progression in the signs and symptoms of rheumatoid arthritis; **AND**~~
- ~~Physician documentation showing previous treatment course did not result in active infection.~~

2. For Chronic Immunothrombocytopenia (ITP):

All of the following criteria must be met:
- Diagnosis of primary chronic ITP **AND**
- Platelet count of < 30,000/mm^3 with active bleeding; or platelet count < 30,000/mm^3 and a documented history of significant bleeding**;** or platelet count < 20,000/mm^3 **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids and/or IVIg*, AND splenectomy (*prior authorization required)

AND
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

~~**Authorization Duration*:** If patient meets criteria for coverage, authorization will be given for one month of treatment with rituximab.~~

AUTHORIZATION DURATION:
For Multiple Sclerosis: 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.

For all other indications: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate ~~(*except for the diagnosis for ITP)~~. 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 **AND**
- For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

Outcome: The committee unanimously voted to accept the recommendation

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

Administrative Medical Drug Policy Update

Recommendation: It is recommended to update the Administrative Medical Drug Policy (MBP 1.0) to adequately address policy and procedure pertaining to the medical benefit.

MBP 1.0 Administrative Medical Drug Policy

I. Policy:

Administrative Medical Drug Policy

II. Purpose/Objective:

1. To define the processes and procedures followed by Geisinger Health Plan for coverage determinations.
2. To provide a policy of coverage regarding medical benefit drugs without specific coverage criteria.
3. To provide a policy of coverage regarding medical benefit drugs with quantity limits.
4. To provide a policy of coverage regarding medical benefit drugs with claims edits.
5. To provide reference to a policy of coverage regarding medical benefit drugs with site of care requirements.

III. Responsibility:

A. Medical Directors

B. Medical Management

C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

1. FDA – Food and Drug Administration.
2. Prescribing healthcare professional – a person who writes, gives or orders medical drugs and is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
3. Providing healthcare provider – a person or entity who administers and/or dispenses medications and is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. GHP – Geisinger Health Plan or “Plan”
5. Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
    a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
    b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
    c. in accordance with current standards good medical treatment practiced by the general medical

community;
   d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
   e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient
6. Coverage Determination – A decision of coverage for a medication (approval/denial)
7. Member – Individual who has enlisted in the benefit
8. CPhT – Certified pharmacy technician
9. LPN – Licensed practical nurse
10. Off-label drug use - use of a drug that has been approved by the Food and Drug Administration (FDA) for other indications, treatment regimens or in patient populations that are not specifically included in the approved labeling.
11. Orphan-drug - a designation granted by the FDA under the Orphan Drug Act of 1983. This designation is granted to a drug or biologic agent intended to treat or prevent a rare disease or condition, defined in the Rare Diseases Act of 2002 as one which affects less than 200,000 people in the United States and for which there is no reasonable expectation that the cost of developing the drug would be recovered from the sale of the drug in the United States

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance

Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

DESCRIPTION:

This policy explains how coverage decisions are determined for GHP members who have medical drug benefits, including Commercial, Affordable Care Act (ACA), GHP Kids, Self-Insured plans, Medicare and Medicaid, unless a specific limitation or exception exists. Coverage exceptions include decisions about the medical necessity of a specific drug, decisions about drugs exceeding quantity limits, and decisions whether a member has satisfied prior authorization requirements, site of care requirements, or claims edit requirements.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

A. Coverage Determination Procedure
   1. A request may be initiated for an exception in accordance with the following:

i. Requests should be directed to the Department of Pharmacy Services
ii. Information needed for a determination include, but is not limited to, the following:
    1. Caller's name and telephone number;
    2. Member's medical record number and insurance identification number;
    3. Prescribing and providing healthcare provider's name and telephone number;
    4. The product and exception requested;
    5. Clinical rationale including medical records, laboratory data, past treatment history and other documentation, as determined by the Plan to be relevant.

2. Requests for exception will be reviewed as follows:
    i. A Certified Pharmacy Technician (CPhT) or License Practical Nurse (LPN), under the supervision of a Health Plan Pharmacist, will perform an initial review of medical record documentation and treatment history to recommend approval or denial of requests where there are explicit utilization management criteria and no clinical judgement is required.
        1. If the request for exception is approved, no further action will be required on the part of the Health Plan Pharmacist or the Licensed Physician (dependent upon the exception requested).
        2. If the CPhT or LPN recommends denial upon initial review, the requests will be forwarded to a Health Plan Pharmacist for review.
    ii. For all requests where clinical judgement is required, explicit utilization management criteria do not exist, or those which a CPhT or LPN recommends denial (or approval, dependent upon the determination requested), a Health Plan Pharmacist will perform an initial review of medical record documentation and treatment history to recommend approval or denial. The request will be approved if, in the professional judgment of the pharmacist reviewer, the services are medically necessary to meet the medical needs of the member of the request.
        1. If the request for exception is approved, no further action will be required on the part of the Licensed Physician.
        2. If the Health Plan Pharmacist recommends denial upon initial review, the request will be forwarded to a Licensed Physician for review.
    iii. A Licensed Physician shall make the final decision in all instances where a Health Plan Pharmacist recommends denial. The request will be approved if, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member of the request.
3. Documentation of the determination of coverage and the notifications will take place within GHP coverage determination decision making or customer service documentation tool(s).

B. Off-Label Requests
1. Off-label drug use for a medical drug is considered to be medically necessary when **all** of the following criteria are met:
    i. The drug has been approved by the FDA for at least one indication; **AND**
    ii. The drug is being prescribed to treat a condition not listed in the product labeling, but for which treatment is medically necessary; **AND**
    iii. Conventional therapies have been tried and failed, are contraindicated, or do not exist; **AND**
    iv. The proposed drug use is supported by any one or more of the following:
        - The National Comprehensive Cancer Network Practice Guidelines™ in Oncology category 1, 2A, or 2B recommendation; **OR**
        - The National Comprehensive Cancer Network Drug & Biologics Compendium™ category of Evidence and consensus 1, 2A, or 2B; **OR**
        - The American Hospital Formulary Service – Drug Information; **OR**
        - Thompson Micromedex DrugDex Compendium (DrugDex®) class I, IIa, or IIb indication; **OR**

- Elsevier Gold Standard's Clinical Pharmacology Compendium (Clinical Pharmacology®); **OR**
- Indication is listed in Lexi-Drugs as "Use: Off-Label" and rated as "Evidence Level A"

2. If a medical policy exists for a specific drug, reference should be made to that document for information regarding the FDA approved use(s) of that drug. When a clinical trial is open for accrual that provides the drug under consideration for the indication requested, and when the insured individual meets the eligibility requirements of that trial, providers are encouraged to consider that option.

C. Quantity Limit Exceptions
1. A quantity limit exception may be made for members who meet the following criteria:
   i. Medical record documentation that requested dose cannot be achieved by using a formulary alternative (e.g. use of one 90mg syringe in place of two 45mg syringes) **AND**
   ii. Medical record documentation that prescribed dosage does not exceed those approved by the Food and Drug Administration (FDA) or accepted standards of care **AND**
   iii. If request is for dose that exceeds Food and Drug Administration (FDA) approved labeling, 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 that exceeds FDA approved labeling **AND**
   iv. Medical record documentation that current quantity limit has been ineffective in management of member's condition or is likely to be ineffective or adversely affect the patient's compliance based on clinical evidence & the known physical and mental characteristics of the member

D. Claims Editing Process
1. A claim edit is developed to ensure the drug is:
   i. Used for industry accepted indications – both on- and off-label.
   ii. Dosed appropriately based on the specific diagnosis.
   iii. Administered at a frequency that is appropriate for the diagnosis.
   iv. Given in accordance with any lifetime maximum units, visits and/or administrations.
   v. Administered to the appropriate age group.
   vi. Administered by an appropriate route.
   vii. Given in conjunction with appropriate laboratory studies and/or monitoring.
   viii. Not given in conjunction with other drugs that might cause adverse drug interactions.
   ix. Reported with an appropriate amount if billed as drug wastage.
   x. Reported with the appropriate National Drug Code (NDC).
2. A review for the medical necessity of a claim not having met requirements set forth by a claim edit shall have the use supported by one or more of the following:
   i. Manufacturer's prescribing information
   ii. Elsevier Gold Standard's Clinical Pharmacology
   iii. Thomson MICROMEDEX® (DRUGDEX®, DrugPoints®)
   iv. American Hospital Formulary System (AHFS) DI
   v. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

E. Site of Care
1. Medical benefit policy (MBP) 181.0 provides a policy of coverage regarding the use of hospital based outpatient facilities as a site of care for drugs that require administration via intravenous infusion or injection for participating lines of business. See MBP 181.0 for information regarding the medical necessity of site of care.

Outcome: The committee unanimously voted to accept the recommendation

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

September 2022 P&T DUR/Adherence Update

Discussion: the September 2022 P&T DUR/Adherence Updatewas presented to the Committee for review.

Outcome: No questions or comments.

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 15, 2022, to August 25, 2022. Responses were received from 27 members (out of 47) 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.

Breyanzi (lisocabtagene maraleucel)

Breyanzi is a CD19-directed genetically modified autologous T cell immunotherapy now indicated for the treatment of adult patients with large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have:

- Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy.
- Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age.

There are no changes recommended to the formulary placement or authorization duration of Breyanzi. It is recommended that the following prior authorization criteria be changed for Medical Benefit Policy 228.0 to incorporate the new indication:

- Medical record documentation that Breyanzi is prescribed by a hematologist/oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy AND
- Medical record documentation of one of the following diagnoses:
    - o High-grade B-cell lymphoma OR
    - o Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma) OR
    - o Primary mediastinal large B-cell lymphoma OR
    - o Follicular lymphoma grade 3B

AND

- One of the following:
    - o Medical record documentation of two or more lines of prior systemic therapy ~~AND~~ OR

~~• Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy~~

- o Medical record documentation of refractory disease to first-line chemoimmunotherapy OR
- o Medical record documentation of relapse within 12 months of first-line chemoimmunotherapy OR
- o Medical record documentation of relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age

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Kymriah (tisagenlecleucel)

Kymriah is a CD19-direct genetically modified autologous T-cell immunotherapy that is now indicated for the treatment of adults with relapsed or refractory (r/r) follicular lymphoma (FL) after two or more lines of systemic therapy.

No changes are recommended to the formulary placement or authorization duration of Kymriah. It is recommended that the following prior authorization criteria be added to the Medical Benefit Policy to incorporate the new indication:

Follicular Lymphoma, Relapsed or Refractory (r/r FL)

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is 18 years of age or older AND
- Medical record documentation of a diagnosis of relapsed or refractory follicular lymphoma (FL) 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

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Kyprolis (carfilzomib)

Kyprolis is now indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy in combination with Isatuximab and dexamethasone.

There are no changes recommended to the formulary placement or auth duration for Kyprolis. The following changes are recommended to the prior authorization criteria:

- Must be prescribed by hematologist or oncologist AND
- Medical record documentation of relapsed or refractory multiple myeloma AND
- Medical record documentation of prior treatment with at least one therapy AND
- Medical record documentation that Kyprolis will be used:
  - o As monotherapy OR
  - o In combination with dexamethasone OR
  - o In combination with dexamethasone and lenalidomide OR
  - o In combination with daratumumab (Darzalex) and dexamethasone OR
  - o In combination with daratumumab and hyaluronidase-fihj (Darzalex Faspro) and dexamethasone OR
  - o In combination with Isatuximab and dexamethasone

Ultomiris (ravulizumab-cwvz)

Ultomiris is now FDA approved for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody–positive.

There are no changes recommended to the formulary placement for Ultomiris. The following changes are recommended to the prior authorization criteria and authorization duration:

For the treatment of Myasthenia Gravis:
• Medical record documentation supporting a confirmed diagnosis of anti-acetylcholine receptor (AchR) antibody positive myasthenia gravis AND
• Prescribed by or in consultation with a neuromuscular specialist AND
• Medical record documentation of medical team recommending meningococcal vaccine according to the most current Advisory Committee on Immunization Practices (ACIP) recommendations AND
• Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IV AND
• Medical record documentation Myasthenia Gravis-Activities of Daily Living (MG-ADL) score of 6 or more at baseline AND
• Medical record documentation of age > 18 years AND
• Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids AND
• Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies OR has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) AND
• Medical record documentation of failure on, intolerance to, or contraindication to intravenous immunoglobulin (IVIG)
• Medical record documentation of failure on, intolerance to, or contraindication to Vyvgart.

AUTHORIZATION DURATION: Initial approval will be given for six months. Subsequent approvals will be for an additional six months and will require:
• Medical record documentation of continued disease improvement or lack of disease progression AND
• Medical record documentation that the member is responding positively to therapy as evidenced by a 2-point reduction in MG-ADL total score.

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

Note:
Class I myasthenia gravis is indicated by any eye muscle weakness, possible ptosis (drooping or falling of the upper eyelid) and no other evidence of muscle weakness elsewhere, Class II to IV include muscle weakness in areas of the body beyond the eye.

Corticosteroids: betamethasone, dexamethasone, methylprednisolone, prednisone
Immunosuppressants: azathioprine, mycophenolate, cyclosporine, Rituxan

Other recommendations: Based on available literature *removal* of the following criteria is recommended from the Soliris policy:
~~• Medical record documentation of failure on intolerance to, or contraindication to rituximab or rituximab biosimilar AND~~
~~• Medical record documentation of therapeutic failure on, intolerance to, or contraindication to cholinesterase inhibitors~~

The following criteria is recommended to be *added* to the Soliris policy:
• Medical record documentation of medical team recommending meningococcal vaccine according to the most current Advisory Committee on Immunization Practices (ACIP) recommendations AND
• Medical record documentation of failure on, intolerance to, or contraindication to Vyvgart.

The following criteria is recommended for *removal* from the Vyvgart policy:
~~• Medical record documentation of therapeutic failure on, intolerance to, or contraindication to cholinesterase inhibitors AND~~

~~• Medical record documentation of failure on intolerance to, or contraindication to rituximab or rituximab biosimilar~~

Veklury (remdesivir)

Veklury is now indicated for pediatric patients (infants 28 days of age and older and weighing at least 3 kg) who have positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are hospitalized OR not hospitalized, but have mild to moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.

There are no changes recommended to formulary placement of Veklury

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Zerbaxa (ceftolozane and tazobactam))

Zerbaxa is now indicated for use in combination with metronidazole for the treatment of adult and pediatric patients (birth to less than 18 years old) with complicated intra-abdominal infections (cIAI) caused by the following susceptible Gram-negative and Gram-positive microorganisms: Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Bacteroides fragilis, Streptococcus anginosus, Streptococcus constellatus, and Streptococcus salivarius.

It is recommended to make the following update to the medical benefit policy:

- o Medical record documentation that the member is greater than or equal to 18 years of age for the indication of Diagnosis of Hospital-acquired Bacterial Pneumonia or Ventilator-associated Bacterial Pneumonia (HABP/VABP) caused by Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, or Serratia marcescens.

Zulresso (brexanolone)

Zulresso is now indicated for the treatment of postpartum depression (PPD) in patients 15 years and older. Previously, it was approved for treatment of PPD in adult patients.

It is recommended to make the following update to the medical benefit policy:

- Prescribed by (or in consultation with) a psychiatrist AND
- Medical record documentation of age greater than or equal to 15 years AND
- Medical record documentation of a diagnosis postpartum depression (PPD) as defined by ALL of the following:
  - o Patient has a diagnosis of a major depressive episode AND
  - o Patient experienced onset of symptoms within the third trimester or within 4 weeks of delivery

AND

- Medical record documentation that patient is less than or equal to 6 months postpartum AND
- Medical record documentation that current depressive episode is moderate to severe based on a standardized and validated questionnaire/scale (e.g. a score of greater than 10 on the Patient Health Questionnaire (PHQ-9), a score of greater than or equal to 17 on the Hamilton Depression Rating Scale (HAM-D), etc.)

Meeting adjourned at 3:28 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on November 15th, 2022 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams