P&T Committee Meeting Minutes
Medicaid
May 17, 2022

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

Call to Order:
Dr Yarczower called the meeting to order at 1:02 p.m., Tuesday, July 19, 2022.

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

DRUG REVIEWS

Enjaymo (sutimlimab-jome)

Review: Enjaymo is a classical complement inhibitor indicated to decrease the need for red blood cell transfusion due to hemolysis in adults with cold agglutinin disease (CAD). CAD is a rare form of autoimmune hemolytic anemia characterized by the premature destruction of red blood cells (hemolysis) attributable to cold agglutinins (autoantibodies with an optimum temperature of 3–4 °C or 37–39 °F). Cold agglutinins trigger hemolysis when they are exposed to temperatures below normal core body temperature. Once a red blood cell is recognized by the cold-induced antibody, it will cause agglutination, or clumping. The red blood cells then become bound to complement. Once the red blood cells are bound to complement, they can be attacked and destroyed by other immune cells. This results in a hemolytic anemia. Most cases of CAD are due to immunoglobulin M (IgM) antibodies. CAD can be primary (meaning the cause is unknown) or secondary (due to another condition, most commonly an infectious disease [especially M. pneumoniae and Epstein-Barr virus infection] or immunoproliferative disease [e.g., non-Hodgkin's lymphoma, chronic lymphocytic leukemia]). The symptoms associated with CAD are generally triggered by exposure to cold temperatures and can be classified into hemolytic and circulatory symptoms. Hemolytic symptoms are characterized by paleness of the skin, fatigue, shortness of breath, dizziness, and palpitations. Severe hemolysis may lead to chest pain, deregulation of heart rate and blood pressure, jaundice, and dark-pigmented urine. Circulatory (or cold-induced) symptoms are characterized by coldness of the fingers and/or toes and painful bluish or reddish discoloration of the skin of the digits, ankles, and wrists (acrocyanosis or Raynaud's phenomenon). In severe cases, ulcers may develop on the extremities of digits. CAD can be diagnosed by laboratory tests. The following are required for diagnosis: Evidence of chronic hemolysis (examples: high reticulocyte count, High LDL, high indirect bilirubin, low haptoglobin), positive polyspecific direct antiglobulin test (DAT), positive monospecific DAT specific for C3d, and cold agglutinin titer ≥ 64 at 4 degrees Celsius. Enjaymo is an immunoglobulin G, subclass 4 (IgG4) monoclonal antibody that inhibits the classical complement pathway and specifically binds to complement protein component 1, s subcomponent (C1s), a serine protease which cleaves C4. Inhibition of the classical complement pathway at the level of C1s prevents deposition of complement opsonins on the surface of red blood cells, resulting in inhibition of hemolysis in patients with CAD. Enjaymo is the first and only approved treatment for people with CAD. Patients should be vaccinated against encapsulated bacteria (e.g., Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae subgroup B) at least 2 weeks prior to treatment, according to the most current recommendations for patients with persistent complement deficiencies. Enjaymo is administered weekly for the first 2 weeks, then every 2 weeks thereafter. The recommended dosage of Enjaymo is based on body weight. Patients weighing 39 kg to <75 kg receive a dose of 6500 mg by intravenous infusion. Patients weighing ≥75 kg receive a dose of 7500 mg by intravenous infusion. The treatment of CAD depends on the severity of the clinical manifestations. Avoidance of cold exposure, particularly to the head, face, and extremities, is necessary to decrease hemolysis and circulatory symptoms. If symptoms are mild or the destruction of red blood cells slows down, no additional treatment is warranted. About 25% of individuals will use supportive measures alone to manage their disease. However, if the rate of red blood cell destruction increases, additional management may be required. Symptomatic primary CAD (anemia, circulatory symptoms, and requirement for transfusion) is usually treated with off-label rituximab as first-line therapy. Rituximab depletes antibody-producing B cells and therefore can reduce the agglutination or clumping

of red blood cells. As monotherapy, rituximab is usually administered as a 375 mg/m2 once weekly via intravenous infusion for 4 doses. Single-agent rituximab has been shown to have an overall response rate of approximately 50% (complete responses are rare), with a median duration of response of around 6 to 11 months. While well tolerated, rituximab can take 1 to 2 months to show effects. Patients who respond to rituximab can repeat treatment once they progress. Rituximab can also be used in combination with chemotherapy agents, such as bendamustine or fludarabine, for patients who can tolerate chemotherapy. Rituximab+bendamustine therapy is the most used combination due to its lower relative toxicity. When administered rituximab 375 mg/m2 on Day 1 and bendamustine 90 mg/m2 on Days 1 and 2 as four 28-day cycles, this combination has shown a 71% overall response rate with 40% of patients achieving a complete response. The median response duration in one study was over 7 years. Plasmapheresis is another option and can remove cold agglutinins by removing IgM antibodies. This however does nothing to decrease IgM production. To date, no large trials have assessed its efficacy in CAD, so plasmapheresis is largely reserved as a temporary or emergency treatment. Transfusions are used when indicated, with use being more common in winter months due to cold temperatures and infection. The efficacy of Enjaymo was assessed in an open-label, single-arm, 6-month trial in 24 patients (CARDINAL, NCT03347396). Following the completion of the 6-month treatment period, patients continued to receive Enjaymo in a long-term safety and durability of response extension phase for an additional 24 months. Efficacy was based on the proportion of patients who met the following criteria: an increase from baseline in Hgb level ≥2 g/dL or a Hgb level ≥12 g/dL at the treatment assessment time point (mean value from Weeks 23, 25, and 26), no blood transfusion from Week 5 through Week 26, and no treatment for CAD beyond what was permitted per protocol from Week 5 through Week 26. Overall, 71% of patients (n = 17) remained transfusion-free from Week 5 to Week 26. An increase in mean hemoglobin level of 2.29 g/dL (SE: 0.308) was observed at Week 3 and 3.18 g/dL (SE: 0.476) at treatment assessment time point.

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

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

Outcome: Enjaymo will be a medical benefit that will be managed by GHP. Enjaymo should not be added to the GHP Family pharmacy formulary. The following prior authorization criteria will apply:

- Documentation of age greater than or equal to 18 years AND
- Medical record documentation that Enjaymo is prescribed by or in consultation with hematologist AND
- Medical record documentation of a diagnosis of primary cold agglutinin disease (CAD) confirmed by all of the following:
    - Evidence of chronic hemolysis (examples: high reticulocyte count, High LDL, high indirect bilirubin, low haptoglobin) AND
    - Positive polyspecific direct antiglobulin test (DAT) AND
    - Positive monospecific DAT specific for C3d AND
    - Cold agglutinin titer ≥ 64 at 4 degrees Celsius

AND

- Hemoglobin ≤ 10.0 g/dL OR transfusion dependent for new starts AND
- History of at least one blood transfusion within 6 months of starting Enjaymo AND
- Medical record documentation that secondary causes of CAD have been ruled out AND
- Medical record documentation of a prescribed dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature AND
- Medical record documentation that Enjaymo will not be used in combination with rituximab ± bendamustine or fludarabine AND

- Medical record documentation that patient is vaccinated against encapsulated bacteria (e.g., *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* subgroup B) at least 2 weeks prior to treatment
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab ± bendamustine or fludarabine

Authorization Duration: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of the treated indication at six (6) months of Enjaymo therapy is required. After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of the treated indication while on Enjaymo therapy.

Attention Reviewer: Abrupt discontinuation of Enjaymo therapy may result in a recurrence of hemolysis unless the underlying condition causing cold agglutinin production has been treated.

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

Gamastan (intramuscular immune globulin (human))

Review: FDA Approved Indication

- Gamastan is a human immune globulin intramuscular solution indicated:
  - For prophylaxis following exposure to hepatitis A. The prophylactic value of Gamastan is greatest when given before or soon after exposure to hepatitis A. Gamastan is not indicated in persons with clinical manifestations of hepatitis A or in those exposed more than 2 weeks previously.
  - To prevent or modify measles in a susceptible person exposed fewer than 6 days previously. A susceptible person is one who has not been vaccinated and has not had measles previously. If a susceptible child who is immunocompromised is exposed to measles it is recommended to give Gamastan immediately.
  - To modify varicella. Passive immunization against varicella in immunosuppressed patients is best accomplished by use of Varicella Zoster Immune Globulin (Human), however if unavailable Gamastan given promptly may also modify varicella.
  - To modify rubella in exposed women who will not consider a therapeutic abortion.
- Limitation of use
  - Gamastan is not standardized with respect to antibody titers against hepatitis B surface antigen (HBsAg) and must not be used for prophylaxis of viral hepatitis type B. Prophylactic treatment to prevent hepatitis B can best be accomplished with use of Hepatitis B Immune Globulin (Human), often in combination with Hepatitis B Vaccine.
  - Gamastan is not indicated for routine prophylaxis or treatment of rubella, poliomyelitis, mumps, or varicella.

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

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

Outcome: Gamastan is a medical benefit that will be GHP managed

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

Pyrukynd (mitapivat)

Review: Pyrukynd is an oral pyruvate kinase activator indicated for the treatment of hemolytic anemia in adult patients with pyruvate kinase deficiency (PKD). PKD is a rare, inherited genetic disorder characterized by a mutation in the pyruvate kinase liver and red blood cell (RBC) PKLR gene, resulting in reduced adenosine triphosphate (ATP), shortened RBC lifespan from their normal lifespan of 120 days to only a few days to weeks, and chronic hemolysis. PKD ranges in disease severity and presents with a range of symptoms, including fatigue, pale skin, jaundice, shortness of breath, and tachycardia. Patients can develop additional complications, including splenomegaly, iron overload secondary to blood transfusions, osteoporosis, and gallstones that can lead to a cholecystectomy. The disease prevalence is estimated at 1 per 20,000 in the Caucasian population. PKD can be diagnosed at birth or go undiagnosed into adulthood. Diagnosis of PKD is done through two diagnostic tests that are only available at specialized laboratories. The first test measures pyruvate kinase activity in RBCs (low activity indicative of PKD), while the second test detects mutations in the PKLR gene to help confirm the diagnosis. Pyrukynd is the first FDA-approved therapy for hemolytic anemia in patients with PKD. Pyrukynd allosterically binds to the pyruvate kinase enzyme, causing an increase in activity of pyruvate kinase. There are no alternative treatments approved for PKD. Supportive therapies have been used to manage PKD prior to Pyrukynd, including blood transfusions, folic acid supplementation, splenectomy, and iron chelation therapy. Pyrukynd is supplied as an oral tablet (5 mg, 20 mg, and 50 mg). The starting dose is 5 mg by mouth twice daily, titrated in 4-week increments to 20 mg twice daily then 50 mg twice daily, if needed. Patients may achieve and maintain normal hemoglobin at any dose; therefore, hemoglobin and transfusion requirements should be assessed before increasing the dose level. Pyrukynd was evaluated in two phase 3 clinical trials, the ACTIVATE trial and the ACTIVATE-T trial. The ACTIVATE trial was a multinational, randomized, double-blind, placebo-controlled trial in 80 adult patients with PKD not being regularly transfused. The ACTIVATE-T trial was a multinational, single-arm, open-label trial in 27 adult patients with PKD that required regular transfusions. In both trials, patients required at least 2 mutant alleles in the PKLR gene, at least 1 of those being a missense mutation. Patients were excluded from the trial if they were homozygous for the R479H mutation or had 2 non-missense mutations. All patients required a hemoglobin concentration less than 10.0 g/dL. In the ACTIVATE trial, patients were randomized 1:1 to Pyrukynd or placebo for 12 weeks. Pyrukynd was increased up to 50 mg twice daily during a 12-week dose titration phase. The primary endpoint was percentage of patients achieving a hemoglobin response (HR), defined as at least a 1.5 g/dL increase in hemoglobin from baseline that was sustained during at least 2 scheduled assessments without any transfusions. HR was achieved by 16 (40%) patients in the Pyrukynd group and 0 patients in the placebo group ($P<0.0001$). In the ACTIVATE-T trial, patients received Pyrukynd 50 mg twice daily for 24 weeks, following a 16-week dose titration phase. The primary endpoint was percentage of patients achieving a reduction in transfusion burden, defined as at least a 33% reduction in the number of RBC units transfused compared to the patient's normal transfusion burden. Reduction in transfusion burden was achieved by 9 (33%) patients (95% CI: 17, 54). Of the patients who achieved the primary endpoint, 6 (22%) patients did not require any transfusions during the treatment period (95% CI: 9, 42). Pyrukynd has a warning to avoid abrupt interruption or discontinuation of therapy to decrease the risk for acute hemolysis. The most common adverse reactions (> 10%) in the ACTIVATE trial were decreased estrone and estradiol in men, increased urate, back pain, and arthralgia. Serious adverse reactions (> 10%) that occurred in 1 patient each are atrial fibrillation, gastroenteritis, rib fracture, and musculoskeletal pain. Pyrukynd is a substrate of

CYP3A and may require dose adjustments when co-administered with moderate inhibitors and inducers. Co-administration of Pyrukynd with strong inhibitors, strong inducers, and substrates with narrow therapeutic indexes should be avoided. Pyrukynd use should be avoided in patients with moderate or severe hepatic impairment. Safety and efficacy have not been established in pediatrics, but there are phase 3 clinical trials planned in pediatric patients aged 1 years and older with PKD. Clinical studies did not include enough patients over 65 to determine response in geriatric patients.

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

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

Outcome: Pyrukynd is a pharmacy benefit that will be managed by GHP and should be added to the GHP Family pharmacy formulary at the Brand tier. The following prior authorization criteria should apply:

- Medical record documentation of age 18 years or older **AND**
- Medical record documentation of diagnosis of pyruvate kinase deficiency (PKD) **AND**
- Medical record documentation of at least 2 mutant alleles in the *PKLR* gene, with at least 1 being a missense mutation **AND**
- Medical record documentation that the member is not homozygous for the R479H mutation **AND**
- Medical record documentation that Pyrukynd is being prescribed by or in consultation with a hematologist **AND**
- Medical record documentation that the member required red blood cell (RBC) transfusions for hemolytic anemia due to PKD within the last 12 months **AND**
- Medical record documentation of hemoglobin level less than or equal to 10 g/dL

Authorization Duration: 6 months
Reauthorization Info Subsequent approvals will be for an additional 6 months. Reauthorization requires medical documentation of an increase in hemoglobin of 1.5 g/dL from baseline OR reduction in transfusion burden

Attention Reviewer: Abrupt discontinuation or interruption of Pyrukynd therapy may result in acute hemolysis and should be avoided.

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

FAST FACTS

Enhertu

Updated Indication: Enhertu is now indicated for the treatment of adult patients with unresectable or metastatic HER2- positive breast cancer who have received a prior anti-HER2 based regimen in the metastatic setting or in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within 6 months of completing therapy. Previously Enhertu had an accelerated approval for treatment of patients who had been treated with two or more prior anti-HER2-based regimens in the metastatic setting

Recommendation: There are no changes recommended to the formulary placement or auth duration for Enhertu. The following changes are recommended to the prior authorization criteria in Medical Benefit Policy 208.0 to incorporate the changes to the breast cancer indication.

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

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.

Opdivo and Yervoy

Updated Indication: Opdivo and Yervoy, used in combination, are now indicated for the first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC). Opdivo, in combination with fluoropyrimidine- and platinum- containing chemotherapy, is now also indicated as first-line treatment of adult patients with unresectable advanced or metastatic ESCC. Previously, Opdivo was indicated for the adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in adult patients who have received neoadjuvant chemoradiotherapy (CRT). It was also indicated for the treatment of adult patients with unresectable advanced, recurrent, or metastatic ESCC after prior fluoropyrimidine- and platinum-based chemotherapy. Previously, Yervoy was not indicated for the treatment of esophageal cancer

Recommendation: No changes are recommended to the formulary placement of Opdivo or Yervoy. It is recommended to edit esophageal squamous cell carcinoma criteria for Medical Benefit Policy 126.0. It is also recommended to add a section of esophageal squamous cell carcinoma to Medical Benefit Policy 91.0 for Yervoy to incorporate the new indication

Medical Benefit Policy 126.0 (Opdivo)

9. Esophageal Squamous Cell Carcinoma

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is 18 years of age or older AND
- One of the following:
    - Medical record documentation of unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC) AND
    - Medical record documentation of previous trial of fluoropyrimidine- and platinum-containing chemotherapy

    OR

    - Medical record documentation of unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) AND

- Medical record documentation that Opdivo will be given in combination with fluoropyrimidine- and platinum-containing chemotherapy OR in combination with ipilimumab (Yervoy) AND
- Medical record documentation that the regimen is being given as first-line treatment

Medical Benefit Policy 91.0 (Yervoy)

7. Esophageal Squamous Cell Carcinoma

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is 18 years of age or older AND
- Medical record documentation of unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) AND
- Medical record documentation that Yervoy is being given in combination with nivolumab (Opdivo)

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.

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

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

Ameluz

Recommendation: Upon annual review and PARP approval, it was found that updated Ameluz labeling requires use of Ameluz in combination with photodynamic therapy (PDT) using a BF-RhodoLED or RhodoLED® XL lamp. Previously, the only FDA approved lamp was the BF-RhodoLED lamp. To obtain DHS approval of MBP 149.0 Ameluz (aminolevulinic acid), GHP updated the Ameluz policy to include the new XL lamp.

No changes are recommended to the formulary placement of Ameluz at this time. It is recommended that MBP 149.0 is updated to account for the additional approved lamp as follows:

- Medical record documentation that Ameluz will be used in conjunction with the BF-RhodoLED lamp OR BF-RhodoLED XL lamp.

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.

Quantity Limit and Benlysta Update

Recommendation: It is recommended that the committee give a blanket approval to allow for the following verbiage to be added to the appropriate drug policies in the event that GHP proposes a quantity limit when DHS does not have a coded quantity limit. These changes will also apply to medical policies for shared indications to ensure consistency between medical and pharmacy policies.

- Medical record documentation that (drug) 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

On annual review, the following was added to MBP 90.0 (initial and reauthorization criteria) to ensure consistency with Pharmacy Policy 1409.0F which was updated in 2021 as part of the quantity limit process:

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

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.

Rituxan

Recommendation: It is recommended to modify reauthorization verbiage of Rituxan, Riabni, Truxima, and Ruxience's policy (MBP 48.0) to align with current strategy of having all members, regardless of diagnosis and if established on a non-preferred product, transition to a preferred biosimilar product for applicable lines of business.

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

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. **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).

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.

Geisinger DUR MCO Survey 2021

Discussion: the 2021 Geisinger DUR MCO Survey was 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.

JUNE ELECTRONIC VOTE

An electronic vote was held from June 15, 2022, to June 24, 2022. Responses were received from 30 members (out of 49) 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.

Fyarro (sirolimus protein-bound particles for injectable suspension) (albumin-bound)

Fyarro is an albumin-bound sirolimus intravenous formulation indicated for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

Fyarro is a medical benefit that will be managed by GHP. The following prior authorization criteria will apply:
• Medical record documentation of age greater than or equal to 18 years AND
• Medical record documentation that Fyarro is prescribed by a hematologist or oncologist AND
• Medical record documentation of locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa)

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 patient experiences toxicity or worsening of disease.

Pluvicto (lutetium Lu 177 [177Lu] vipivotide tetraxetan)

Pluvicto (lutetium Lu 177 [177Lu] vipivotide tetraxetan) is indicated for the treatment of adult patients with prostate specific membrane antigen (PSMA)–positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.

Pluvicto is a medical benefit that will be managed by GHP and will require a prior authorization. The following prior authorization criteria will apply:
• Medical record documentation that Pluvicto is prescribed by a hematologist or oncologist AND
• Medical record documentation of age greater than or equal to 18 years AND
• Medical record documentation of prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) AND

• Medical record documentation of prior treatment with an androgen-receptor pathway inhibitor and a taxane-based chemotherapy AND
• Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently OR member has had bilateral orchiectomy

GPI Level: GPI-12

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.

Macrilen (macimorelin)

Macrilen is a growth hormone (GH) secretagogue receptor agonist indicated for the diagnosis of adult growth hormone deficiency (AGHD).

Macrilen will be a medical benefit that will be managed by GHP. No prior authorization criteria will apply.

PreHevbrio (Hepatitis B Vaccine (Recombinant))

PreHevbrio is a vaccine indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older.

PreHevbrio will be covered as a medical or pharmacy benefit and will not require prior authorization. The following age limit should apply: 18 years and older (due to Vaccines for Children program age limit for GHP Family will be age 19 and older for pharmacy benefit)

Anjeso (meloxicam injection)

Anjeso is an NSAID indicated for use in adults for the management of moderate-to-severe pain.

Anjeso is a medical benefit that will be GHP managed. The following prior authorization criteria should apply:

• Medical record documentation of age greater than or equal to 18 years of age AND
• Medical record documentation of moderate-to-severe post-operative pain AND
• Medical record documentation of prescriber attestation that the patient requires therapy by an intravenous route of administration AND
• Medical record documentation that the total daily dose will not exceed 30 mg per day AND
• Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternative medications, one of which must be oral meloxicam
Authorization Duration: Approval will be for one (1) week and will be limited to one (1) treatment course (up to 30 mg per day for up to 7 days total) (Facets RX count 210, Darwin RX count 7).

Meeting adjourned at 5:15 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on September 20th, 2022 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams