

**P&T Committee Meeting Minutes
Medicaid
January 21, 2020**

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

Call to Order:

Dr. Bret Yarczower called the meeting to order at 1:04 p.m., Tuesday, January 17, 2020.

Review and Approval of Minutes:

Dr. Bret Yarczower asked for a motion or approval to accept the November 19, 2019 minutes as written. Kevin Szczecina accepted the motion and Todd Sponenberg seconded the motion. None were opposed.

Kevin

DRUG REVIEWS

The following quantity limits were presented and approved:

Drug	Dosage Form	Formulary Therapeutic Recommendation	Outcome
Adhansia XR	Capsule	Add QL of 1 per day	Approved via electronic vote.
Bijuva	Tablet	Add QL of 1 per day	Approved via electronic vote.
Cequa	Drops	Add QL of 2 vials per day	Approved via electronic vote
Drizalma Sprinkle	Capsule	Add QL of 2 daily	Approved via electronic vote
Jornay PM	Capsule	Add QL of 1 daily	Approved via electronic vote
Kaspargo	Capsule	Add QL of 1 daily for 25 mg 50 mg 100 mg, QL of 2 daily for 200 mg	Approved via electronic vote
Ezallor	Capsule	Add QL of 1 daily	Approved via electronic vote
Qmiiz	Tablet	Add QL of 1 daily	Approved via electronic vote
Sympazan	Film	Add QL of 2 daily	Approved via electronic vote
Rinvoq	Tablet	Add QL of 1 daily	No comments or questions. Aubrielle Prater made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.
Brukinsa	Capsule	Add QL of 4 daily	No comments or questions. Todd Sponenberg made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.
Rybelsus	Tablet	Add QL of 30 within a 180 day period for 3 mg, 1 daily for 7 mg and 14 mg	No comments or questions. Keith Hunsicker made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

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

BAQSIMI (glucagon)

Review: Baqsimi is an intranasal formulation of glucagon indicated for the treatment of severe hypoglycemia in patients with diabetes age 4 years and older. Unlike other available formulations of glucagon, it doesn't require reconstitution and has been shown to have higher rates of successful administration in usability studies. It does not need to be inhaled since the Baqsimi is passively absorbed through the nasal mucosa and can be administered to patients who are unresponsive.

The efficacy of Baqsimi was investigated in two randomized multicenter open-label crossover non-inferiority studies in adults and one randomized, quasi-blinded, quasi-crossover study in pediatric patients. In adult studies, patients were given an insulin infusion in a controlled environment to induce severe hypoglycemia (plasma glucose levels < 60 mg/dL) then randomized to receive Baqsimi 3 mg intranasally or GlucaGen HypoKit 1 mg intramuscularly. Baqsimi was found to be non-inferior to IM GlucaGen HypoKit for the primary efficacy endpoint of successful treatment, defined as an increase in plasma glucose to ≥ 70 mg/dL or an increase of ≥ 20 mg/dL from plasma glucose nadir within 30 minutes of glucagon administration. The mean time to treatment success in minutes was 11.6 for Baqsimi and 9.9 for GlucaGen in Study 1 and 15.9 for Baqsimi and 12.1 for GlucaGen in Study 2.

In the pediatric study, patients were assigned to one of 3 cohorts determined by age. The two cohorts that included patients between the ages of 4 and 12, randomized patients 1:1 to receive one of two crossover treatment sequences of Baqsimi 2 and 3 mg or one treatment with IM GlucaGen HypoKit (0.5 or 1 mg dose based on weight). For the third cohort of patients between the age of 12 and 17, patients were randomized to receive Baqsimi 3 mg or IM GlucaGen. For all cohorts, patients were given an IV infusion to reduce plasma glucose level to < 80 mg/dL in a controlled environment. The primary efficacy endpoint, successful reversal of lowered blood glucose levels by at least 25 mg/dL within 20 minutes following glucagon administration, was achieved in 100% of the Baqsimi 3 mg compared to 100% in patients treated with IM GlucaGen HypoKit. One patient in the Baqsimi 2 mg treatment group did not achieve the primary endpoint attributed to the patient blowing his nose immediately following the administration of the Baqsimi 2 mg. This patient later achieved the primary endpoint when dosed with the Baqsimi 3 mg treatment. Mean times to plasma glucose increase by ≥ 25 mg/dL were comparable between all treatment groups.

Overall the adverse events during clinical trials with Baqsimi were comparable to the known safety profile of intramuscular glucagon with similar incidences of non-nasal/facial side effects reported between treatment groups. Patients treated with Baqsimi did have an increased incidence of headache, nasal congestion, and other nasal and facial adverse events compared to intramuscular glucagon which is expected given the route of administration of Baqsimi.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, clinical trials of Baqsimi did not include sufficient numbers of patients over age 65 years to determine if they respond differently than younger patients. Limited clinical trial experience has not identified differences in the responses between the elderly and younger patients.

Clinical Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Aubrielle Prater made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

Outcome: Baqsimi is a pharmacy benefit that will be added to the Brand tier. A QL of 2 units per 30 days will be added.

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

GVOKE (glucagon)

Review: Gvoke is a prefilled syringe or autoinjector containing glucagon indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and above. The easy administration of Gvoke reduces the steps required to prepare and administer glucagon in emergency situations arising from low blood sugar levels. Two multicenter, randomized, single-blind, two way crossover studies comparing Gvoke to Glucagon emergency kits in adult patients with Type 1 diabetes proved Gvoke to be non-inferior to Glucagon emergency kits. In both trials, patients received and IV infusion of insulin to a hypoglycemic state (plasma glucose < 50 mg/dL) then randomized 1:1 to receive Gvoke or Glucagon emergency kit. Gvoke achieved non-inferiority for the primary efficacy endpoint assessing patients for positive response, defined as an increase in plasma glucose to >70 mg/dL within 20 minutes of glucagon administration.

Clinical trials showed Gvoke had a similar safety profile to the known adverse event profile of glucagon. The most commonly reported adverse reactions reported during clinical trials in adult patients was nausea, vomiting, headache, and injection site edema (raised 1 mm or greater). Pediatric patients also reported abdominal pain, hypoglycemia, hyperglycemia, urticaria in addition to those reported in adult patients. These two studies, along with other pharmacokinetic studies, show that Gvoke is a safe and effective treatment option for hypoglycemia in adult and pediatric patients age 2 years and older with diabetes.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, clinical trials of Gvoke did not include sufficient numbers of patients 65 years of age and older to determine if they respond differently than younger patients. Limited clinical trial experience has not suggested any differences in responses between elderly and younger patients.

Clinical Discussion: No comments or questions. Tricia Heitzman made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Tricia Heitzman made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed.

Outcome: Gvoke is a pharmacy benefit that will be added to the Brand tier. A QL of 2 units per 30 days will be added.

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

TRIKAFTA (elexacaftor, tezacaftor, and ivacaftor)

Review: Trikafta (elexacaftor, tezacaftor, and ivacaftor) is indicated for the treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene. Trikafta is the first FDA-approved triple combination therapy available for CF and is the first indicated to treat patients who only have one F508del mutation (heterozygous mutations). It is anticipated that patients with at least one mutation in F508del make up approximately 90% of the 30,000 patients in the US with CF.

Previously approved therapies include Orkambi (lumacaftor/ivacaftor), which is only indicated for patients who are homozygous for the *F508del* mutation in the *CFTR* gene; Symdeko (tezacaftor/ivacaftor), which is indicated for patients who are homozygous for the *F508del* mutation or have at least one mutation in the *CFTR* gene; and Kalydeco (ivacaftor), which is not indicated for *F508del* mutations, but instead only for patients who have one mutation in the *CFTR* gene that is responsive to ivacaftor potentiation.

Trikafta is supplied as a fixed dose combination tablet containing elexacaftor 100 mg, tezacaftor 50 mg, and ivacaftor 75 mg, co-packaged with ivacaftor 150 mg tablets to be taken as two combination tablets in the morning and one ivacaftor tablet in the evening, approximately 12 hours apart. Efficacy was shown in two phase 3 trials, in which Trikafta improved FEV₁ and sweat chloride concentrations, amongst other efficacy measures, compared to placebo in heterozygous and homozygous patients and compared to Symdeko in homozygous patients at 4 weeks. Ongoing trials are investigating the efficacy of Trikafta in patients 6 to 11 years of age.

Warnings exist for elevated liver function tests, drug interactions with CYP3A inducers and inhibitors, and cataracts. Patients with severe hepatic impairment (Child-Pugh Class C) should not be treated with Trikafta. Use is not recommended in patients with moderate hepatic impairment (Child-Pugh Class B) unless the benefit exceeds the risk. If used in patients with moderate hepatic impairment, Trikafta should be used with caution and at a reduced dose.

Trikafta was approved by the FDA using all available programs, including Priority Review, Fast Track, Breakthrough Therapy, and orphan drug designations, to approve this therapy 5 months ahead of its review goal date. Guidelines have not yet been updated to include Trikafta. However, it is anticipated that Trikafta will be a mainstay of therapy and that some existing users of previously approved therapies will transition therapy to Trikafta due to inadequate response. Additionally, those experiencing adverse events to lumacaftor specifically may benefit from a change in therapy to Trikafta.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, clinical studies did not include any patients aged 65 years and older.

Clinical Discussion: No comments or questions. Todd Sponenberg made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Tricia Heitzman made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Outcome: Trikafta is a pharmacy benefit that will be added to the Brand tier. The following prior authorization criteria will apply:

- Medical record documentation that the patient is 12 years of age or older **AND**
- Medical record documentation of a diagnosis of cystic fibrosis **AND**
- Medical record documentation that the patient has at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene as determined by an FDA-cleared cystic fibrosis mutation test **AND**
- Medical record documentation that the medication is prescribed by, or in consultation with, a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.

QUANTITY LIMITS: 3 tablets per day

AUTHORIZATION DURATION: Initial approval will be for four (4) months and subsequent approvals will be for twelve (12) months. Additional authorizations will require medical record documentation of improvement or stabilization in the signs and symptoms of cystic fibrosis. The medication will no longer be covered if the member experiences worsening of disease.

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

OGIVRI (trastuzumab-dkst)

Review: Ogivri was the first FDA approved biosimilar for Herceptin, and the second available in the US following Kanjinti, and shares the FDA approved indications of Herceptin in the treatment of adjuvant breast cancer, metastatic breast cancer, and metastatic gastric cancer. Trastuzumab products, including Ogivri, combined with chemotherapy in patients with HER2 positive metastatic breast and gastric cancer has significantly improved response rates, progression free survival, and overall survival as well as improved survival in early HER2 positive breast cancer. NCCN recommends Ogivri as a substitution for trastuzumab in the treatment of breast cancer and gastric cancer (category 2A). NCCN does not currently recommend one biosimilar over another, stating that “an FDA-approved biosimilar is an appropriate substitution for trastuzumab”.

The approval of Ogivri was based on the results of pharmacokinetic studies comparing the pharmacokinetics and pharmacodynamics of Ogivri compared to Herceptin and a randomized, double-blind, parallel group study comparing the efficacy of Ogivri to Herceptin in patients with previously untreated HER2-positive metastatic breast cancer. In the clinical trial, 458 patients without previous exposure in the metastatic settings were randomized 1:1 to receive Ogivri or Herceptin every 3 weeks for a minimum 8 treatment cycles in combination with a taxane. After 8 cycles, chemotherapy could be discontinued and Ogivri or Herceptin treatments continued until disease progression or unacceptable toxicity. Ogivri was found to be statistically therapeutically equivalent to Herceptin for the primary efficacy endpoint of overall response rate at 24 weeks (69.6% vs. 64.0%, respectively). Secondary endpoints measuring time to first progression, progression free survival, and overall survival also showed no statistically significant differences between the two groups.

During clinical trials, adverse events occurred were comparable between Ogivri and Herceptin in regard to type, severity, and incidence. The most frequently reported Grade 3 or higher adverse events were neutropenia and leukopenia, and the most frequently reported non-hematologic adverse events were peripheral neuropathy, diarrhea, asthenia, and nausea. The safety and immunogenicity profiles of Ogivri were generally consistent with the known profile of Herceptin and no new safety concerns were identified during clinical trials. Ogivri shares the same warnings, precautions, and black box warnings as Herceptin.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, the risk of cardiac dysfunction was increased for patients over 65 compared to younger patients in clinical trials for both adjuvant and metastatic breast cancer. Differences in study design and data limitations precluded the determination of differences between the toxicity profiles in elderly and younger patients. In a clinical study of trastuzumab in metastatic breast cancer, no overall differences in safety and efficacy were observed.

Clinical Discussion: No comments or questions. Keith Hunsicker made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Keith Hunsicker made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed.

Outcome: Ogivri will be covered as a medical benefit.

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

XENLETA (lefamulin)

Review: Xenleta (lefamulin) is an antibiotic that is first in its class. It comes as a tablet or single-use vial for IV infusion. The treatment duration is 5 days for the tablet and 5-7 days for the IV formulation. It is FDA approved to treat community acquired bacterial pneumonia that is susceptible to *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydia pneumoniae*. Of the most common bacterial causes for CABP, as described by the Clinical Practice Guideline of the American Thoracic Society and Infectious Diseases Society of America. lefamulin only does not cover *Moraxella catarrhalis*. Lefamulin is not recommended for empiric therapy. In two clinical trials, LEAP 1 and LEAP 2, lefamulin was shown to be noninferior to moxifloxacin. The main adverse event for the oral formulation is GI upset, mainly diarrhea, but nausea and vomiting were also noted. The most common adverse event with the injection was injection site reactions. Lefamulin can cause QT prolongation, embryo-fetal toxicity, *Clostridium difficile*-associate diarrhea (CDAD), and inappropriate use may lead to the development of drug resistant bacteria. Lefamulin has interactions within the CYP3A and P-gp systems. Currently, Xenleta is not recommended in guidelines but the 2019 Clinical Practice Guideline of the American Thoracic Society and Infectious Diseases Society of America mentioned that further outpatient validation is needed.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, no dose adjustments necessary based on age.

Clinical Discussion: Steve commented that the IV product now has a unique J-code associated with it. 1 unit= 1 mg. Medical system should be configured with a RX count up to 2100 units. Tricia Heitzman made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

Outcome: Xenleta vials will be a medical benefit. Xenleta tablets should be added to the formulary on the Brand tier. The following prior authorization criteria should apply:

- Prescription is written by or in consultation with Infectious Disease **AND**
- Medical record documentation of a diagnosis of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydia pneumoniae* **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to **two (2)** alternative antibiotics shown to be susceptible on the culture and sensitivity **OR**
- Medical record documentation that treatment with Xenleta was initiated within an inpatient setting

QUANTITY LIMITS:

- Medical – Facets RX Count: up to 2100 units
- Medicare QL – 10 tablets per 5 days

AUTHORIZATION DURATION:

- Medical – Up to 7 days of total treatment
- Medicaid - 5 days

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

TRUXIMA (rituximab-abbs)

Review: Truxima is a biosimilar CD20-directed cytolytic antibody that is highly similar to the US-licensed reference product, Rituxan, indicated for the treatment of adults with chronic lymphocytic leukemia (CLL) and various instances of Non-Hodgkin's Lymphomas (NHL). Truxima targets the CD20 antigen on the surface of pre-B and mature B-lymphocytes to mediate B-cell lysis through complement dependent cytotoxicity and/or antibody dependent cell mediated cytotoxicity. Truxima is not accompanied with a hyaluronidase product to allow for subcutaneous administration at this time.

No new clinical trials were included in the Truxima prescribing information. The clinical trials in the prescribing information are consistent with those presented in the Rituxan prescribing information (for comparable indications). The Truxima 3.3 trial demonstrated non-inferiority of pharmacokinetic (PK) parameters of Truxima and reference rituximab as well as no significant differences between the two products in progression free survival and overall survival. The Truxima 3.4 trial demonstrated a statistically similar overall response between Truxima and reference rituximab. The secondary endpoints also showed no statistically significant differences. A study of real-world clinical effectiveness in DLBCL showed a 70% complete response and 23% partial response in patients treated with Truxima. A Phase III study in patients with rheumatoid arthritis indicated similar efficacy results between Truxima, US reference rituximab, and EU reference rituximab. A phase I study in patients with rheumatoid arthritis indicated equivalent PKs and highly similar efficacy endpoints when comparing Truxima to reference rituximab. An extension of the Phase I study indicated that patient can be effectively switched from reference rituximab to Truxima without changes in efficacy or safety (however, note that this trial does not meet necessary requirements as an interchangeability study for the associated designations).

The safety profile of Truxima was consistent with the known safety profile of reference rituximab, and no significant differences were seen between Truxima and reference rituximab in terms of safety endpoints. The most common reported adverse events included neutropenia, infusion related reactions, fatigue, anemia, peripheral neuropathy, nausea, constipation, and diarrhea. In the switching study, similar instances of anti-drug antibodies were detected between Truxima treated patients and reference rituximab treated patients. Patients were able to switch from reference rituximab to Truxima without changes in adverse events. Rapid infusion clinical trials indicated that Truxima can be administered via rapid infusion with effects similar to that of reference rituximab.

The NCCN guidelines indicate that Truxima may be a substitute for rituximab in the treatment of B-cell lymphomas and chronic lymphocytic leukemias/small lymphocytic lymphomas.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, no overall differences in safety or effectiveness were observed between patients age 65 years and older and younger patients with DLBCL and with low-grade or follicular NHL. In an exploratory analysis defined by age in CLL clinical trials, there was no observed

benefit from the addition of rituximab to FC among patients 70 years of age or older. These same patients had a higher incidence of grade 3 or 4 adverse reactions compared to younger patients.

Clinical Discussion: No comments or questions. Tricia Heitzman made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

Financial Discussion: No comments or questions. Tricia Heitzman made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

Outcome: Truxima will be a medical benefit requiring prior authorization to match its reference product Rituxan.

MBP 48.0

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 adalimumab (Humira); **AND**

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.

For Chronic Immunothrombocytopenia (ITP):

All of the following criteria must be met:

- Diagnosis of primary chronic ITP **AND**
- Platelet count of < 30,000/mm³ with active bleeding or < 20,000/mm³ with increased risk of bleeding **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND** IVIg* **AND** splenectomy (*prior authorization required)

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

For Chronic Lymphoid Leukemia:

Note: Prior authorization is not required for diagnosis codes C91.10, C91.11 and C91.12. In the event a requestor would like a medical necessity review completed the following criteria would apply:

- Medical record documentation of a diagnosis of Chronic Lymphocytic Leukemia (CLL)

For Microscopic Polyarteritis Nodosa

- Medical record documentation of a diagnosis of microscopic polyarteritis nodosa used in combination with glucocorticoids

For Wegner's Granulomatosis

- Medical record documentation of a diagnosis of Wegner's granulomatosis used in combination with glucocorticoids

For Non-Hodgkin Lymphoma

Note: Prior authorization is not required for diagnosis codes C82.00 through C85.99 and C86.0 through C88.9. In the event a requestor would like a medical necessity review completed the following criteria would apply:

- Medical record documentation of a diagnosis of Non-Hodgkin Lymphoma

For Multiple Sclerosis (MS)

Note: Prior authorization is not required for diagnosis code G35. In the event a requestor would like a medical necessity review completed the following criteria would apply:

- Medical record documentation of a diagnosis of Multiple Sclerosis

For Refractory Chronic Debilitating Myasthenia Gravis

- Medical record documentation of refractory Chronic Debilitating Myasthenia Gravis **AND**
- Prescribed by or in consultation with a neuromuscular specialist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one corticosteroid **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one cholinesterase inhibitor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one non-steroidal immunosuppressive therapy

*Note: Corticosteroids: betamethasone, dexamethasone, methylprednisolone, prednisone
Cholinesterase inhibitors: pyridostigmine, neostigmine
Immunosuppressants: azathioprine, mycophenolate, cyclosporine, Rituxan*

For Pemphigus Vulgaris (PV)

- Prescription written by a dermatologist **AND**
- Member is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of moderate to severe pemphigus vulgaris **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on corticosteroids **AND** a 12-week trial of at least one (1) nonsteroidal immunomodulatory medication (e.g. azathioprine, cyclophosphamide, or mycophenolate).

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 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 patient experiences toxicity or worsening of disease.

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

FAST FACTS

CLENPIQ (sodium picosulfate/magnesium oxide/anhydrous citric acid)

Updated Indication: Clenpiq is combination of sodium picosulfate, a stimulant laxative, and magnesium oxide and anhydrous citric acid, which form magnesium citrate, an osmotic laxative, indicated for cleansing of the colon as a preparation for colonoscopy in adults and pediatric patients ages 9 years and older.

Previously Clenpiq was indicated for cleansing the colon as preparation for colonoscopy in adults.

Current formulary status: Brand tier

Recommendation: Because there are currently no age restrictions on Clenpiq and it is available without a prior authorization, no changes will be made to Clenpiq at this time.

Discussion: No comments or questions.

Outcome: Megan Ammon made a motion to accept the recommendations as presented. Keith Hunsicker seconded the motion. None were opposed.

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 indicated as part of combination therapy in adult and pediatric patients (12 to less than 18 years of age and weighing at least 30 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Reserve Sirturo for use when an effective treatment regimen cannot otherwise be provided.

Limitations of Use: Do not use Sirturo for the treatment of latent, extrapulmonary or drug-sensitive tuberculosis or for the treatment of infections caused by non-tuberculous mycobacteria. Safety and efficacy of Sirturo in HIV-infected patients with MDR-TB have not been established, as clinical data are limited.

Previously, Sirturo was indicated for adult patients (≥ 18 years).

Current formulary status: Sirturo is a pharmacy benefit and is non-formulary, requiring a prior authorization.

Recommendation: There will be no updates to formulary placement at this time. However, it is recommended to update the prior authorization criteria to the following:

- Must be prescribed by infectious disease specialist AND
- Medical record documentation of one of the following:
 - Age greater than or equal to 18 years OR
 - Age greater than or equal to 12 years, weighing at least 30 kg AND
- Medical record documentation of resistance to isoniazid AND rifampin AND
- Medical record documentation that an effective treatment regimen cannot be attained with other available treatment options AND
- Medical record documentation of one of the following:
 - Sirturo is being prescribed in combination with at least 3 other drugs to which the patient's multi-drug resistant tuberculosis (MDR-TB) isolate has been shown to be susceptible to in vitro OR
 - If in vitro testing results are unavailable, Sirturo is being prescribed in combination with at least 4 other drugs to which the patient's MDR-TB isolate is likely to be susceptible

Approval will be given for a total duration of 24 weeks. A 28 day supply limit per fill will apply. A quantity limit of 56 tablets will be applied to the first fill. Subsequent fill will be for a total of 24 tablets.

Discussion: No comments or questions.

Outcome: Keith Hunsicker made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

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

ORKAMBI (ivacaftor/lumacaftor)

Updated Indication: Orkambi is indicated for the treatment of cystic fibrosis (CF) in patients age 2 years and older who are homozygous for the *F508del* mutation in the *CFTR* gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *F508del* mutation on both alleles of the *CFTR* gene.

Previously, Orkambi was only indicated in patients age 6 years and older.

Current formulary status: Orkambi is a pharmacy benefit available at the Specialty tier requiring a prior authorization.

Recommendation: There is no change to formulary placement at this time. The current policy reflects the updated indication and the quantity limits are appropriate, therefore no policy changes are recommended.

Discussion: No comments or questions.

Outcome: Keith Hunsicker made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

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

TECENTRIQ (atezolizumab)

Updated Indication: Tecentriq is now indicated in combination with paclitaxel protein-bound and carboplatin for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.

Previously it was indicated in combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations and for adult patients with metastatic NSCLC who have disease progression during and following platinum-containing chemotherapy. Tecentriq is also indicated for urothelial carcinoma, triple-negative breast cancer, and small cell lung cancer.

Current formulary status: Medical Benefit requiring prior authorization

Recommendation: There are no changes recommended to the current formulary placement or authorization duration of Tecentriq. The following changes are recommended to the prior authorization criteria to incorporate the new indication.

Medical Benefit Policy 144.0

2. Non-Small Cell Lung Cancer:

- Prescription written by an oncologist **AND**
 - Medical record documentation of a diagnosis of non-small cell lung cancer meeting one of the following situations:
 - Medical record documentation of disease progression during or following platinum-containing chemotherapy
- OR**
- Medical record documentation of disease progression on at least one FDA-approved therapy targeting EGFR or ALK if the patient has EGFR or ALK genomic tumor aberrations (e.g. mutation, deletion, insertion, etc.)
- OR**
- Medical record documentation of a non-squamous histologic subtype **AND**
 - Medical record documentation that Tecentriq will be given as first-line treatment **AND**
 - Medical record documentation that Tecentriq will be given in combination with one of the of the following:
 - bevacizumab, paclitaxel, **AND** carboplatin **OR**
 - paclitaxel protein-bound and carboplatin **AND**
 - Medical record documentation that the patient does not have an EGFR or ALK genomic tumor aberration

Discussion: No comments or questions.

Outcome: Keith Hunsicker made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

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

BENLYSTA (belimumab)

Updated Indication: Benlysta is a B-lymphocyte stimulator (BLyS)-specific inhibitor now indicated for the treatment of patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.

Previously, Benlysta was only indicated in adult patients.

Current formulary status: Benlysta vials: Medical benefit requiring prior authorization (GHP managed); Benlysta Subcutaneous (autoinjector or prefilled syringe): Brand tier requiring prior authorization (GHP managed)

Recommendation: There are no changes recommended to the current formulary placement of Benlysta. It is recommended to update the age in the Medical Benefit Policy 90.0 as follows

Medical Benefit Policy 90.0

Benlysta (belimumab) will be considered medically necessary for the treatment of **insured individuals** with active, autoantibody positive, systemic lupus erythematosus (SLE) when ALL of the following criteria are met:

- **Medical record documentation of age ≥ 5 years**

Other Recommendations: Benlysta administered subcutaneously is only indicated in adult patients and has not be updated to include pediatric patients. Since age is not currently addressed in the Benlysta subcutaneous policies, it is recommended to update GHP Family Policy 1409.0F with the following criteria:

GHP Family Policy 1409.0F Benlysta Subcutaneous

- **Medical record documentation of age ≥ 18 years**
- Medical record documentation a diagnosis of active systemic lupus erythematosus **AND**
- Medical record documentation that Benlysta SC is prescribed by a rheumatologist **AND**
- Medical record documentation of a positive ANA/anti-sdDNA antibody **AND**
- Medical record documentation that member is concurrently receiving a stable treatment regimen with prednisone, an NSAID, anti-malarial or immunosuppressant **AND**
- Medical record documentation of no active severe nephritis or central nervous system (CNS) involvement

QUANTITY LIMIT: Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 4 mL per 28 days

AUTHORIZATION DURATION: Each authorization will be for a period of 12 months. Re-review is required with medical record documentation showing a clinical benefit of one of the following:

- Improvement in functional impairment
- Decrease in the number of exacerbations since the start of Benlysta
- Decrease in the daily required dose of oral corticosteroids such as prednisone

Discussion: No comments or questions.

Outcome: Keith Hunsicker made a motion to accept the recommendations as presented. Melissa Renn seconded the motion. None were opposed.

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

UPDATES

DUR and Adherence updates for GHP Family

Drug Use Evaluations (DUEs)

- Statin Use in Persons with Diabetes DUE
 - This is the 2019 4th quarter MedImpact DUE for Commercial/Exchange and GHP Family
 - From this report, we identified **89 members** whose medication history was suggestive of the presence of diabetes and who were not receiving a statin drug during the previous three-month period.
 - Brandy P. completed the mail merge and sent out the letters to the member's providers on 12/5/2019.

- We will have Adam K. re-run this data in March 2020 to show us the effectiveness of the letter.
- Asthma DUE
 - This is the 2019 3rd quarter MedImpact DUE for all LOBs
 - From this report, we identified **90 members** who received 4 or more prescriptions for an asthma medication over a 12-month period but did not receive an asthma controller medication in that same 12-month period.
 - Brandy P. completed the mail merge and sent out the letters to the member's providers on 8/26/2019.
 - Adam K. was able to re-run the data on this population on 12/13/2019 and of the original 90 members that we sent letters to 81 members are still active. Of those 81 members 6 members now have a claim for an ACEI or ARB medication. This equates to 7.4% of the members.
- Congestive Heart Failure DUE
 - This is the 2019 2nd quarter MedImpact DUE for Commercial/Exchange and GHP Family
 - From this report, we identified **90 members** who have a presumed diagnosis of heart failure taking metoprolol succinate, carvedilol, or bisoprolol, and who were not taking an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin II receptor blocker (ARB) drug therapy in a 3-month timeframe.
 - Adam K. was able to re-run the data on this population on 9/25/2019 and of the original 90 members that we sent letters to 76 members are still active. Of those 76 members 7 members now have a claim for an ACEI or ARB medication. This equates to 9.2% of the members.
- Coronary Artery Disease DUE
 - This is the 2019 1st quarter MedImpact DUE for all LOBs
 - From this report, we identified **100 members** age 40-75 years who are not on a statin drug therapy in a 3-month timeframe and who have at least one of the following cardiovascular disease (CVD) risk factors: diabetes, hypertension, or smoking.
 - Brandy P. completed the mail merge and sent out the letters to the member's providers on 2/19/2019
 - Adam K. was able to re-run the data on this population and of the original 100 members that we sent letters to 94 members are still active. Of those 94 members 13 now have a claim for a statin medication. This equates to 13.8% of the members.

In Progress

- STENT Adherence Report
 - Currently in the process of functionalizing an adherence report to replace the current STENT program
 - We will identify members on an antiplatelet medication and then flag for betablocker and statin medication claims
 - We will assess adherence to all 3 medications and outreach to members with PDC <80% via letter and/or telephonic outreach
- HEDIS Reports
 - Statin Therapy for Patients with Diabetes (SPD)
 - In the process of functionalizing a report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
 - We will reach out to providers to initiate therapy and members to encourage adherence via letter
 - Statin Therapy for Patients with Cardiovascular Disease (SPC)

- In the process of functionalizing a report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
 - We will reach out to providers to initiate therapy and members to encourage adherence via letter

Ongoing

- DUR Duplicate Anticoagulant Report
 - We get this report weekly for **all LOBs** flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/pharmacy of the flagged members to confirm proper medication therapy.
 - For GHS30 in 2019 we have reviewed **107 members** and have made interventions for **5 members**
- Duplicate Specialty Therapy
 - We run an in-house retrospective report quarterly for **all LOBs** with help from Adam Kelchner and Aubrielle Prater. These members are identified and written up and sent to a medical director if follow up is needed.
 - For Family 2019-we have reviewed report through Q3 and have discussed 2 members with Dr. Yarczower for intervention
- Duplicate Buprenorphine Therapy
 - We are getting this report quarterly with help from Adam Kelchner. The report works to identify members who have at least a 7 day overlap period of generic Buprenorphine and generic Buprenorphine/naloxone products. Members identified as being on both products are being forwarded to Dr. Meadows for further outreach.
 - For GHS30 in 2019 we have reviewed **13 members** and no outreach is needed at this time.
- Suboxone with an Opioid Report
 - We are getting this report weekly for **all LOBs** from Adam Kelchner and we are writing up each member that flags on the report. These members are being forwarded to Dr. Meadows, and he is looking into whether it is appropriate to end the opioid authorizations still in place
 - For GHS30 in 2019, we have reviewed **131 new members**, and **37 members** were referred to Dr. Meadows
- Ending Opioid Authorizations
 - We are working on identifying members who have active opioid authorizations in place but have since started Buprenorphine therapy. The letter is sent to the members notifying them the opioid authorization has been ended due to the start of buprenorphine therapy.
 - For GHS30 in 2019, we have sent **36 members** letters notifying them of the end of their opioid authorization
- Medicaid Opioid Overutilization Report
 - We are getting this report monthly from MedImpact and we are writing up each member that flags on the report. We have been monitoring the members that are continuously showing up on the report by any change in their MED. For those members we deem appropriate we will send a letter to their PCP.
 - For GHS30 in 2019, we have reviewed **15 cases** so far, referred **2 patients** to Dr. Meadows, and did not send any prescriber letters
- FWA Reports

- We are getting this report **weekly** for **all LOBs** from Marie Strausser. We prepare this report by determining which claims need to be verified, and the Wilkes pharmacy students/GHP technicians have been making the calls to pharmacies.
- We review claims for anti-hypertensives, statins, 1-day supply, and inhalers
- For GHS30 in 2019, we have reviewed **494 cases** so far and **corrected 358 claims**, resulting in a **cost savings of \$24,310.13**
- Stent Antiplatelet Adherence Program
 - We continue to identify new stent patients for **all LOBs** at GMC/GWV/CMC/Susq and follow these members for 1 year after discharge to ensure adherence to their aspirin, beta blocker, antiplatelet, and statin therapy regimens.
 - For GHS30 in 2019, we have identified and outreached to **80 new stent patients**.
 - As of November 2019, this program was terminated and the STENT adherence report that is currently in progress will take its place
- Severity Report
 - This is a **monthly** report for **all LOBs** on members who have filled a medication that has a level one interaction with another medication they have a claim for
 - For GHS30 in 2019, we have sent letters to providers on **208 GHP Family members**
- Duplicate Antipsychotics
 - Adam Kelchner runs this report **quarterly**, and we send letters to the PCPs to address potential duplicate therapy issues.
 - For GHS30 in 2019, we have sent letters to **419 providers** so far concerning patients on multiple antipsychotics.
- Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
 - Kayla Stanishefski runs this report **monthly**, and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
 - HEDIS Specifications: The percentage of members 19-64 years of age during the measurement year with schizophrenia or schizoaffective disorder who were dispensed and remained on an antipsychotic medication for at least 80% of their treatment period.
 - For GHS30 in 2019, we have sent letters to **9 members** so far to encourage adherence.
- Enbrel Overutilization for Treating Plaque Psoriasis
 - A **monthly** report was created to determine members who have been overutilizing Enbrel twice weekly dosing as outlined by the FDA approved dose. One (1) member flagged on the February 2019 report, and the case was written up and sent to Dr. Yarczower on 2/13/19. The member has since switched to once weekly dosing.
 - We put in place QLs for Enbrel, so we should not be seeing these cases moving forward for new starts and at re-authorization periods for members currently on therapy
 - Working on follow up to ensure members are on proper therapy.
- Tobacco Cessation Program
 - Quarterly meeting with Wellness/MTDM RPhs to create a program that identifies GHP members who may benefit from tobacco cessation interventions/medications.
 - We gathered drug utilization data to determine which medications are being commonly prescribed and assessed proper utilization. We also informed the group of the Chantix updates approved at the March 2018 P&T meeting: Chantix was added to the Brand Tier for GHP Family without prior authorization.
 - We send a letter and resource pamphlet to members on prolonged tobacco cessation treatment to provide additional behavioral health support through Geisinger Health and Wellness.
 - For GHS30 in 2019 we have sent letters to **204 members** so far.

- Antidepressant Medication Management
 - Kayla Stanishefski runs this proactive HEDIS report **monthly**, and we send letters to the flagged members who appear non-adherent to their antidepressant medications.
 - For GHS30 in 2019, we have sent letters to **128 members** so far to encourage compliance.
- Asthma Medication Ratio
 - Kayla Stanishefski runs this proactive HEDIS report **monthly**, and we send letters to the flagged members who have a ratio of controller to total asthma medications of <0.5.
 - For GHS30 in 2019, we have sent letters to **35 members** so far to encourage compliance.
- Medication Management for People with Asthma
 - Kayla Stanishefski runs this proactive HEDIS report **monthly**, and we send letters to the flagged members who appear non-adherent to their asthma controller medications.
 - For GHS30 in 2019, we have sent letters to **172 members** so far to encourage compliance.
- Antipsychotic with Opioid Report
 - This is a **quarterly** report to identify **Medicaid** members with an overlap of 8 or more days between an opioid and antipsychotic medication.
 - We send a letter with claims data to both the opioid prescriber and the antipsychotic prescriber to encourage collaboration in medication management.
 - For GHS30 in 2019, we have identified **255 patients** and sent letters to **389 opioid prescribers** and **368 antipsychotic prescribers**.

The **2020 GHP Family Supplemental Formulary** was presented to the Committee for review. Todd Sponenberg made a motion to accept the recommendations as presented. Aubrielle Prater seconded the motion. None were opposed.

RESULTS OF ELECTRONIC VOTE

The following products were presented to the committee as an electronic vote in December of 2019. The below recommendations were approved by the P&T Committee on December 31, 2019 with 18 votes of approval. None were opposed.

KHAPZORY (levoleucovorin)

Recommendation: Khapzory is a medical benefit requiring prior authorization. Requests for coverage will require the following:

- Medical record documentation of intolerance to or contraindication to preferred levoleucovorin calcium products.

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

SIKLOS (hydroxyurea)

Recommendation: Siklos will be a pharmacy benefit and should be added to the formulary at the Brand tier. The following prior authorization criteria should apply.

- Prescription written by or in consultation with a hematologist AND
- Medical record documentation of the member being ≥ 2 years of age AND
- Medical record documentation of a diagnosis of sickle cell anemia AND
- Medical record documentation of intolerance to, or contraindication to, or therapeutic failure on a minimum 3 month trial of generic hydroxyurea.

Note:

Siklos can be dispersed in a small quantity of water in a teaspoon and administered immediately.

Hydroxyurea is available as 500 mg capsules.

Droxia (hydroxyurea) is available as 200 mg, 300 mg, 400 mg capsules.

Siklos is available in 100 mg and 1,000 mg tablets. The 100 mg tablets can be split into 2 parts (50 mg each). The 1,000 mg tablets can be split into 4 parts (250 mg each).

Other Recommendations: Endari requires “medical record documentation of therapeutic failure on, intolerance to, or contraindication to hydroxyurea”, with a note to the reviewer explaining per the NHLBI guidelines, a clinical response to treatment with hydroxyurea may take 3-6 months. To match the language for Siklos, it is recommended to replace that specific criterion with the following for all lines of business (when able).

“Medical record documentation of intolerance to, or contraindication to, or therapeutic failure on a minimum 3 month trial of generic hydroxyurea.”

The following note can be removed from the Endari policies for all lines of business:

“Per the NHLBI guidelines, a clinical response to treatment with hydroxyurea may take 3-6 months”

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

YUTIQ (fluocinolone acetonide)

Recommendation: Yutiq will be covered as a medical benefit not requiring prior authorization.

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

Meeting adjourned at 3:47 pm.

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, March 17, 2020 at 1:00 HCN3A & 3B Conference room

All of these meetings are scheduled to be held at Geisinger Health Plan, Hughes Center North and South Buildings; 108 Woodbine Lane; Danville, PA 17821.