P&T Committee Meeting Minutes
Medicaid
November 17, 2020

Present (via Skype):	**Absent:**
Bret Yarczower, MD, MBA – Chair Megan Ammon, Pharm.D Kristen Bender, Pharm.D. Kim Castelnovo Kimberly Clark, Pharm.D. Rajneel Farley, Pharm.D. Kelly Faust Pharm.D. Tricia Heitzman, Pharm.D. Nichole Hossler, MD Keith Hunsicker, Pharm.D. Kelli Hunsicker, Pharm.D Phillip Krebs, R.EEG T Perry Meadows, MD Jamie Miller, RPh Aubrielle Prater Pharm.D. Kimberly Reichard Pharm.D. Melissa Renn, Pharm.D. Angela Scarantino Kristen Scheib, Pharm.D. Michael Shepherd, MD Richard Silbert, MD Michael Spishock, RPh Todd Sponenberg, Pharm.D. Robert Strony, MD MBA Jill Stone, Pharm.D. Kevin Szczecina, RPh Adam Root (non-voting participant)	Kenneth Bertka, MD Holly Bones, Pharm.D. Dean Christian, MD Alyssa Cilia, RPh Michael Evans, RPh Jason Howay, Pharm.D. Steven Moscola, RPh Jonas Pearson, RPh William Seavey, Pharm.D

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:03 p.m., Thursday, September 17, 2020

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the September 15, 2020 minutes as written. Minutes approved unanimously. None were opposed.

QUANTITY LIMITS

The following authorization durations were presented and approved unanimously:

Drug	Formulary Therapeutic Recommendation
Onureg	12-month auth duration

Gavetro	12-month auth duration
Wakix	12-month auth duration

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

DRUG REVIEWS

Dojolvi (triheptanoin)

Review: Dojolvi is a medium-chain triglyceride indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD).

LC-FAODs are a group of rare, life-threatening autosomal recessive genetic disorders in which the body is unable to convert long-chain fatty acids into energy, resulting in the accumulation of potentially toxic fatty-acid intermediates in cells. The inability to produce energy from fatty acids can also lead to the severe depletion of glucose in the body, causing serious complications (e.g. cardiomyopathy, rhabdomyolysis, arrhythmias, hypoglycemia, liver failure). Current treatment options for LC-FAODs are limited and include avoidance of fasting, low-fat/high-carbohydrate diets, and MCT supplementation. MCT oil is a medical food product – the over-the-counter supplement contains a mixture of even-carbon fatty acid chains (8, 10, or 12 carbon atoms), which works in the treatment of LC-FOADs by generating acetyl-CoA.

Dojolvi is the first agent to be FDA-approved for the treatment of LC-FAOD. Dojolvi contains odd-number carbon chains and provides substrates for both acetyl-CoA (to initiate the TCA cycle) and propionyl-CoA (which additionally replenishes TCA cycle intermediates in a process known as anaplerosis). Unlike even-chain fatty acids, odd-fatty acids can be converted to new glucose through the Krebs cycle, which can potentially be beneficial when glucose levels are too low.

The recommended target daily dosage of Dojolvi is up to 35% of the patient's total prescribed DCI divided into at least four doses, to be administered with meals or snacks. Dojolvi provides 8.3 kcal/mL. The total daily dosage is converted to a volume of Dojolvi to be given in mL using the following calculation: Total daily dose (mL) = [patient's DCI (kcal) x target % dose of DCI] / 8.3 (kcal/mL of Dojolvi).

The NDA submission included an open open-label Phase 2 study in 29 patients; a long-term safety and efficacy extension study in 75 patients (including 20 patients who were previously naïve to Dojolvi); a retrospective medical record review of 20 original compassionate-use patients; data from 70 patients treated through expanded access; and a randomized controlled, investigator-sponsored study of 32 patients with LC-FAOD.

The Phase 2 single-arm, open-label study evaluated 29 pediatric and adult patients (age range: 10 months to 58 years) with LC-FAOD. The frequency of major clinical events (MCEs) (hospitalizations, ER visits, and emergency home interventions) due to rhabdomyolysis, hypoglycemia, and cardiomyopathy occurring during the 78 weeks of triheptanoin treatment was compared to events collected retrospectively from medical records for 78 weeks before triheptanoin initiation. At week 78, 48.1% reduction (P=0.021) in mean annualized rate of MCEs and 50.3% reduction (P=0.028) in mean annualized duration rate of all MCEs after 78 weeks of treatment, compared with mean annualized number and duration of events in the 18-24 months prior to treatment with triheptanoin. Hospitalizations due to rhabdomyolysis comprised the majority of events.

Data from the ongoing long-term safety and efficacy study have been reported and included a total of 75 patients, including 24 patients who were previously enrolled in the Phase 2 study, 20 naïve patients who had not been previously treated, and 31 patients from expanded access or investigator-sponsored trials. Patients who previously completed the Phase 2 company-sponsored study and rolled over to the extension study (n=24) have received treatment for an additional 78 weeks (minimum of 3 years of total treatment). Over the entire treatment period, patients had a 67% reduction in median annualized event rate and 66% reduction in the median annualized duration rate. Patient who were naïve to triheptanoin (n=20) at study entry have received up to 78 weeks of

treatment. These patients have demonstrated a 70% reduction in the median annualized event rate and an 80% reduction in the median annualized duration rate.

The efficacy of Dojolvi as a source of calories and fatty acids was evaluated in Study 3 (NCT01379625), a phase 2, 4-month, double-blind, randomized controlled study that compared Dojolvi (which contains 7-carbon chain fatty acids) to trioctanoin (which consists of 8-carbon chain fatty acids). The study enrolled 32 adult and pediatric patients with a confirmed diagnosis of LC-FAOD, as evidenced by at least one significant episode of rhabdomyolysis and at least two of the following diagnostic criteria: 1) disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma, 2) low enzyme activity in cultured fibroblasts, or 3) one or more known pathogenic mutations in CPT2, ACADVL, HADHA, or HADHB. After 4 months, patients in both groups had similar mean changes from baseline in left ventricular ejection fraction and wall mass on resting echocardiogram, as well as similar maximal heart rates on treadmill ergometry. Rates of rhabdomyolysis were similar between groups: five patients experienced 7 events of rhabdomyolysis in the Dojolvi group, and four patients experienced 7 events of rhabdomyolysis in the trioctanoin group. No differences were observed between the Dojolvi and trioctanoin groups in blood markers of metabolism including glucose, insulin, lactate, total serum, ketones, acylcarnitines, and serum-free fatty acid concentrations.

Dojolvi bears no black box warnings or contraindications. It carries warnings and precautions for feeding tube dysfunction and intestinal malabsorption in patients with pancreatic insufficiency. The most common adverse reactions to Dojolvi (≥ 10%) were abdominal pain, diarrhea, vomiting, and nausea. The safety and effectiveness of Dojolvi have been established in pediatric patients.

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

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

Outcome: It is recommended to not add Dojolvi to the GHP Family formulary. The following prior authorization criteria should apply.

- Prescription written by or in consultation with a metabolic disease specialist or a physician who specializes in the management of long-chain fatty acid oxidation disorders AND
- Medical record documentation of a diagnosis of long-chain fatty acid oxidation disorders (LC-FAOD) confirmed by at least two of the following:
  - Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma
  - Low enzyme activity in cultured fibroblasts
  - One or more known pathogenic mutations in a gene associated with a long-chain fatty acid oxidation disorder (e.g. *CPT2, ACADVL, HADHA,* or *HADHB)*

- Medical record documentation that the member is currently managed on a treatment regimen, which may include a low-fat, high carbohydrate; avoidance of fasting; and/or medium-chain triglyceride (MCT) oil.

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

*Signs of improvement for a patient with LC-FAOD can include any of the following, but are not limited to: gross motor development/motor function for infants and young children, exercise tolerance and endurance for older children and adults, and a decrease in the frequency of major medical episodes of hypoglycemia, rhabdomyolysis, and exacerbation of cardiomyopathy.

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

Uplizna (inebilizumab-cdon)

Review: Uplizna is a CD19-directed cytolytic antibody indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. Neuromyelitis optica spectrum disorder (NMOSD) is a very rare autoimmune disease, resulting from inflammation of the central nervous system leads to demyelination and axonal damage, mostly targeting the spinal cord and optic nerve.

Treatment is broken down into two sections: acute attacks and prevention of attacks. Patients are initially treated with high-dose IV methylprednisolone (1 gram for three to five consecutive days) for acute attacks. Experts believe that long-term therapy should be given to all NMOSD patients to prevent attacks. These therapies include rituximab, azathioprine, and mycophenolate. Soliris is FDA approved for the treatment of NMOSD in anti-AQP4 antibody positive patients. Uplizna and Enspryng (approval in August 2020, subQ monthly injection) are now available to treat the same population.

Uplizna is initially administered as an IV infusion of at 300 mg followed by a second dose of 300 mg 2 weeks later. Uplizna is then administered as a single 300 mg IV infusion every 6 months (starting 6 months from the first infusion).

The efficacy of Uplizna was established in a randomized, double-blind, placebo-controlled trial that enrolled a total of 230 patients with NMOSD; 213 patients who are anti-AQP4 antibody positive and 17 who are anti-AQP4 antibody negative. Patients included in the trial had a history of one or more relapses that required rescue therapy within the year prior to screening, or 2 or more relapses that required rescue therapy in 2 years prior to screening. Patients also were included if they had an Expanded Disability Status Scale (EDSS) score of 7.5 or less (patients with an EDSS score of 8.0 were eligible if they were deemed capable of participating). The EDSS scale ranges from 1 to 10 units of 0.5. The higher the number the worse the disability. Of the 213 patients enrolled anti-AQP4 antibody positive patients, 161 were randomized to receive treatment with Uplizna and 52 were randomized to receive placebo. Uplizna was administered according to the recommended dosage regimen. The primary efficacy endpoint was the time to onset of the first adjudicated relapse on or before Day 197. The time to first adjudicated relapse was significantly longer in patients treated with Uplizna compared to patients who received placebo. Inthe anti-AQP4 antibody positive population, Uplizna reduced the risk of NMOSD relapse by 77%. There was no evidence of benefit in patients who were anti-AQP4 antibody negative.

Uplizna is contraindicated in patients with a history of a life-threatening infusion reaction to Uplizna, active hepatitis B infection, and active or untreated latent tuberculosis. Uplizna has warning for infusion reactions, infections, reduction in immunoglobulins, and fetal risk. The most common adverse reactions (at least 10% of patients treated with Uplizna and greater than placebo) were urinary tract infection and arthralgia. The safety and effectiveness in pediatric patients have not been established.

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

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

Outcome: Uplizna is not managed by the PDL and will be covered as a medical benefit for GHP family members. The following prior authorization criteria should apply.

- Prescribed by or in consultation with a neurologist AND

- Medical record documentation that member is 18 years or older AND
- Medical record documentation of diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) AND
- Medical record documentation that member is anti-aquaporin-4 (AQP4) antibody positive AND
- Medical record documentation of failure on, intolerance to, or contraindication to rituximab or rituximab biosimilar

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

Quantity Limit:
Initial 12-month Authorization: Rx count of 3
Subsequent 12 month authorizations: 30 mL per 180 days; max qty supply: 30; min day supply: 168; max day supply: 180

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

Phexxi (lactic acid/citric acid/potassium bitartrate)

Review: Zepzelca is an alkylating agent that offers a second-line treatment option for patients with metastatic SCLC. It binds guanine residues in the minor groove of DNA, resulting in adduct formation and bending the DNA resulting in double strand breaks that lead to cell death. It has been shown to have antiproliferative and cytotoxic activity in multiple tumor cell lines.

The efficacy of Zepzelca was investigated in one cohort of a single arm, open-label, multi-cohort trial (Study B-005) in 105 adult patients with small cell lung cancer (SCLC) who had disease progression on or after platinum-based chemotherapy. Patients in the trial received Zepzelca 3.2 mg/m^2 by intravenous infusion every 21 days (one cycle) and received a median of 4 cycles of Zepzelca. All patients also received antiemetic prophylaxis. The major efficacy outcome, confirmed investigator-assessed overall response rate (ORR), showed 37 (35.2%) patients had an overall response and all were partial responses. The median duration of response was 5.3 months and investigator assessed median progression-free survival was 3.5 months in the overall population. At data cutoff, median overall survival was 9.3 months in the overall population. Post-hoc analysis of the 37 patients who had an initial objective response showed that median overall survival exceeded 1 year in the overall population.

There are no black box warnings for Zepzelca. Warnings and precautions for Zepzelca include myelosuppression, hepatotoxicity and embryo-fetal toxicity. The most common adverse reactions during clinical trials were leukopenia, lymphopenia, fatigue, anemia, neutropenia, thrombocytopenia, increased ALT and AST, nausea, decreased appetite, musculoskeletal pain, constipation, diarrhea, vomiting, cough, and dyspnea.

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

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

Outcome: Phexxi is a pharmacy benefit that will be managed by GHP and should not be added to the Medicaid pharmacy formulary. The following prior authorization criteria should apply:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives.

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

FAST FACTS

Ilaris (canakinumab)

Updated Indication: laris is now indicated for the treatment of Active Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older.

Recommendation: Make the following addition to the prior authorization criteria:

Active Still's Disease

Ilaris may be considered to be medically necessary in individuals 2 years of age and older with Systemic Juvenile Idiopathic Arthritis when the following criteria are met

- Must be prescribed by a rheumatologist **AND**
- Must not be used in conjunction with tumor necrosis factor inhibitors **AND**
- Medical record documentation of active Systemic Juvenile Idiopathic Arthritis (SJIA) diagnosed prior to age 16 years **AND**
- Medical record documentation of contraindication to, intolerance to or therapeutic failure on Actemra

Ilaris may be considered to be medically necessary in individuals 16 years of age and older with Adult Onset Still's Disease when the following criteria are met

- Must be prescribed by a rheumatologist **AND**
- Must not be used in conjunction with tumor necrosis factor inhibitors **AND**
    - Medical record documentation of Adult Onset Still's Disease diagnosed after age 16 years with active disease characterized by:
        - Disease activity based on Disease Activity Score 28 (DAS28) ≥ 3.2 **AND**
        - At least 4 painful and 4 swollen joints at screening and baseline

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 (nivolumab)/Yervoy (ipilimumab)

Updated Indication: Approved for use in comination for first-line treatment of adult patients with unresectable malignant pleural mesothelioma.

Recommendations: Update existing criteria to include use as first line treatment of adult patients with unresectable malignant pleural mesothelioma.

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.

Recarbrio (imipenem/cilastatin/relebactam)

Updated Indication: Recarbrio is now indicated for the treatment of patients 18 years of age and older with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, caused by the following susceptible gram-negative microorganisms: *Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Serratia marcescens.*

Recommendations: Include the new indication in the prior authorization policy.

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.

Sirturo (bedaquiline)

Updated Indication: Sirturo is a diarylquinolone antimycobacterial drug indicated as part of combination therapy in the treatment of adult and pediatric patients (5 years and older and weighing at least 15 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Reserve Sirturo for use when an effective treatment regimen cannot otherwise be provided. This indication is approved under accelerated approval based on time to sputum culture conversion. Previously Sirturo was indicated in adult and pediatric patients 12 years and older weighing at least 30 kg.

Recommendations: No changes are recommended to the formulary placement or authorization duration of Sirturo. The following changes are recommended to the criteria and quantity limit.
o Age greater than or equal to 5 years and weighing at least 15 kg

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

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UPDATE

Xyrem (Sodium Oxybate)

Recommendation: here are no changes recommended to formulary status or criteria, however it is recommended to add an authorization duration to reassess efficacy.
Authorization Duration:
Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following is required:

- Medical record documentation of reduction in frequency of cataplexy attacks OR
- Medical record documentation of reduction in symptoms of excessive daytime sleepiness

After the initial 12 month approval, subsequent approvals will be for a duration of 12 months. Reevaluation will be every 12 months requiring the following:

- Medical record documentation of continued or sustained reduction in frequency of cataplexy attacks OR
- Medical record documentation

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

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Santyl Ointment (collagenase)

Recommendation: Santyl ointment is a pharmacy benefit available at the Brand tier. Santyl ointment does not require a prior authorization. There are no changes to formulary status however, it is recommended to add a prior authorization with the following criteria.

- Medical record documentation that the member has been evaluated by a burn, a wound care specialist, or other specialist with experience in the management of severe wounds AND
- Medical record documentation of the wound length and width AND
- Medical record documentation of anticipated duration of therapy AND
- Medical record documentation that the prescribed dose is medically necessary based on the size and intended duration of therapy*

*Note: Please calculate the dose on the manufacturer's website to confirm it is within a medically appropriate range- https://santyl.com/hcp/dosing

Authorization Duration: Initial approval will be for 3 months. Subsequent approval will be for 3 months. Reauthorization will require medication record documentation that continued use of Santyl ointment is medically necessary because debridement of necrotic tissue is incomplete, and granulation of tissue is not well established.

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

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Minimum and Maximum Day Supply

Recommendation: PerformRx is able to code minimum and maximum day supplies for medications without GHP having to manually enter them into the authorizations. If a claim is billed less than the minimum day supply or over the maximum day supply, the claim will block. The following minimum and maximum day supplies will apply to all fills, unless an authorization is entered to override this.

Drug Name	Benefit	Min Day Supply	Max Day Supply
Abilify Maintena	Medical	28	30
Actemra	Pharmacy	28	28
Aristada 1064 mg	Medical	56	60
Aristada 441 mg	Medical	28	30

Aristada 662 mg	Medical	28	30
Aristada 882 mg	Medical	28	42
Benlysta subQ	Pharmacy	28	28
Boniva/Ibandronate	Medical	84	90
Botox	Medical	-	90
Cimzia syringe	Pharmacy	28	28
Cinqair	Medical	28	28
Cotellic	Pharmacy	28	28
Dysport	Medical	-	90
Eligard 22.5 mg	Medical	84	90
Eligard 30 mg	Medical	112	120
Eligard 45 mg	Medical	168	180
Eligard 7.5 mg	Medical	28	30
Enbrel	Pharmacy	28	28
Entyvio	Medical	56	56
Eylea	Medical	28	84
Farydak	Pharmacy	21	21
Fasenra	Medical	56	56
Firmagon	Medical	28	28
Forteo	Pharmacy	28	28
Galafold	Pharmacy	28	28
Humira	Pharmacy	28	28
Ibrance	Pharmacy	28	28
Ibrandronate	Pharmacy	28	30
Ilaris	Medical	28	28
Ilumya	Medical	84	84
Iluvien	Medical	1080	1095
Inflectra	Medical	28	56
Invega Sustenna	Medical	28	30
Invega Trinza	Medical	84	84
Kevzara	Pharmacy	28	28
Kisqali	Pharmacy	28	28
Kisqali Femara Co-Pack	Pharmacy	28	28
Kynamro	Pharmacy	28	28
Lemtrada	Medical	365	365
Lonsurf	Pharmacy	28	28
Lucentis	Medical	28	84
Lupaneta Pack 1 month	Medical	28	30
Lupaneta Pack 3 month	Medical	84	90
Lupron 22.5 mg	Medical	84	90
Lupron 3.75 mg	Medical	28	30

Lupron 30 mg	Medical	112	120
Lupron 45 mg	Medical	168	180
Lupron 7.5 mg	Medical	28	30
Lupron Deport-Ped 15 mg (1-month)	Medical	28	30
Lupron Depot-Ped 11.25 mg (1-month)	Medical	28	30
Lupron Depot-Ped 11.25 mg (3-month)	Medical	84	90
Lupron Depot-Ped 30 mg (3-month)	Medical	84	90
Lupron Depot-Ped 7.5 mg	Medical	28	30
Lurpon 11.25 mg	Medical	84	90
Macugen	Medical	42	42
Mavyret	Pharmacy	28	28
Medroxyprogesterone 104 mg/mL IM syringe	Pharmacy	84	98
Medroxyprogesterone 150 mg/mL IM syringe	Pharmacy	84	91
Myobloc	Medical	-	90
Ninlaro	Pharmacy	28	28
Nucala	Medical	28	28
Nucala prefilled syringe/auto-injector	Pharmacy	28	28
Nuvaring	Pharmacy	28	28
Ocrevus	Medical	180	180
Onpattro	Medical	21	21
Orencia	Pharmacy	28	28
Orencia	Medical	28	28
Perseris	Medical	28	30
Praluent	Pharmacy	28	28
Probuphine	Medical	168	180
Prolia	Medical	180	180
Reclast	Medical	365	365
Reflexis	Medical	28	56
Remicade	Medical	28	56
Repatha	Pharmacy	28	28
Retisert	Medical	900	900
Revlimid	Pharmacy	28	28
Risperdal	Medical	28	28
Rydapt	Pharmacy	28	28
Sandostatin LAR	Medical	28	28
Signifor LAR	Medical	28	28
Simponi	Pharmacy	28	28
Simponi Aria	Medical	56	56
Somatuline Depot	Medical	28	56
Spinraza	Medical	120	120
Stelara 45 mg	Pharmacy	84	84

Stelara 90 mg	Pharmacy	56	84
Stivarga	Pharmacy	28	28
Sublocade	Medical	28	30
Supprelin LA	Medical	365	365
Sutent	Pharmacy	28	42
Synagis	Medical	28	30
Takhzyro	Pharmacy	28	28
Taltz	Pharmacy	28	28
Trelstar 11.25 mg	Medical	84	84
Trelstar 22.5 mg	Medical	168	168
Trelstar 3.75 mg	Medical	28	28
Tremfya	Pharmacy	56	56
Triptodur	Medical	168	180
Tymlos	Pharmacy	30	30
Tysabri	Medical	28	56
Tyvaso	Pharmacy	28	28
Vivitrol	Medical	28	28
Xeomin	Medical	-	90
Xgeva	Medical	28	28
Yutiq	Medical	1080	1095
Zyprexa Relprevv	Medical	28	28

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

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August Electronic Vote

Due to the volume of full drug reviews, fast facts, and updates that must reviewed by the P&T Committee an additional electronic vote was held from October 22, 2020 to October 29, 2020. Responses were received from 21 members (out of 35) and all voted to approve.

The following was approved for GHP Family:

Drug	Recommendation
Blenrep	Blenrep is a medical benefit that will be managed by Geisinger and should not be added to the GHP Family pharmacy formulary. The following prior authorization criteria should apply: • Medical record documentation that Blenrep 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 a diagnosis of relapsed or refractory multiple myeloma AND

	• Medical record documentation of treatment with at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent **AUTHORIZATION DURATION:** Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.
Inqovi	Inqovi will be a pharmacy benefit and will not be managed by the PDL. It is recommended that Inqovi be added to the GHP Family formulary. Inqovi will require a prior authorization with the following criteria: • Prescription written by or in consultation with an oncologist or hematologist AND • Medical record documentation of age greater than or equal to 18 years AND • Medical record documentation of a diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups. **Authorization Duration:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease. **Quantity Limit**: 5 per 28 days; max qty supply: 5; min day supply: 28; max day supply: 28
Tecartus	Tecartus is a medical benefit and should not be added to the GHP Family pharmacy formulary. The following prior authorization criteria should apply: • Medical record documentation that Tecartus is prescribed by a hematologist/oncologist AND • Medical record documentation of age greater than or equal to 18 years AND • Medical record documentation of diagnosis of relapsed or refractory mantle cell lymphoma (MCL) **Authorization duration:** One-time authorization for one administration of Tecartus
Darzalex	No changes are recommended to the formulary placement or authorization duration for Darzalex. It is recommended that the following criterion be added to the policy: OR ▪ Medical record documentation that Darzalex will be prescribed in combination with carfilzomib (Kyprolis) and dexamethasone
Emplicity	There are no changes recommended to the formulary placement or authorization duration of Empliciti. It is recommended to add the following criterion to the policy: OR o Medical record documentation that the patient has previously been treated with at least two prior therapies for multiple myeloma, including lenalidomide and a proteasome inhibitor AND medical record documentation of use in combination with pomalidomide (Pomalyst) and dexamethasone

Kyprolis	No changes are recommended to the formulary placement or authorization duration for Kyprolis. It is recommended that the following criterion be added to the policy: • In combination with daratumumab (Darzalex) and dexamethasone
Freestyle Libre 2.0	The Freestyle Libre policy will be updated to include the following criteria and quantity limits: • If the request is for FreeStyle Libre: Medical record documentation of member age greater than or equal to 18 years OR • If the request is for FreeStyle Libre 2.0: Medical record documentation of member age greater than or equal to 4 years **QUANTITY LIMIT:** • FreeStyle Libre 2.0 reader: 1 reader every 2 years • FreeStyle Libre 2.0 sensors: 2 sensors per 28 days

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

Meeting adjourned at 3:31 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, January 19, 2020 at 1:00 via Microsoft Teams.