Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:03 p.m., Tuesday, September 15, 2020.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the July 21st, 2020 and August 19th, 2020 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS
FINTEPLA (fenfluramine)

Review: Fintepla (fenfluramine) is the third agent FDA approved for the treatment of seizures associated with Dravet syndrome. It is a serotonergic modulator that is thought to reduce seizure activity by increasing extracellular levels of the neurotransmitter serotonin and exhibiting agonist activity at serotonin 5-HT2 receptors. Although originally marketed as a weight loss drug in the 1980s, Fintepla was shown to have some anti-epileptic activity in
case series and observation studies in children. It was subsequently withdrawn from the market in 1997 due to the risk of cardiac valve injury and pulmonary hypertension but continued to be available for treatment of Dravet syndrome through a compassionate use program. Some patients have been given fenfluramine for up to 30 years with reductions in seizure frequency and no evidence of cardiopulmonary disease. Additional clinical trials are evaluating the efficacy of Fintepla in the treatment of other epileptic disorders.

The efficacy of Fintepla was investigated in the combined results from two identical, randomized, double-blind, placebo-controlled trials in patients age 2-18 years with a clinical diagnosis of Dravet syndrome with seizures not completely controlled by current antiepileptic drugs that included at least one antiepileptic drug (AED). After a 6-week baseline period, patients were randomized 1:1:1 to receive Fintepla 0.2 mg/kg/day or 0.7 mg/kg/day or placebo. Patients receiving 0.7 mg/kg/day were titrated up over a two week period while the other two groups received dummy titrations. After the titration period, patients were maintained on their final dose for 12 weeks (14 total weeks in treatment period). In the primary and all key secondary endpoints, a dose response was observed between the two Fintepla groups studied. A statistically significant reduction in convulsive seizure frequency per 28 days occurred in both Fintepla 0.2 mg/kg/day and 0.7 mg/kg/day compared to placebo (-32.4 and -62.3 respectively). Patients in the Fintepla 0.7 mg/kg/day treatment group required significantly fewer days of rescue medication (0.9 vs 3.1 for placebo). Ten patients in the Fintepla 0.7 mg/kg/day treatment group, five patients in the 0.2 mg/kg/day group, and zero patients in the placebo group reported 1 or fewer seizures during the 14 week treatment period.

A third randomized, double blind, placebo-controlled study investigated the efficacy of Fintepla 0.4 mg/kg/day in combination with stiripentol and either clobazam, valproate, or both in 85 patients age 2 to 18 years of age with a clinical diagnosis of Dravet syndrome who were inadequately controlled on AED regimen which included stiripentol plus clobazam and/or valproate. This trial consisted of a 6-week baseline period to establish seizure frequency, followed by a three week titration period to a Fintepla dose of 0.4mg/kg/day (maximum of 17 mg/day) and additional 12 week maintenance period at a stable dose. The study achieved the primary endpoint with a 54.0% greater reduction in seizure frequency compared to placebo. Seizure-free intervals were also significantly longer in patients treated with Fintepla compared to placebo (22.0 days vs. 13.0 days). Five patients treated with Fintepla experienced only 1 seizure during the 15 week treatment period compared to 0 patients in the placebo group.

There is an association of valvular heart disease with the use of serotonergic drugs, including Fintepla, that have an affinity for serotonin 2b (5-HT2B) receptors which are located on mitral and aortic valves. The serotonin 2b (5-HT2B) receptor may also be implicated in pulmonary arterial hypertension. Because of the risk, cardiac monitoring with ECHO is required prior the start of treatment, during treatment, and after treatment with Fintepla concludes. Cardiac monitoring allows for early detection by identifying evidence of valvular heart disease and pulmonary arterial hypertension prior to development of symptoms. In clinical trials of Fintepla of up to 3 years in duration, no patients receiving Fintepla developed valvular heart disease or pulmonary hypertension. Fintepla is only available through the FINTEPLA REMS program. Patients must enroll in the program through their provider and receive a baseline echocardiogram (ECHO) prior to initiating Fintepla treatment as well as an ECHO every 6 months during treatment, and a final ECHO within 3-6 months of their last Fintepla dose should they terminate treatment. Fintepla will only be available through certified pharmacies participating in the FINTEPLA REMS which will ship the medication directly to the patients.

Other warnings and precautions include risk of suicidal thoughts and behaviors, serotonin syndrome, increases in blood pressure and hypertensive crisis, and somnolence, lethargy, and sedation potentiated by other CNS depressants. During clinical trials, the most common adverse events were decreased appetite, somnolence, sedation, lethargy, diarrhea, constipation, abnormal echocardiogram, fatigue, malaise, asthenia, ataxia, balance disorder, gait disturbance, blood pressure increased, drooling, salivary hypersecretion, pyrexia, upper respiratory tract infection, vomiting, decrease weight, fall, and status epilepticus.
A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: Bret asked what would be used to monitor response to therapy and if baseline seizure frequency should be established. Nothing other than decreased seizure frequency. No authorization duration being set in criteria, so therefore baseline frequency not needed. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Fintepla is a pharmacy benefit that will be added to the specialty tier or brand non-preferred tier for patients with a three-tier benefit for the Commercial, Marketplace, and GHP Kids formularies. The following prior authorization criteria will apply:

- Medical record documentation of age greater than or equal to 2 years AND
- Medical record documentation that Fintepla is written by a neurologist AND
- Medical record documentation of a diagnosis of Dravet Syndrome AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary alternatives.

QUANTITY LIMIT: 12 mL per day

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

RUKOBA (fostemavir)

Review: Rukobia, a human immunodeficiency virus type 1 (HIV-1) gp120-directed attachment inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations. Rukobia, fostemsavir, is a prodrug of temsavir that has no antiviral activity. Temsavir, the active moiety, binds glycoprotein 120 (gp120) inhibiting the interaction between the virus and surface receptors on CD4 cells, preventing attachment and entry into host T cells and other immune cells. Rukobia has no in vitro cross-resistance to other classes of antiretroviral drugs including entry inhibitors. It offers a new mechanism of action providing a new treatment option for patients with extensive antiretroviral drug resistance.

The efficacy of Rukobia was investigated in the BRIGHT trial, a partially-randomized, international, double-blind, placebo-controlled trial in 371 heavily treatment-experienced adult patients with HIV-1 infection who had failure of their current antiretroviral regimen (HIV-1 RNA ≥ 400 copies per mL) and no viable antiretroviral combination therapy available to them due to exhaustion of at least four of six antiretroviral classes. Patients with one or two fully active antiretroviral treatment options at screening were enrolled in the randomized cohort where patients received either blinded Rukobia 600 mg twice daily (n=203) or placebo (n=69) in addition to the current failing regimen for 8 days of functional monotherapy. After Day 8, randomized subjects received open-label Rukobia 600 mg twice daily plus investigator-selected optimized background therapy (OBT). All endpoints were evaluated in the randomized cohort.

Analysis of the primary endpoint, the mean change in the log_{10} level of HIV-1 RNA from day 1 to day 8, demonstrated superiority of Rukobia compared to placebo with a difference of -0.625 in viral load change from baseline (p-value < 0.0001). At Day 8, 65% of patients had a reduction in viral load of > 0.5 log_{10} copies/mL and
46% had a reduction of > 1 log\textsubscript{10} copies/mL compared to a reduction in the placebo group of 19% and 10%, respectively. Virologic response (HIV-1 RNA level < 40 copies per mL) analysis showed that 53% of patients receiving Rukobia had a virologic response at week 24 and 60% had a virologic response at week 96. Mean changes in the CD4+ cell count from baseline increased over time (90 cells/mm\textsuperscript{3} at week 24, 205 cells/mm\textsuperscript{3} at week 96).

Rukobia contains no black box warnings, but warnings and precautions include immune reconstitution syndrome, QTc prolongation (at 4 times the recommended dose), and transaminase elevations in patients with hepatitis B or C virus coinfections (sometimes consistent with hepatitis B reactivation). Serious drug reactions occurred in 3% of patients and included 3 cases of severe immune reconstitution inflammatory syndrome. Adverse reactions that occurred in more than 2% of patient in the randomized cohort included nausea, diarrhea, vomiting, dyspepsia, abdominal pain, headache, fatigue, rash, sleep disturbance, somnolence, and immune reconstitution inflammatory syndrome. In the non-randomized cohort, the most common adverse reactions were fatigue, nausea, and diarrhea.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Rukobia is a pharmacy benefit that will be added to the brand preferred tier of the Commercial, Marketplace and GHP Kids formularies. Rukobia will not require a prior authorization. The following quantity limits will apply:

**QUANTITY LIMIT:** 2 tablets per day

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

**DAYVIGO (lemborexant)**

**Review:** Dayvigo is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. Dayvigo enters the market as an alternative to Belsomra to improve sleep latency and maintenance in adult patients. There have been no head-to-head studies comparing lemborexant and suvorexant. Both products are orexin receptor antagonists and would be expected to have similar efficacy and both products share the same indication.

Dayvigo is available in 5 mg and 10 mg tablets. The recommended dose is 5 mg taken no more than once per night, immediately before going to bed, with at least 7 hours remaining before the planned time of awakening. Dosage may be increased to 10 mg based on clinical response and tolerability. Dose adjustments are indicated for moderate hepatic impairment (maximum dose is 5 mg) but are not necessary in renal impairment. Dayvigo is not recommended in patients with severe hepatic impairment.

Dayvigo was evaluated in two clinical trials of patients meeting the DSM-5 criteria for insomnia disorder, characterized by difficulties with sleep onset and/or sleep maintenance.
Study 1 (SUNRISE-I) was a 1-month, randomized, double-blind, placebo/active-controlled, parallel-group trial in female patients 55 years and older and male patients 65 years and older randomized to Dayvigo 5 mg, Dayvigo 10 mg, placebo, or zolpidem ER 6.25 mg active comparator. The primary efficacy endpoint was the change from baseline in latency to persistent sleep from baseline to end of treatment. Latency to persistent sleep was defined as time from lights off to the first 10 consecutive minutes of non-wakefulness. Also, the trial evaluated the mean change from baseline to end of treatment in sleep efficiency, calculated as minutes asleep over total time from lights off. An additional secondary endpoint was the change from baseline to end of treatment in wake after sleep onset, defined as amount of time spent awake after awakening from first sustained sleep period. Across all three endpoints, both strengths of Dayvigo demonstrated statistically significant improvement as compared to placebo and the active comparator at 30 days.

Study 2 (SUNRISE-2) was a 6-month, randomized, double-blind, placebo-controlled trial in patients 18 or older. Patients were randomized to placebo, Dayvigo 5 mg, or Dayvigo 10 mg. The primary efficacy endpoint was change in subjective sleep onset latency (sSOL) from baseline to end of treatment. sSOL is defined as the estimated number of minutes from the time the patient attempted to sleep until sleep onset. The trial also evaluated subjective sleep efficiency, defined as proportion of time spent asleep per time in bed, and subjective wake after sleep onset defined as minutes of wake from the onset of sleep until wake time (i.e. number of minutes spent awake after first time falling asleep). Across all three endpoints, both strengths of Dayvigo demonstrated a statistically significant improvement as compared to placebo at 6 months.

Dayvigo is contraindicated in patients with narcolepsy. Dayvigo has warnings for sleep paralysis, hypnagogic/hypnopompic hallucinations, and cataplexy like symptoms, complex sleep behaviors (e.g. sleep-walking, sleep-driving), worsening of depression/suicidal ideation. The most common adverse reactions (reported in 5% or more of patients) was somnolence. The most common adverse events leading to discontinuation were somnolence and nightmares. The safety and effectiveness in pediatric patients have not been established.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: Nichole asked if medication was studied in any subgroups, and if outcome was clinically significant. Nothing noted within product labeling. The committee unanimously voted to accept the recommendations as presented. None were opposed

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed

Outcome: Dayvigo will be a pharmacy benefit that will not be added to the Commercial, Marketplace, or GHP Kids formularies. Dayvigo will require a prior authorization with the following criteria

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of insomnia AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

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

- 1 tablet per day

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.
**MONJUVI**  
*(tafasitamab-cxix)*

**Review:** Monjuvi is a CD19-directed cytolytic antibody indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). It is a humanized monoclonal antibody that binds the CD19 antigen expressed on both normal and malignant B-cells and causes B-cell lysis through apoptosis and immune effector mechanisms, including antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP). In vitro studies in DLBCL tumor cells showed that the combination of Monjuvi and lenalidomide produced and increase in ADCC activity compared to either agent alone.

The efficacy of Monjuvi in combination with lenalidomide followed by Monjuvi as monotherapy was evaluated in L-MIND, and open-label, single arm trial in 71 adult patients with relapsed or refractory DLBCL after 1 to 3 prior therapies, including a CD20-directed cytolytic antibody, who were not candidates for high-dose chemotherapy followed by autologous stem cell transplantation (ASCT). Patients received Monjuvi 12 mg/kg intravenously (dosed according to recommended schedule) in combination with lenalidomide (25 mg orally on Days 1 to 21 of each 28 day cycle) for a maximum of 12 cycles, followed by Monjuvi as monotherapy until disease progression or unacceptable toxicity.

The primary efficacy endpoint evaluating overall response rate showed 39 out of 71 patients (55%) achieved a response with 37% achieving a complete response and 18% achieving a partial response. The median duration of response was 21.7 months. At a median follow-up of 17.3 months for progression-free survival, the median progression-free survival was 12.1 months. At a median follow-up of 19.6 months for overall survival, 36% of patients had died and the median overall survival was not reached.

Monjuvi has no black box warnings, but contains warnings for infusion related reactions, myelosuppression, including neutropenia, thrombocytopenia, and anemia, serious and potentially fatal infections, and embryo-fetal toxicity. In the L-MIND clinical trial, serious adverse reactions occurred in 52% of patients. The most common adverse reactions were neutropenia, fatigue, anemia, diarrhea, thrombocytopenia, cough, pyrexia, peripheral edema, respiratory tract infection, and decreased appetite.

Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Monjuvi will be coverage as a medical benefit and will not be added to the Commercial, Marketplace, of GHP Kids formularies. The following prior authorization criteria will apply:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Monjuvi is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma **AND**
- Medical record documentation that the member is not eligible for autologous stem cell transplant (ASCT) **AND**
- Medical record documentation that Monjuvi will be used in combination with Revlimid (lenalidomide)
AUTHORIZATION DURATION: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

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

ISTURISA (osilodrostat)

Review: Isturisa is indicated for the treatment of adult patients with Cushing’s disease for whom pituitary surgery is not an option or has not been curative. Isturisa is the first oral cortisol synthesis inhibitor to be approved by the Food & Drug Administration (FDA) and joins Signifor (pasireotide diaspbate) and Signifor LAR (pasireotide pamoate) for the subpopulation of Cushing’s Disease (CD) for whom pituitary surgery is not an option or has not been curative. Prior to Isturisa’s approval, ketoconazole, mitotane, metyrapone, and etomidate have been used off-label, though each has its own limitations. All of these agents work by acting as adrenal enzyme inhibitors at various enzyme targets that would otherwise lead to cortisol production.

Isturisa is available as 1 mg, 5 mg, and 10 mg tablets. The recommended initial dose of Isturisa is 2 mg orally twice daily, without regard to food. The maintenance dose requires patient individualization based upon cortisol levels, tolerability, and signs/symptoms of CD. The maximum recommended dose is 30 mg twice daily.

The efficacy of Isturisa was assessed in a 48-week, multicenter study (called the Core Period) that consisted of four study periods. The trial enrolled CD patients with persistent or recurrent disease despite pituitary surgery or de novo patients for whom surgery was not indicated or who had refused surgery. Overall, 96% of patients had received previous treatments for CD prior to entering the study, of which 88% had undergone surgery. Persistence or recurrence of CD was evidenced by the mean of three 24-hour UFC (mUFC) > 1.5x upper limit of normal (ULN). Period 1 (Week 1 to 12) 137 patients received a starting dose of 2 mg Isturisa orally twice daily that could be titrated up to a maximum of 30 mg twice daily at no greater than 2-week intervals to achieve a mUFC within the normal range. Period 2 (Week 13 to 24) 130 patients entered Period 2. The daily dose for patients that achieved a mUFC within the normal range in Period 1 was maintained during Period 2. Patients who did not require further dose increase, tolerated the drug, and had a mUFC ≤ ULN at Week 24 (end of Period 2) were to be considered responders and eligible to enter the Randomization Withdrawal phase (Period 3). Patients whose mUFC became elevated during Period 2 could have their dose increased further, if tolerated, up to 30 mg twice daily. These patients were considered non-responders and did not enter Period 3, but they continued open-label treatment. Period 3 (Week 26 to 34) At Week 26, 71 patients were considered responders and were randomized 1:1 to continue receiving Isturisa (n = 36) or to switch to placebo (n = 35) for 8 weeks. Period 4 (Week 26 or 34 to 48) This period included patients who were not eligible for randomization (n = 47) at Week 26, patients who were considered non-responders during Period 3 (n = 29), and patients who were considered responders during Period 3 (n = 41). Open-label treatment with Isturisa continued in these patients until Week 48. The primary efficacy endpoint of the study was to compare the percentage of complete responders at the end of the 8-week randomized withdrawal period (Period 3) between patients randomized to continue Isturisa versus the patients switched to placebo. A complete responder for the primary endpoint was defined as a patient who had mUFC ≤ ULN based on central laboratory result at the end of Period 3 (Week 34), and who neither discontinued randomized treatment or the study nor had any dose increase above their Week 26 dose. At the end of Period 3, the percentage of complete responders for the primary endpoint was 86% and 29% in the Isturisa and placebo group.

The most common adverse reactions (> 20%) are adrenal insufficiency, fatigue, nausea, headache, and edema. There are no black box warnings or contraindications for Isturisa. However, there are warnings for hypocortisolism.
(including the potential for life-threatening adrenal insufficiency), QTc prolongation (dose-dependent) leading to cardiac arrhythmias, and elevations in adrenal hormone precursors and androgens (leading to hypokalemia, worsening hypertension, and edema). As such, patients should have hypokalemia and hypomagnesemia corrected prior to starting Isturisa along with a baseline electrocardiogram (ECG). ECG should be repeated within one week after initiation, and as clinically indicated thereafter. Temporary discontinuation of Isturisa should be considered in the case of an increase in QTc interval > 480 ms. The safety and effectiveness in pediatric patients have not been established.

Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: Bret asked if initial nonresponders/drop-outs were included in the analysis. Nonresponders were allowed to continue in open treatment. Will look further into if they were included in final outcome analysis. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Isturisa will be covered as a pharmacy benefit. Isturisa will not be added to the Commercial, Marketplace, GHP Kids formularies. The following prior authorization criteria will apply:
- Medical record documentation of age 18 years or older AND
- Prescription written by an endocrinologist AND
- Medical record documentation of a diagnosis of Cushing’s disease AND
- Medical record documentation that pituitary surgery is not an option or has not been curative AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the following: ketoconazole, metopirone, Signifor, Signifor LAR

Authorization Duration: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. Reauthorization requires medical record documentation of improvement in urinary free cortisol levels compared to baseline.

Quantity Limit:
- 1 mg tablets: 8 tablets per day, 30 day supply per fill
- 5 mg tablets: 2 tablets per day, 30 day supply per fill
- 10 mg tablets: 6 tablets per day, 30 day supply per fill

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

ZEPZELCA (lurbinectedin)

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/m² 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.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

**Clinical Discussion:** Bret asked if anyone was excluded from study due to specific oncogenes. Nothing called out in study, but NCCN usually recommends specific targeted therapies over non-specific therapies. The committee voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

**Outcome:** Zepzelca will be covered as a medical benefit and will not be added to the Commercial, Marketplace, or GHP Kids formularies. The following prior authorization criteria will apply:
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Zepzelca is written by a hematologist or oncologist **AND**
- Medical record documentation of metastatic small cell lung cancer (SCLC) **AND**
- Medical record documentation of disease progression on or after platinum-based chemotherapy

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

**EUCRISA (crisaborole)**

**Updated Indication:** Eucrisa is now indicated for the treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age and older.

Previously, Eucrisa was only indicated in patients 2 years of age and older.

**Current formulary status:** Brand Non-Preferred requiring PA

**Recommendation:** No changes are recommended to the formulary placement of Eucrisa at this time. It is recommended that the following criteria be removed to account for the updated indication.

- Medical record documentation that Eucrisa is prescribed by or in consultation with a dermatologist AND
- Medical record documentation of age greater than or equal to 2 years AND
- Medical record documentation of a diagnosis of mild to moderate atopic dermatitis AND
- For patients 2 years of age or greater: Medical record documentation of contraindication to, intolerance to, or therapeutic failure on tacrolimus ointment AND
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on at least two (2) formulary topical corticosteroids unless deemed inadvisable due to potential risks such as (a) use on sensitive skin areas (face, axillae, or groin) or (b) patient is between 2 and less than 15 years of age

*NOTE:* calcineurin inhibitors only labeled for use in those 2 years of age and older.

**Discussion:** Keith asked if the committee felt that tacrolimus alternative would be appropriate for children less than 2 years of age. Some thought due to risk of lymphoma in calcineurin inhibitors would warrant not requiring failure of as a prerequisite in that age group.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

**REBLOZYL (luspatercept-aamt)**

**Updated Indication:** Reblozyl is indicated for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T).

**Current formulary status:** Medical Benefit requiring a prior authorization

**Recommendation:** No changes are recommended to the formulary placement or authorization duration of Reblozyl. It is recommended to add the following criteria to Medical Benefit 210.0 to incorporate the new indication.

**Prior Authorization Criteria:**

- Medical record documentation of age greater than or equal to 18 years AND
• Medical record documentation of diagnosis of myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) with one of the following:
  o Documentation of greater than or equal to 15% ring sideroblasts OR
  o Documentation of greater than or equal to 5% ring sideroblasts AND an SF3B1 mutation
AND
• Medical record documentation of very low to intermediate risk AND
• Medical record documentation that patient requires 2 or more red blood cell units over 8 weeks AND
• Medical record documentation of baseline number of transfusions and red blood cell (RBC) units required for the previous six (6) months AND
• Medical record documentation of therapeutic failure, intolerance to, or contraindication to an erythropoiesis stimulating agent AND
• Medical record recommendation that Reblozyl is being dosed consistent with FDA-approved labeling**

Notes:
*In clinical trials for β-thalassemia, regular red blood cell transfusions was considered to be 6 to 20 red blood cell units per 24 weeks with no transfusion-free period greater than 35 days.

**Per current labeling: For β-thalassemia: 1mg/kg every 3 weeks increasing to a maximum of 1.25mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen. Dose should not exceed 1.25mg/kg every 3 weeks
For MDS-RS and MDS/MPN-RS-T: 1mg/kg every 3 weeks increasing to a dose of 1.33 mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen, then increasing up to a maximum of 1.75mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen. Dose should not exceed 1.75mg/kg every 3 weeks.

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. After the initial six (6) month approval, subsequent approvals will be for a duration of six (6) months, requiring medical record documentation of:
- a decrease in red blood cell (RBC) transfusion burden AND
- Reblozyl is being dosed consistent with FDA-approved labeling**

Ongoing subsequent approvals will be for a duration of six (6) months, requiring medical record documentation of:
- A sustained reduction of red blood cell (RBC) transfusion burden AND
- Reblozyl is being dosed consistent with FDA-approved labeling**

LIMITATIONS: Reblozyl will no longer be covered if the patient does not experience a decrease in transfusion burden after nine (9) weeks of treatment (administration of three (3) doses) at the maximum dose level or if unacceptable toxicity occurs at any time.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

**Updated Indication:** Corlanor is now indicated for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate.

**Current formulary status:** BrandNP tier, requiring a prior authorization

**Recommendation:** No changes are recommended to the formulary placement of Corlanor. The following changes are recommended to Commercial Policy 382.0 Corlanor:

- Medical record documentation that Corlanor is prescribed by a cardiologist \textbf{AND}
- Medical record documentation of being in sinus rhythm with resting heart rate greater than or equal to the lower limit of the normal range based on age* \textbf{AND}
- Medical record documentation of one of the following:
  - Medical record documentation of age greater than or equal to 18 years \textbf{AND}
  - Medical record documentation of stable, symptomatic heart failure with a left ventricular ejection fraction less than or equal to 35% \textbf{AND}
  - Medical record documentation of hospitalization for worsening heart failure within the previous 12 months.

\textbf{OR}

- Medical record documentation of age greater than or equal to 6 months and less than 18 years \textbf{AND}
  - Medical record documentation of stable, symptomatic heart failure due to dilated cardiomyopathy \textbf{AND}
  - Medical record documentation of class II to IV heart failure according to New York Heart Association [NYHA] functional class or Ross classification \textbf{AND}
  - Medical record documentation of a left ventricular ejection fraction less than or equal to 45%.

\textbf{AND}

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to the maximum tolerated dose of 2 formulary beta-blockers, one of which must be carvedilol \textbf{AND}
- If the request is for Corlanor Solution: documentation of one of the following:
  - Medical record documentation of patient weight less than 40 kg \textbf{OR}
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Corlanor tablets \textbf{OR}
  - Medical record documentation that patient has dysphagia or is unable to swallow tablets

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

- Corlanor tablets: 2 tablets per day
- Corlanor solution: 20 mL per day

\textbf{*NOTE: Lower limit of Normal Heart Rate Based on age}

- Age 6 – 12 months: HR \( \geq 105 \text{ bpm} \)
- Age 1 – 3 years: HR \( \geq 95 \text{ bpm} \)
- Age 3 -5 years: HR \( \geq 75 \text{ bpm} \)
- Age 5 and older: HR \( \geq 70 \text{ bpm} \)

**Discussion:** No comments or questions.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.
Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

**COSENTYX (secukinumab)**

**Updated Indication:** Cosentyx is now FDA approved for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

**Current formulary status:** Cosentyx is a pharmacy benefit and is currently available on the Commercial, Marketplace, and GHP Kids formularies on the Specialty Tier, or the Brand Non-Preferred tier for members with a 3-tier benefit requiring prior authorization.

**Recommendation:** No changes are recommended to formulary placement at this time. Recommend adding the following criteria to the existing Cosentyx policy:

**For Nonradiographic Axial Spondyloarthritis (nr-axSpA):**

- Medical record documentation of a diagnosis of non-radiographic axial spondylarthritis **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Cosentyx is prescribed by a rheumatologist **AND**
- Medical record documentation of at least one of the following:
  - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) **OR**
  - Sacroilitis on magnetic resonance imaging (MRI) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) nonsteroidal anti-inflammatory drugs (NSAIDs) **AND**
- Medical record documentation that Cosentyx is **not** being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation that the medication is being dosed as 150 mg every 4 weeks with or without a loading dose of 150 mg at Weeks 0, 1, 2, 3, and 4

**QUANTITY LIMIT/AUTHORIZATION PARAMETERS:** Authorization should be approved by NDC-11 for the requested dosage form (prefilled syringe: 00078-0639-98; sensoready pen: 00078-0639-41).

<table>
<thead>
<tr>
<th>If requesting a dose of:</th>
<th>Initial – One-time, one-week authorization</th>
<th>Remainder/Subsequent</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 mg at week 0, 1, 2, 3, 4 followed by 150 mg every 4 weeks</td>
<td>Quantity limit: 4 mL per 28 days Max quantity supply: 4 Min day supply: 28 Max day supply: 28</td>
<td>Quantity limit: 2 mL per 56 days Max quantity supply: 2 Min day supply: 56 Max day supply: 56</td>
</tr>
<tr>
<td>150 mg every 4 weeks</td>
<td>Quantity limit: 2 mL per 56 days Max quantity supply: 2 Min day supply: 56 Max day supply: 56</td>
<td></td>
</tr>
</tbody>
</table>

**AUTHORIZATION DURATION:** 6 months initial, 1 year renewal

For continuation of coverage, there must be medical record documentation of clinical improvement or maintenance of condition. Subsequent approvals for coverage will be for a duration of 12 months. Reevaluation of coverage will require medical record documentation of improvement of signs and symptoms or maintenance of condition.
Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

TALTZ (ixekizumab)

Updated Indication: Taltz is now approved for the following indications:

1) Treatment of patients aged 6 years and older with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
2) Treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation

Current formulary status: Taltz is a pharmacy benefit and is currently available on the Commercial, Marketplace, and GHP Kids formularies on the Specialty Tier, or the Brand Non-Preferred tier for members with a 3-tier benefit requiring prior authorization.

Recommendation: No changes to formulary placement of Taltz are recommended at this time. Recommend adding the following prior authorization criteria to the existing policy:

For the treatment of pediatric plaque psoriasis:

- Medical record documentation that Taltz is prescribed by a dermatologist AND
- Medical record documentation of age greater than or equal to 6 years AND
- Medical record documentation that the prescribed dosing is appropriate for patient’s weight AND
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease affecting crucial body areas such as hands, feet, face or genitals AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two topical corticosteroids AND
- Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

Authorization Duration: 6 months initial, 1 year renewal
For continuation of coverage, there must be medical record documentation of clinical improvement or maintenance of condition. Subsequent approvals for coverage will be for a duration of 12 months.
Reevaluation of coverage will require medical record documentation of improvement of signs and symptoms or maintenance of condition

Quantity Limits:

At time of initial authorization (loading dose):
- One-time, one-week authorization of 3 mL per 28 days
- Remainder of six (6) month authorization duration: 1 mL per 28 days

For ongoing or reauthorization: 1 mL per 28 days
For the treatment of non-radiographic axial spondyloarthropathy:

- Medical record documentation of a diagnosis of non-radiographic axial spondylarthritis AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Taltz is prescribed by a rheumatologist AND
- Medical record documentation of at least one of the following:
  - C-reactive protein (CRP) level above the upper limit of normal (10 mg/dL) OR
  - Sacroiliitis on magnetic resonance imaging (MRI) AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Cosentyx*
- Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent

**AUTHORIZATION DURATION:** 6 months initial, 1 year renewal

For continuation of coverage, there must be medical record documentation of clinical improvement or maintenance of condition. Subsequent approvals for coverage will be for a duration of **12 months**. Reevaluation of coverage will require medical record documentation of improvement of signs and symptoms or maintenance of condition

**QUANTITY LIMITS:** 1 mL per 28 days

**Discussion:** Bret asked about the participants who tried other modalities in the study prior to receiving Taltz, and if they failed them, or only switched therapies. Not called out in the studies. No comments or questions.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

**DOVATO (dolutegravir/lamivudine)**

**Updated Indication:** Dovato is now indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Dovato.

Previously Dovato was only indicated in treatment-naïve patients.

**Current formulary status:** BrandP, QL: 1 tablet per day

**Recommendation:** A prior authorization is not required for Dovato and there were no changes to the recommended dosage for virologically suppressed patients, so no changes are needed for the formulary placement and quantity limits at this time.

**Discussion:** No comments or questions.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.
Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

**PREZCOBIX (darunavir/cobicistat)**

**Updated Indication:** Prezcobix is now indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in treatment-naïve and treatment-experienced adults and pediatric patients weighing at least 40 kg with no darunavir resistance-associated substitutions (V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V).

Previously this indication was limited to the adult population.

**Current formulary status:** BrandP tier, QL: 1 tablet per day

**Recommendation:** A prior authorization for Prezcobix is not required and there were no changes to the recommended dosage for the new patient population, so no changes are needed for the formulary placement and quantity limits at this time

**Discussion:** No comments or questions.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

**EVOTAZ (atazanavir/cobicistat)**

**Updated Indication:** Evotaz is now indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in adults and pediatric patients weighing at least 35 kg.

Previously this indication was limited to the adult population.

**Current formulary status:** BrandP tier, QL: 1 tablet per day

**Recommendation:** We currently do not require a prior authorization for Evotaz and there were no changes to the recommended dosage for the new patient population, so no changes are needed for the formulary placement and quantity limits at this time.

**Discussion:** No comments or questions.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

**Updated Indication:** Spravato is indicated, in conjunction with an oral antidepressant, for the treatment of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

*Previously, Spravato was only indicated for treatment-resistant depression in adults in conjunction with an oral antidepressant.*

Limitations of Use: The effectiveness of Spravato in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated. Use of Spravato does not preclude the need for hospitalization if clinically warranted, even if patients experience improvement after an initial dose of Spravato. Spravato is not approved as an anesthetic agent.

**Current formulary status:** Spravato is a medical benefit and requires a prior authorization

**Recommendation:** There will be no changes to formulary status at this time. It is recommended to update the new indication and add a section regarding drug interactions to both indications.

**For Treatment Resistant Depression:**
- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation of diagnosis of major depression disorder (MDD) **AND**
- Medical record documentation of Spravato being used for treatment-resistant depression as defined by failure of at least two antidepressants at an optimized dose for at least 6 weeks **AND**
- Medical record documentation that Spravato will be used in combination with a newly initiated antidepressant **AND**
- Medical record documentation of the patient’s baseline depression status using an appropriate rating scale (e.g. PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to olanzapine/fluoxetine capsules **AND**
- Medical record documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary about the risks associated with the use of both medications when they interact)

**For acute suicidal ideation and behavior:**
- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation that Spravato will be used in combination with an oral antidepressant **AND**
- Medical record documentation of diagnosis of major depression disorder (MDD) **AND**
- Medical record documentation of a recent hospital admission (within 4 weeks) due to depressive symptoms with acute suicidal ideation and behavior **AND**
- Medical record documentation that Spravato was started inpatient **AND**
- Medical record documentation that Spravato will not exceed the FDA-approved duration of 4 weeks **AND**
- Medical record documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary about the risks associated with the use of both medications when they interact)

*Note to reviewer:* The standard of care for patients with acute suicidal ideation and behavior is to hospitalize for safety. Spravato should be started inpatient for acute suicidal ideation requests.
AUTHORIZATION DURATION FOR TREATMENT RESISTANT DEPRESSION:
Initial approval will be for 1 month or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following criteria is required.
- Medical record documentation of clinical improvement in depression symptoms as measured by an appropriate rating scale (compared to previous measurement)
Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following criteria is required.
- Medical record documentation of clinical improvement or lack of progression in depression symptoms as measured by an appropriate rating scale (compared to previous measurement)

QUANTITY LIMITS FOR TREATMENT RESISTANT DEPRESSION:
For the initial 1 month authorization: 23 devices per 28 days
For subsequent authorizations: 12 devices per 28 days

AUTHORIZATION DURATION FOR DEPRESSIVE EPISODES WITH ACUTE SUICIDAL IDEATION:
Approval will be for one (1) 4 week approval for the FDA approved maximum of 24 devices. Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member’s healthcare outcome will be improvement by dosing beyond the FDA-approved treatment duration.

QUANTITY LIMITS FOR DEPRESSIVE EPISODES WITH ACUTE SUICIDAL IDEATION:
56 mg dose pack: 16 devices per 28 days
84 mg dose pack: 24 devices per 28 days

Discussion: Dr. Silbert questioned if something should be specified in the policy about concomitant benzodiazepine use (causing excess sedation). Could be considered, but we usually don’t list it if not contraindicated or black box in type. Could also consider adding a requirement to check PDMP. May be more applicable to treatment resistant depression rather than acute treatment of MDD with SI.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

EPIDIOLEX (cannabidiol)

Updated Indication: Epidiolex is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients 1 year of age and older.

Previously, it was indicated for patients 2 years and older with Lennox-Gastaut syndrome or Dravet syndrome.

Current formulary status: BrandNP, requiring prior authorization

Recommendation: No changes are recommended to the formulary placement of Epidiolex. The following changes are recommended to Commercial Policy 538.0 Epidiolex to incorporate the new indication.
- Medical record documentation that Epidiolex is prescribed by a neurologist AND
- Medical record documentation of age greater than or equal to 1 year AND
• Medical record documentation of a diagnosis of Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex **AND**
• **For Lennox-Gastaut syndrome:** Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) generic formulary alternatives **OR** member is between 1 and 2 years of age

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

**XPOVIO (selinexor)**

**Updated Indication:** Xpovio is now indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy.

Previously Xpovio was indicated in adult patients with relapsed or refractory multiple myeloma who received at least 4 prior therapies.

**Current formulary status:** OralOncBrandNP tier, requiring a prior authorization

**Recommendation:** There are no changes recommended for the formulary placement or authorization duration of Xpovio. The following changes are recommended for the prior authorization criteria for Commercial Policy 584.0:

**Relapsed or Refractory Diffuse Large B-cell Lymphoma (DLBCL)**

- Medical record documentation that Xpovio is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age 18 years or older **AND**
- Medical record documentation of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma **AND**
- Medical record documentation of treatment with at least two prior lines of therapy

**QUANTITY LIMIT:** Pharmacist note to CSR: Authorization should be entered by HICL, Restriction NO, check the Formulary PA required, Formulary and Step Therapy boxes (no QLs need to be entered within the authorization but will need to go in the letters).

<table>
<thead>
<tr>
<th>Dosage</th>
<th>Tablets / 28 days</th>
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</thead>
<tbody>
<tr>
<td>40 mg once weekly</td>
<td>8</td>
</tr>
<tr>
<td>60 mg once weekly</td>
<td>12</td>
</tr>
<tr>
<td>80 mg weekly</td>
<td>16</td>
</tr>
<tr>
<td>100 mg weekly</td>
<td>20</td>
</tr>
<tr>
<td>60 mg <strong>twice</strong> weekly</td>
<td>24</td>
</tr>
<tr>
<td>80 mg <strong>twice</strong> weekly</td>
<td>32</td>
</tr>
</tbody>
</table>

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.
Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

**SIVEXTRO (tedizolid)**

**Updated Indication:** Sivextro is now indicated for the treatment of adults and pediatric patients ≥ 12 years of age with acute bacterial skin and skin structure infections caused by susceptible isolates of the following gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant and methicillin-susceptible isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus* group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), and *Enterococcus faecalis*

**Current formulary status:** Sivextro tablets are a pharmacy benefit and are currently available on the Commercial, Marketplace, and GHP Kids formularies on the Specialty Tier, or the Brand Non-Preferred tier for members with a 3-tier benefit requiring prior authorization. Sivextro vials are covered as a medical benefit requiring prior authorization.

**Recommendation:** No changes are recommended to the current formulary placement of Sivextro tablets or vials. It is recommended the prior authorization criteria be updated as follows:

**Pharmacy Benefit:**
- Medical record documentation that patient is greater than or equal to 12 years of age AND
- Medical record documentation of a diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by: *Staphylococcus aureus, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus, or Enterococcus faecalis* which have been diagnosed and documented with Infectious Disease consultation AND
- Medical record documentation of 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 other antibiotics shown to be susceptible on the culture and sensitivity OR
- Medical record documentation that Sivextro therapy was started during an inpatient setting

**QUANTITY LIMIT:** 6 tablets every 30 days

**AUTHORIZATION DURATION:** one-time, 6 day approval

**Medical Benefit:**
- Medical record documentation that patient is ≥ 12 years of age AND
- Medical record documentation of a diagnosis of an acute bacterial skin and skin structure infection (including cellulitis/erysipelas, wound infection, and major cutaneous abscess) caused by: *Staphylococcus aureus, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus, Streptococcus intermedius, Streptococcus constellatus, or Enterococcus faecalis* which has been diagnosed and documented with Infectious Disease consultation 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 other antibiotics shown to be susceptible on the culture and sensitivity OR
- If Sivextro was initiated during an inpatient stay, 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 other antibiotics shown to be susceptible on the culture and sensitivity

**AUTHORIZATION LIMIT:** If approved, Sivextro IV will be authorized for a max of 6 doses; [Facets RX Count: 200 (J3090 units) per dose]

**Discussion:** No comments or questions.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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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**BAVENCIO (avelumab)**

**Updated Indication:** Bavencio is now indicated for maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum containing chemotherapy.

Previously Bavencio was indicated in patients with locally advanced or metastatic urothelial carcinoma who had disease progression following platinum chemotherapy as well as indications for metastatic Merkel cell carcinoma and advanced renal cell carcinoma.

**Current formulary status:** Medical Benefit requiring a prior authorization

**Recommendation:** No changes are recommended to the formulary placement or authorization duration of Bavencio. The following changes are recommended to Medical Benefit Policy 152.0 to incorporate the new indication:

**Urothelial Carcinoma**

- Prescribed by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**
- Medical record documentation of one of the following:
  - Documentation that Bavencio will be used as maintenance treatment with no progression following first-line platinum-containing chemotherapy **OR**
  - Disease progression during or following platinum-containing chemotherapy **OR**
  - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

**Renal Cell Carcinoma**

- Prescribed by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of advanced renal cell carcinoma (RCC) **AND**
- Medical record documentation that Bavencio will be given in combination with axitinib (Inlyta) **AND**
- Medical record documentation that Bavencio and axitinib are being used as first-line treatment

**AUTHORIZATION DURATION:** Initial approval will be for **6 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.
Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

**TAZVERIK (tazemetostat)**

**Updated Indication:** Tazverik is now indicated for the treatment of:
- Adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies
- Adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options

**Current formulary status:** OralOncBrandNP tier, requiring a prior authorization

**Recommendation:** No changes are recommended to the formulary placement, quantity limits, or authorization duration for Tazverik. The following prior authorization criteria should be added the Commercial Policy 613.0 to incorporate the new indication:

**Relapsed or Refractory Follicular Lymphoma**
- Medical record documentation that Tazverik is prescribed by or in consultation with a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of relapsed or refractory follicular lymphoma AND
- Medical record documentation of one of the following:
  - Documentation of an EZH2 mutation as detected by an FDA-approved test* AND documentation that member has received at least 2 prior systemic therapies
  - Documentation of no satisfactory alternative treatment options

*NOTE: The FDA-approved test for the detection of EZH2 mutation in relapsed or refractory lymphoma is the cobas EZH2 Mutation Test. The cobas® EZH2 Mutation Test is a real-time allele-specific PCR test for qualitative detection of single nucleotide mutations for Y646N, Y646F or Y646X (Y646H, Y646S, or Y646C), A682G, and A692V of the EZH2 gene.

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as presented. 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**

**TIVICAY AND TIVICAY PD (dolutegravir)**

**Discussion**
Dolutegravir, the active ingredient in Tivicay and Tivicay PD, is metabolized by UGT1A1 with some contribution from CYP3A as well as a substrate of UGT1A3, UGT1A9, BCRP, and P-gp in vitro. Drugs that induce those enzymes and transporters may decrease dolutegravir plasma concentration and reduce the therapeutic effect of dolutegravir. When administered with certain UGT1A or CYP3A inducers, that the dose of Tivicay and Tivicay PD should be administered twice daily.

**Recommendations**
The following quantity limits for Tivicay 10 mg and Tivicay PD should be updated to allow for twice daily administration when coadministered with certain uridine diphosphate (UDP) glucuronosyl transferase 1A1 (UGT1A) or cytochrome P450 (CYP3A) inducers:

**QUANTITY LIMITS:**
- Tivicay 10 mg tablets: 8 tablets per day
- Tivicay 25 mg tablets: 2 tablets per day
- Tivicay 50 mg tablets: 2 tablets per day
- Tivicay PD: 12 tablets per day

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

**ZENPEP (pancrelipase)**

**Discussion**
The rebate for Zenpep was recently terminated by the manufacturer due to a company merger. A rebate continues to be available for Creon. This prompted an evaluation of the formulary status of Zenpep and the other pancreatic enzyme products.

There are currently no head to head trials comparing the effectiveness of the pancreatic enzymes. Items of note include:
- All products are of porcine origin and contain the digestive enzymes lipase, protease, and amylase.
- All follow a similar dosing schedule as recommended by the Cystic Fibrosis Foundation Guidelines.
- All are enteric coated with the exception of Viokace which must be administered with a proton pump inhibitor.
- All are approved for use in infants with the exception of Viokace which is only approved for adults.
- The main difference between these products is the available strengths.

**Recommendations**
Due to the clinical equivalence amongst products and the current market share of Creon it is recommended that Creon is the sole preferred pancreatic enzyme on the Commercial/GHP Kids and Marketplace formularies. A prior authorization will be added to Zenpep to ensure use for an appropriate indication and prior use of Creon. Zenpep
will move to the brand non-preferred tier. Members currently utilizing Zenpep will be allowed to continue on therapy, but will also receive a letter informing them of the tier change.

Additionally, Pancreaze will be added to the existing prior authorization policy and the criteria will be updated to no longer require failure of Zenpep:

An exception for coverage of Viokace may be made for members who meet the following criteria:

• Medical record documentation of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy AND
• Medical record documentation of age greater than or equal to 18 years AND
• Medical record documentation that Viokace is being prescribed in conjunction with a proton pump inhibitor AND
• Medical record documentation of therapeutic failure on, contraindication to, or intolerance to Creon AND Zenpep

An exception for coverage of Pancreaze, Zenpep, or Pertzye may be made for members who meet the following criteria:

• Medical record documentation of exocrine pancreatic insufficiency AND
• Medical record documentation of therapeutic failure on, contraindication to, or intolerance to Creon AND Zenpep

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

**ZIEXTENZO (pegfilgrastim-bmez)**

**Discussion**
At the July 2020 P&T meeting, Ziextenzo was reviewed and recommended to be added the commercial pharmacy formulary at the specialty tier (or brand non-preferred tier for members with a 3-tier benefit) requiring prior authorization to match the tiering of the other pegfilgrastim biosimilar products (Udenyca and Fulphila). Upon additional review, it was confirmed that Udenyca, Fulphila, and Neulasta are all on the specialty tier (brand preferred tier for members with a 3-tier benefit) requiring prior authorization. As a result, Ziextenzo was inappropriately tiered.

**Recommendations**
It is recommended that the tiering of Ziextenzo for commercial members be updated to the Brand Preferred tier for members with a 3-tier benefit. No changes are necessary to the drug policy, authorization duration, or quantity limit of Ziextenzo at this time. No changes are necessary to the exchange line of business at this time. This change will ensure consistency in tiering between the pegfilgrastim biosimilar products.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.
Wet Age-Related Macular Degeneration Step Therapy update

Current State
There are currently five intravitreal anti-vascular endothelial growth factor (VEGF) agents available for the treatment of neovascular age-related macular degeneration (AMD) and diabetic macular edema (DME):

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avastin</td>
<td>bevacizumab</td>
</tr>
<tr>
<td>Eylea</td>
<td>aflibercept</td>
</tr>
<tr>
<td>Lucentis</td>
<td>Ranibizumab</td>
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<tr>
<td>Beovu</td>
<td>brolucizumab-dbll</td>
</tr>
<tr>
<td>Macugen</td>
<td>pegaptanib</td>
</tr>
</tbody>
</table>

Beovu was only recently approved by the FDA (October 2019) and will be reviewed at a future P&T committee meeting. Unlike bevacizumab, aflibercept, and ranibizumab, pegaptanib treatment does not improve visual acuity on average in patients with new onset neovascular AMD and is rarely used in current clinical practice.1

Current formulary status: Currently, Avastin, Eylea, and Lucentis are all freely available through the medical benefit.

Recommendation: The AAO guidelines indicate that there is not a clinically significant difference in the efficacy and safety of Avastin, Eylea, and Lucentis. Given the significant cost differential it is recommended that a prior authorization is added to Eylea and Lucentis to promote utilization of Avastin when used for neovascular AMD. The step through Avastin will be applicable to new starts only. The following criteria are recommended:

**Lucentis**
- Medical record documentation of a diagnosis of neovascular age-related macular degeneration **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Avastin

 **OR**

- Medical record documentation of a diagnosis of diabetic retinopathy with or without macular edema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Avastin

 **OR**

- Medical record documentation of a diagnosis of macular edema following retinal vein occlusion **OR**
  myopic choroidal neovascularization

NOTE: Indicators of Avastin failure may include:
- Worse or unchanged intraretinal or subretinal fluid.
- Persistent subretinal or intraretinal fluid.
- Recurrent intraretinal or subretinal fluid at current interval or extended interval.
- New subretinal hemorrhage
- In the absence of subretinal fluid, intraretinal fluid, or subretinal hemorrhage a failure documented as evidence of growth of the neovascular membrane on clinical exam or multimodal imaging.
- Any ocular or systemic adverse event thought related to the use of intravitreal bevacizumab.
Eylea
- Medical record documentation of a diagnosis of neovascular age-related macular degeneration AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Avastin

OR
- Medical record documentation of a diagnosis of diabetic retinopathy with or without macular edema AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Avastin OR
- Medical record documentation of baseline visual acuity 20/50 or worse

OR
- Medical record documentation of a diagnosis of macular edema following retinal vein occlusion

NOTE: Indicators of Avastin failure may include:
- Worse or unchanged intraretinal or subretinal fluid.
- Persistent subretinal or intraretinal fluid.
- Recurrent intraretinal or subretinal fluid at current interval or extended interval.
- New subretinal hemorrhage
- In the absence of subretinal fluid, intraretinal fluid, or subretinal hemorrhage a failure documented as evidence of growth of the neovascular membrane on clinical exam or multimodal imaging.
- Any ocular or systemic adverse event thought related to the use of intravitreal bevacizumab.

Discussion: Bret asked if the definition of “therapeutic failure” is specific to the eye or generalized for the patient. Kim believes it is specific to the eye, as different agents can be used in different eyes, but will look into further.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

Discussion
On October 1st, 2019 Geisinger Health Plan (GHP) implemented a new site of care program, which directs members to the most cost-effective, yet clinically appropriate location to receive certain drug infusions under the medical benefit. The site of care program is administered as part of the existing prior authorization program which requires clinical approval of the medication as well as approval at hospital based outpatient facilities via the following prior authorization criteria.

On October 1st, 2020 GHP will implement the Phase IV drug, Cinryze, to the site of care program, and on December 1st, 2020 GHP will implement Phase V drugs (Xolair, Nucala, and Fasenra) to the site of care program. The current Site of Care Policy (MBP 181.0) will apply in addition to the drugs’ respective existing clinical prior authorization program.

Recommendations
It is recommended that the following changes (additions highlighted in green and deletions highlighted in Red with a strikethrough) be made to MBP 181.0 so that this policy may apply to the Phase IV and Phase V drugs (Cinryze, Xolair, Nucala, and Fasenra). It is recommended that the following highlighted criteria changes be made to MBP 181.0 to account for appropriate exceptions for Xgeva given with concomitant in clinic intravenous chemotherapy be made. Additionally, it is recommended that criteria be added to require failure of a self-injectable formulation (when available) prior to being approved for a Site of Care exception.

MBP 181.0 Site of Care
I. Policy:
Site of Care Review Guidelines for Infusion Drugs and Specialty Medications

II. Purpose/Objective:
To provide a policy of coverage regarding the use of hospital-based outpatient facilities as a site of care for drugs that require administration via intravenous infusion or injection. This policy applies to these medications:

1. Abatacept (Orencia IV)
2. Belimumab (Benlysta IV)
3. Benralizumab (Fasenra) [effective 12/1/20]
4. Cinryze (C1 esterase Inhibitor [Human]) [effective 10/1/20]
5. Denosumab (Prolia, Xgeva) [effective 7/1/20]
6. Golimumab (Simponi Aria)
7. Immune Globulin (IVIG)
8. Infliximab & infliximab biosimilar products
9. Mepolizumab (Nucala) [effective 12/1/20]
10. Omalizumab (Xolair) [effective 12/1/20]
11. Tocilizumab (Actemra IV)
12. Vedolizumab (Entyvio)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.
6. Site of Care – choice of physical location for administration of intravenous infusions or injections. Site of care locations include hospital inpatient, hospital-based outpatient facilities, physician’s office, ambulatory
infusion centers, or home infusion services.

8. Alternative less intensive site of care facilities include non-hospital affiliated outpatient infusion centers such as ambulatory infusion centers or physician’s offices and home infusion

9. Hospital based outpatient facilities include ER services, intravenous drug infusions or injections, observation services, outpatient surgery, lab tests, or x-rays, or any other hospital services where the patient is not admitted as an inpatient.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;

b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;

c. in accordance with current standards good medical treatment practiced by the general medical community;

d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and

e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

DESCRIPTION:

Specific intravenous and injectable drugs must meet applicable medical necessity criteria for coverage. If these criteria are met, this coverage policy will be used to determine the medical necessity of administration in the hospital-based outpatient setting. If medical necessity criteria for administration in the hospital-based outpatient setting are not met, an alternative less intensive site of care facility should be utilized.

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

Administration in the hospital-based outpatient setting will be considered medically necessary and LIMITED to a duration of 60 days when one of the following criteria are met:

- This is the initial medication infusion OR
- Member is reinitiating treatment after not receiving any treatments for at least 6 months.

AUTHORIZATION DURATION: Initial approval will be for a duration of 60 days. Administration in the hospital-based outpatient setting for longer than 60 days will be required to meet the authorization criteria in the section below.

Administration in the hospital-based outpatient setting will be considered medically necessary for a duration of greater than 60 days when one of the following criteria are met:

- The medication has a site of care restriction for administration per the FDA approved label OR
- Documented previous history of severe or potentially life-threatening adverse event during or following administration and the adverse event cannot be managed using pre-medication(s) or adjusting the rate of infusion OR
- Both of the following:
  - All alternate non-hospital outpatient settings are not within a reasonable distance from the member’s home (within 50 miles) AND
  - Home healthcare or infusion provider has determined that the patient, home caregiver, or home environment is not appropriate for home infusion or home infusion services are not available due to limited network access AND
  - For request of a provider administered drug, for which a self-administered formulation is available, including but not limited to abatacept, belimumab, benralizumab, golimumab, mepolizumab and tocilizumab: medical record documentation of a therapeutic failure of or intolerance to a 3 month trial of the self-administered formulation of the respective product.
• For IVIG any of the above criteria OR
  o Change of immune globulin products (one infusion will be permitted in the hospital outpatient setting) OR
  o Laboratory confirmed immunoglobulin A (IgA) deficiency with anti-IgA antibodies
• For Xgeva (denosumab) any of the above criteria OR
  o Patient is receiving Xgeva concomitantly with intravenous chemotherapy as part of the same encounter

AUTHORIZATION DURATION: Initial approval will be for the same length of time as the authorization of the specific drug being administered. Subsequent approvals will be required if the specific drug requires subsequent authorizations.

NOTE: To prevent a delay in care and allow adequate transition time for members to an alternate infusion site, members already established on therapy who do not meet any of the above criteria will be given a 60-day transition auth to allow them to continue receiving therapy at their current hospital based outpatient facility while they transition to a different infusion site.

LIMITATIONS: If none of the above criteria are met and the proposed hospital-based outpatient facility is considered a least costly site of care, the hospital outpatient infusion would be approved.

LINE OF BUSINESS:
This policy does not apply to the Medicaid or Medicare line of business. Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

Outcome: The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.
**TIER ASSIGNMENT FOR MEDICAL BENEFIT COST SHARE MEDICATIONS**

**Discussion**
The Geisigner Health Plan Benefit Review Team (BRT) has approved the removal of the medical benefit cost share copayment when the below listed medications are processed at a specialty pharmacy. In order for members to continue to receive these therapies at an in-network specialty pharmacy it is necessary to assign an appropriate pharmacy benefit cost sharing tier. All clinical utilization management criteria (prior authorization, step therapy, quantity limits, authorization durations, etc.) will continue to apply without change. The estimated cost and proposed tier assignment is presented in the below chart.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Proposed Triple Tier Formulary Placement</th>
<th>Proposed 4 Tier Formulary Placement</th>
<th>Proposed Marketplace Formulary Placement</th>
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<tbody>
<tr>
<td>Abilify Maintena (aripiprazole)</td>
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<td>Specialty (Tier 4)</td>
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<td>Abraxane (paclitaxel protein-bound)</td>
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<td>Actemra IV (tocilizumab)</td>
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<td>Fasenra (benralizumab)</td>
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<td><strong>Flebogamma (intravenous immune globulin)</strong></td>
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<td><strong>Gamifant (emapalumab-lzsg)</strong></td>
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<td><strong>Gammagard (subcutaneous/intravenous immune globulin)</strong></td>
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<td><strong>Gammaked (subcutaneous/intravenous immune globulin)</strong></td>
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<td><strong>Gazyva (obinutuzumab)</strong></td>
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<td><strong>Gel-One (cross-linked hyaluronate)</strong></td>
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<td><strong>Halaven (eribulin mesylate)</strong></td>
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<td>Marqibo (vincristine sulfate liposome injection)</td>
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<td>MicRhogam Ultra Filtered (rho(d) immune globulin)</td>
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<td>Nplate (romiplostim)</td>
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<td>Octagam (intravenous immune globulin)</td>
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<td>Onivyde (irinotecan (liposomal))</td>
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<td>Recarbrio (imipenem/cilastatin sodium/telebactam)</td>
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<td>Specialty</td>
<td>Specialty</td>
</tr>
<tr>
<td>Reclast (zoledronic acid)*</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty</td>
<td>Specialty</td>
</tr>
<tr>
<td>Remicade (infliximab)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty</td>
<td>Specialty</td>
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<tr>
<td>Remodulin (treprostinil)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty</td>
<td>Specialty</td>
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<tr>
<td>Renflexis (infliximab-abda)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty</td>
<td>Specialty</td>
</tr>
<tr>
<td>Retisert (fluocinolone acetonide [ophthalmic implant])</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty</td>
<td>Specialty</td>
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<tr>
<td>Revco (elapegademase-lvrl)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty</td>
<td>Specialty</td>
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<tr>
<td>Rhogam (rho(d) immune globulin)</td>
<td>Brand Preferred (Tier 2)</td>
<td>Brand Preferred (Tier 2)</td>
<td>Brand Preferred (Tier 3)</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Brand Preferred (Tier 2)</td>
<td>Brand Preferred (Tier 2)</td>
<td>Brand Preferred (Tier 3)</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>--------------------------</td>
<td>--------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Rhophylac (rho(d) immune globulin)</td>
<td>Brand Preferred (Tier 2)</td>
<td>Brand Preferred (Tier 2)</td>
<td>Brand Preferred (Tier 3)</td>
</tr>
<tr>
<td>Risperdal Consta (risperidone microspheres)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Rituxan (rituximab)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Rituxan Hycela (rituximab/hyaluronidase)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Romidepsin</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Ruconest (Cl esterase inhibitor [recombinant])</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Ruxience (rituximab-pvvr)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Sandostatin LAR (octreotide)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Sarclisa (isatuximab-irfc)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Scenesse (afamelanotide)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Signifor LAR (pasireotide pamoate)</td>
<td>Excluded (Obsolete)</td>
<td>Excluded (Obsolete)</td>
<td>Excluded (Obsolete)</td>
</tr>
<tr>
<td>Simponi Aria (golimumab)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Sivextro (tedizolid)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Soliris (ecluzumab)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Somatuline Depot (lanreotide)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Spinraza (nusinersen)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Spravato (esketamine)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Stelara (ustekinumab)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Sublocade (buprenorphine)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Supartz/Supartz FX (hyaluronate sodium)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Supprellin LA (histrelin acetate)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Surfaxin (lucinactant)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Sustol (granisetron)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Sylvant (siltuximab)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Synagis (palivizumab)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Synribo (omacetaxine mepesuccinate)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Synvisc (hylan G-F 20)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Synvisc-One (hylan G-F 20)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Tecentriq (atezolizumab)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Teflaro (ceftaroline fosamil)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Temsirolimus</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Speciality (Tier 4)</td>
<td>Specialty (Tier 5)</td>
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<td>Drug Name</td>
<td>Formulary Level</td>
<td>Formulary Level</td>
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</tr>
<tr>
<td>---------------------------------</td>
<td>----------------</td>
<td>----------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Tepadina (thiotepa)</td>
<td>Non-Formulary</td>
<td>Non-Formulary</td>
<td>Non-Formulary</td>
</tr>
<tr>
<td>Tepezza (teprotumumab-trbw)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Thiotepa</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Thyrogen (thyrotropin alfa)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Torisel (tepsirolimus)</td>
<td>Non-Formulary (Generic Available)</td>
<td>Non-Formulary (Generic Available)</td>
<td>Non-Formulary (Generic Available)</td>
</tr>
<tr>
<td>Trazimera (trastuzumab-qyyp)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Treanda (bendamustine)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Trelstar (triptorelin)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Treprostinil</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Triptodur (triptorelin pamoate)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Trisenox (arsenic trioxide)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Trivisc (sodium hyaluronate)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Trodelvy (sacituzumab govitecan)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Truxima (rituximab-abbs)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Tysabri (natalizumab)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Ultomiris (ravulizumab-cwvz)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Unituxin (dinutuximab)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Vectibix (panitumumab)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Velcade (bortezomib)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Veltefr (epoprostenol)*</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Vimizim (elosulfase alfa)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Visco-3 (sodium hyaluronate)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Visudyne (verteporfin)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Vivitrol (naloxone injection)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Voraxaze (glucarpidase)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>VPRIV (velaglucerase alfa)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Vyepti (optinezumab-jjmr)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Vyondys 53 (golodirsen)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Vyxeos (daunorubicin/cytarabine (liposomal))</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Brand/Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>------------------------------</td>
<td>--------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>WinRho (rho(D) immune globulin)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Xembify (immune globulin subcutaneous, human-klhw)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Xeomin (incobotulinumtoxina)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Xgeva (denosumab)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Xiaflex (collagenase clostridium histolyticum)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Xofigo (radium RA 223 dichloride)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Xolair (omalizumab)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Yervoy (ipilimumab)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Yescarta (axicabtagene ciloleucel)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Yonelis (trabectedin)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Yutiq (fluocinolone acetonide)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Zaltrap (ziv-aflibercept)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Zemaira (alpha1-proteinase inhibitor, human)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Zemdri (plazomicin sulfate)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Zerbaxa (ceftepoxate/tazobactam)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Zevalin (ibrutinomab tiuxetan)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Zinplava (bezlotoxumab)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Zirabev (bevacizumab-bvzr)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Zoledronic Acid</td>
<td>Generic (Tier 1)</td>
<td>Generic (Tier 1)</td>
<td>Generic Non-Preferred (Tier 2)</td>
</tr>
<tr>
<td>Zolgensma (Onasemnogene Abepravovec)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Zometa (zoledronic acid)</td>
<td>Non-Formulary (Generic Available)</td>
<td>Non-Formulary (Generic Available)</td>
<td>Non-Formulary (Generic Available)</td>
</tr>
<tr>
<td>Zulresso (brexanolone)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
<tr>
<td>Zyprexa Relprevv (olanzapine)</td>
<td>Brand Non-Preferred (Tier 3)</td>
<td>Specialty (Tier 4)</td>
<td>Specialty (Tier 5)</td>
</tr>
</tbody>
</table>

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.
TRAVATAN Z (travoprost)

**Discussion**
The rebate for Travatan Z was recently terminated by the manufacturer due to the availability of an AB rated generic product.

<table>
<thead>
<tr>
<th></th>
<th>AWP per mL</th>
<th>Utilizing Members 1/1/2020 – 8/31/2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Travatan Z</td>
<td>$91.11</td>
<td>70</td>
</tr>
<tr>
<td>Travoprost</td>
<td>$59.99</td>
<td>116</td>
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</table>

**Recommendations**
It is recommended that brand name Travatan Z is moved to a non-formulary position. Members currently utilizing Travatan Z will be notified of the need to change to the generic formulation or to submit for a prior authorization exception. Requests for exception will be reviewed using the Brand vs. Generic Policy.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

KRISTALOSE PACKETS (lactulose)

**Discussion**

<table>
<thead>
<tr>
<th></th>
<th>AWP per mL</th>
<th>Utilizing Members since 1/1/2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kristalose 10 g packet</td>
<td>$9.68 per packet</td>
<td>2</td>
</tr>
<tr>
<td>Kristalose 20 g packet</td>
<td>$10.03 per packet</td>
<td>6</td>
</tr>
<tr>
<td>Lactulose 10 g/15 mL</td>
<td>$0.33 per 10 g</td>
<td>210</td>
</tr>
</tbody>
</table>

**Recommendations**
In order to promote utilization of the less expensive liquid formulation of lactulose prior to Kristalose powder packets, it is recommended that a prior authorization is added for new starts of Kristalose packets with the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to lactulose liquid

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

ALBUTEROL INHALERS

**Discussion**
During the initial phases of the COVID pandemic all albuterol inhalers were added to the Commercial, Marketplace, and GHP Kids formularies due to a shortage issue. Prior to the pandemic the only preferred formulary agent was Ventolin. Following resolution of the shortage a prior authorization for new starts only was added to all products other than Ventolin. This prompted an evaluation of the current costs of the available albuterol inhalers.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Current Formulary Status</th>
<th>Cost per Inhaler</th>
</tr>
</thead>
<tbody>
<tr>
<td>VENTOLIN HFA 90 MCG INHALER</td>
<td>Generic</td>
<td>$45.36 (net of rebate)</td>
</tr>
<tr>
<td>ALBUTEROL SUL HFA 90 MCG INH (GENERIC PROAIR)</td>
<td>Generic, PA for New Starts only</td>
<td>$21.17</td>
</tr>
<tr>
<td>ALBUTEROL SUL HFA 90 MCG INH (GENERIC VENTOLIN)</td>
<td>Generic, PA for New Starts only</td>
<td>$44.82</td>
</tr>
<tr>
<td>ALBUTEROL SUL HFA 90 MCG INH (GENERIC PROVENTIL)</td>
<td>Generic, PA for New Starts only</td>
<td>$16.68</td>
</tr>
<tr>
<td>PROAIR HFA 90 MCG INHALER</td>
<td>Brand Preferred, PA for New Starts Only</td>
<td>$66.81</td>
</tr>
<tr>
<td>PROAIR DIGIHALER 90 MCG</td>
<td>Brand Preferred, PA for New Starts Only</td>
<td>$146.67</td>
</tr>
<tr>
<td>PROAIR RESPICLICK INHAL POWDER 90 MCG</td>
<td>Brand Preferred, PA for New Starts Only</td>
<td>$62.52</td>
</tr>
<tr>
<td>PROVENTIL HFA 90 MCG INHALER</td>
<td>Brand Preferred, PA for New Starts Only</td>
<td>$79.73</td>
</tr>
</tbody>
</table>

**Recommendations**

Based on the low cost of the generic albuterol inhalers it is recommended that brand name Ventolin, ProAir, and Proventil are moved to a non-formulary status. The prior authorization will be removed from the generic albuterol inhalers. The move to non-formulary on the branded products will be delayed for 6 months following the removal of the prior authorization on the generics in order to allow a natural transition of members from the brand to generic. Members who continue on the branded product despite the addition of the generic will be sent a letter notifying them that they will need to transition to the generic or request a new prior authorization.

ProAir Digihaler and Respiclick will continue to be reviewed with the Albuterol HFA policy (444.0). The policy will be renamed to ProAir Digihaler/Respiclick and will be updated to require failure on a generic albuterol HFA. ProAir HFA, Proventil HFA, and Ventolin HFA will be reviewed with the Brand vs. Generic policy.

A formulary exception for coverage of ProAir Digihaler or ProAir Respiclick **Albuterol-HFA** may be made for members who meet the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to **albuterol Ventolin HFA**
**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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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**DALIRESP (roflumilast)**

**Discussion**
There are currently two preferred long-acting antimuscarinic antagonists (LAMA) on the Commercial, Marketplace, and GHP Kids formularies, Spiriva and Incruse Ellipta.

**Recommendations**
In consideration that the guidelines do not recommend a specific LAMA agents be tried prior to adding Daliresp to the patients treatment regimen, it is recommended that the current Daliresp policy be updated as follows:

- Medical record documentation of a diagnosis of chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Spiriva, one long acting antimuscarinic antagonist AND one long acting beta agonist

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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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**ERY-TAB (erythromycin)**

**Discussion**

<table>
<thead>
<tr>
<th></th>
<th>Cost per Tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ery-Tab 333 mg</td>
<td>$11.12</td>
</tr>
<tr>
<td>Erythromycin 333 mg</td>
<td>$10.97</td>
</tr>
</tbody>
</table>

**Recommendations**
Given the generic availability of erythromycin 333 mg tablets, it is recommended that Ery-Tab 333 mg is moved to non-formulary.

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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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**DAY SUPPLY LIMITATION UPDATES**
### Recommendations

<table>
<thead>
<tr>
<th></th>
<th>Current Day Supply Limit</th>
<th>Recommended Day Supply Limit</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fondaparinux</strong></td>
<td>14</td>
<td>34</td>
<td>Indications range in duration of therapy from 10 days (VTE prophylaxis) to ≥ 3 months (unprovoked DVT/PE treatment).</td>
</tr>
<tr>
<td><strong>Leukine</strong></td>
<td>7</td>
<td>34</td>
<td>Current claims data indicate prescribed anywhere from 2 – 30 days supply per fill. Moving to 34 days will be consistent with the benefit limit of 34 day supply per month.</td>
</tr>
<tr>
<td><strong>Neupogen</strong></td>
<td>7</td>
<td>34</td>
<td>Current claims data indicate prescribed anywhere from 2 – 30 days supply per fill. Moving to 34 days will be consistent with the benefit limit of 34 day supply per month.</td>
</tr>
</tbody>
</table>

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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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### ALUNBRIG (brigatinib)

**Discussion**
When first approved by the Food and Drug Administration (FDA) in 2017 Alunbrig was only available as a 30 mg and 90 mg tablet. The FDA has since approved a 180 mg dosage as well as a dose pack containing 90 mg and 180 mg tablets. Dose reductions due to adverse events are permitted to no lower than 60 mg once daily.

**Recommendations**
It is recommended that the quantity limit is updated as follows due to the availability of the 180 mg tablet:

<table>
<thead>
<tr>
<th></th>
<th>Current Quantity Limit</th>
<th>Recommended Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alunbrig 30 mg</td>
<td>120/30</td>
<td>60/30</td>
</tr>
<tr>
<td>Alunbrig 90 mg</td>
<td>30/30</td>
<td>30/30</td>
</tr>
<tr>
<td>Alunbrig 180 mg</td>
<td>30/30</td>
<td>30/30</td>
</tr>
<tr>
<td>Alunbrig Starter Pack (90 &amp; 180 mg)</td>
<td>30/30</td>
<td>30/30</td>
</tr>
</tbody>
</table>

**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.
Drug Use Evaluations (DUEs)

- Asthma DUE
  - This is the 2020 3rd quarter MedImpact DUE for all LOBs
  - From this report, we identified 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.
  - The Print Shop completed the mail merge and sent out letters to the member's providers on 8/26/2020.
  - We will have Adam K. re-run this data in December 2020 to show us the effectiveness of the letter.
  - See below for letters sent:
    - For GHS01: 98
    - For GHS25: 4
    - For GT023: 2
    - For GT045: 5
    - For GT056: 3
    - For GT070: 1
    - For GT095: 22
    - For GT140: 2
    - For GT291: 1
    - For GT400: 96

- Congestive Heart Failure DUE
  - This is the 2020 2nd quarter MedImpact DUE for Commercial/Exchange and GHP Family
  - From this report, we identified 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
  - The Print Shop completed the mail merge and sent out letters to the member’s providers on 6/30/2020.
  - We will have Adam K. re-run this data in October 2020 to show us the effectiveness of the letter.
  - See below for letters sent:
    - For GHS01: 89
    - For GHS25: 6
    - For GT038: 51 - Life Geisinger
    - For GT062: 13
    - For GT095: 22
    - For GT400: 92

- Coronary Artery Disease DUE
  - This is the 2020 1st quarter MedImpact DUE for all LOBs
  - From this report, we identified 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. is completed the mail merge and sent out letters to the member’s providers on 2/21/2020.

See below for letters sent:

- For GHS01: 91
- For GHS25: 36
- For GT023: 54
- For GT036: 12
- For GT041: 15
- For GT046: 100
- For GT062: 100
- For GT065: 100
- For GT088: 18
- For GT095: 100
- For GT107: 14
- For GT140: 31
- For GT210: 22
- For GT260: 30
- For GT400: 100
- For GHS05: 87
- For GHS90: 100
- For GT033: 32
- For GT038: 14
- For GT045: 100
- For GT064: 14
- For GT070: 27
- For GT089: 74
- For GT106: 23
- For GT108: 14
- For GT180: 13
- For GT230: 65
- For GT310: 28
- For GT900: 100

Adam K. was able to re-run the data on this population on 8/5/2020 and of the original 1,296 members that we sent letters to, 1,195 are still active. Of those 1,195 members, 128 now have a claim for a statin. This equates to 11% of the members.

**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 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.

See below for letters sent:

- For GHS01: 93
- For GHS25: 14
- For GT023: 8
- For GT038: 3
- For GT045: 34
- For GT056: 6
- For GT064: 2
- For GT072: 7
- For GT075: 1
- For GT089: 14
- For GT095: 99
- For GT107: 3
- For GT180: 3
- For GT230: 18
- For GT260: 2
- For GT310: 6
- For GHS05: 91
- For GHS90: 98
- For GT036: 1
- For GT039: 1
- For GT046: 31
- For GT062: 98
- For GT065: 90
- For GT074: 1
- For GT088: 4
- For GT093: 4
- For GT106: 3
- For GT140: 10
- For GT210: 4
- For GT231: 1
- For GT280: 6
- For GT400: 100
For GT900: 13
  o Adam K. was able to re-run the data on this population on 3/27/2020 and of the original 871 members that we sent letters to 741 are still active. Of those 741 members, 158 now have a claim for a statin. This equates to 21% of the members.

In Progress
  • Nothing currently in progress

Ongoing
  • DUR Duplicate Anticoagulant Report
    o We get this report weekly for all LOBs flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/pharmacy/patient of the flagged members to confirm proper medication therapy.
      o For 2020:
        ▪ For GHS01: 1 member reviewed and 0 interventions made
        ▪ For GHS02: 1 member reviewed and 0 interventions made
        ▪ For GHS05: 2 members reviewed and 1 intervention made
        ▪ For GHS90: 7 members reviewed and 2 interventions made
        ▪ For GT045: 2 members reviewed and 0 interventions made
        ▪ For GT062: 1 member reviewed and 0 interventions made
        ▪ For GT065: 4 members reviewed and 1 intervention made
        ▪ For GT095: 1 member reviewed and 0 interventions made
        ▪ For GT400: 5 members reviewed and 0 interventions made
        ▪ For GT900: 1 member reviewed and 0 interventions made
  • Duplicate Specialty Therapy
    o 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.
      o For Commercial/Exchange 2020, we have reviewed the Q1 and Q2 reports and have discussed the following patients with Dr. Yarczower for intervention:
        ▪ GHS01: 1
        ▪ GHS90: 2
        ▪ GT095: 4
        ▪ GT400: 1
  • Suboxone with an Opioid Report
    o We are getting this report weekly for all LOBs from Adam Kelchner. 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.
      o For Commercial/Exchange and TPAs in 2020, see below for the new members reviewed and those referred to Dr. Meadows
      o For 2020:
        ▪ For GHS01: we have reviewed 2 new members and 0 members were referred to Dr. Meadows
For GHS05: we have reviewed 2 new members and 1 member was referred to Dr. Meadows
For GHS90: we have reviewed 4 new members and 3 members were referred to Dr. Meadows
For GT023: we have reviewed 1 new member and 0 members were referred to Dr. Meadows
For GT400: we have reviewed 4 new members and 1 member was referred to Dr. Meadows
For GT902: we have reviewed 1 new member and 0 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 Commercial/Exchange and TPAs in 2020, see below for the number of letters we have sent to members notifying them that we are ending their opioid authorization(s):
    - For GHS05: 1
    - For GHS90: 2
    - For GT400: 1

- **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 Commercial/Exchange and TPAs in 2020, see below for the number of reviewed cases.
    - For GHS90: 2 patients were reviewed, and 1 case was sent to Dr Meadows for further review

- **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 GHS01 in 2020, we have reviewed 36 cases so far and corrected 21 claims, resulting in a cost savings of $1,178.66
    - For GHS02 in 2020, we have reviewed 9 cases so far and corrected 1 claim, resulting in a cost savings of $0
    - For GHS05 in 2020, we have reviewed 29 cases so far and corrected 21 claims, resulting in a cost savings of $1,248.95
    - For GHS25 in 2020, we have reviewed 1 case so far and corrected 1 claim, resulting in a cost savings of $0
- For GHS90 in 2020, we have reviewed 68 cases so far and corrected 42 claims, resulting in a cost savings of $1,154.95
- For GT038 in 2020, we have reviewed 12 cases so far and corrected 3 claims, resulting in a cost savings of $36.02
- For GT045 in 2020, we have reviewed 4 cases so far and corrected 3 claims, resulting in a cost savings of $31.05
- For GT046 in 2020, we have reviewed 4 cases so far and corrected 1 claim, resulting in a cost savings of $1.00
- For GT056 in 2020, we have reviewed 2 cases so far and corrected 2 claims, resulting in a cost savings of $321.13
- For GT062 in 2020, we have reviewed 9 cases so far and corrected 2 claims, resulting in a cost savings of $21.09
- For GT065 in 2020, we have reviewed 34 cases so far and corrected 27 claims, resulting in a cost savings of $1,511.61
- For GT070 in 2020, we have reviewed 1 case so far and corrected 1 claim, resulting in a cost savings of $0.40
- For GT095 in 2020, we have reviewed 23 cases so far and corrected 9 claims, resulting in a cost savings of $768.21
- For GT180 in 2020, we have reviewed 2 cases so far and corrected 2 claims, resulting in a cost savings of $1.90
- For GT400 in 2020, we have reviewed 36 cases so far and corrected 19 claims, resulting in a cost savings of $2,251.61
- For GT900 in 2020, we have reviewed 3 cases so far and corrected 1 claim, resulting in a cost savings of $0

**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 Commercial/Exchange in 2020, we have sent letters to providers on the below members:
  - For GHS01: 10
  - For GHS05: 8
  - For GHS90: 12
  - For GT038: 3
  - For GT062: 2
  - For GT065: 7
  - For GT095: 7
  - For GT400: 9
  - For GT900: 1
- *We are working on a revision to this report that will result in a substantial increase of the interactions identified/outreached on*

**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.

- We put in place QLs for Enbrel, so we should not be seeing these cases moving forward for new starts or for re-authorization
  - For 2020, we have not identified any members

**Tobacco Cessation Program**
- We are getting this report monthly to identify members on prolonged tobacco cessation treatment. We send a letter and resource pamphlet to provide additional behavioral health support through Geisinger Health and Wellness.
- For Commercial/Exchange in 2020, we have sent letters to the below members:
  - For GHS01: 3
  - For GHS05: 1
  - For GHS90: 3
  - For GT062: 1
  - For GT065: 4
  - For GT230: 1
  - For GT400: 1

**STENT Adherence Report**
- This is a monthly report to identify members on an antiplatelet medication and then flag for betablocker and statin medication claims.
- In 2020, we have sent letters encouraging adherence to the below members:
  - **Members for Antiplatelet:**
    - GHS01: 74
    - GHS05: 43
    - GHS25: 1
    - GHS90: 119
    - GT017: 1
    - GT023: 1
    - GT036: 1
    - GT038: 19
    - GT039: 1
    - GT041: 1
    - GT045: 3
    - GT056: 1
    - GT062: 14
    - GT065: 16
    - GT089: 2
    - GT095: 20
    - GT180: 1
    - GT230: 2
    - GT400: 28
    - GT900: 4
  - **Members for Beta-Blocker:**
    - GHS01: 50
    - GHS05: 30
    - GHS25: 1
    - GHS90: 81
    - GT023: 1
    - GT036: 1
    - GT038: 14
    - GT039: 1
    - GT041: 1
    - GT045: 1
    - GT056: 1
    - GT062: 11
    - GT065: 12
    - GT089: 1
    - GT095: 11
    - GT180: 1
    - GT230: 2
    - GT400: 17
Members for Statin:

- GHS01: 57
- GHS05: 31
- GHS25: 1
- GHS90: 84
- GT023: 1
- GT036: 1
- GT038: 14
- GT039: 1
- GT045: 3
- GT056: 1
- GT062: 11
- GT065: 12
- GT089: 1
- GT095: 17
- GT230: 2
- GT400: 23
- GT900: 3

*member may flag for more than one measure and are included in the count for each measure.

We are also attempting telephonic outreach to members who are non-adherent in all 3 measures to encourage adherence.

HEDIS Initiatives:

- **Asthma Medication Ratio (AMR)**
  - 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 Commercial/Exchange in 2020, see below for letters sent to members:
      - GHS01: 10
      - GHS90: 3

- **Antidepressant Medication Management (AMM)**
  - 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 Commercial/Exchange in 2020, see below for letters sent to members:
      - Effective Acute Phase:
        - GHS01: 6
        - GHS90: 1
      - Effective Continuation Phase:
        - GHS01: 98
        - GHS90: 82

- **Medication Management for People with Asthma (MMA)**
  - 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 Commercial/Exchange in 2020, see below for letters sent to members:
      - GHS01: 35
      - GHS05: 3
      - GHS90: 30

- **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 Commercial/Exchange in 2020, **0 letters** were sent to members so far.
- **Statin Therapy for Patients with Cardiovascular Disease (SPC)**
  - This is a **monthly** report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
    - For Commercial/Exchange in 2020, see below for letters sent to **providers** to encourage statin therapy initiation:
      - GHS01: **35**
      - GHS02: **1**
      - GHS05: **1**
      - GHS90: **18**
    - For Commercial/Exchange in 2020, see below for letters sent to **members** to promote statin adherence:
      - GHS01: **22**
      - GHS90: **6**
- **Statin Therapy for Patients with Diabetes (SPD)**
  - This is a **monthly** report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
    - For Commercial/Exchange in 2020, see below for letters sent to **providers** to encourage statin therapy initiation:
      - GHS01: **456**
      - GHS05: **2**
      - GHS90: **195**
    - For Commercial/Exchange in 2020, see below for letters sent to **members** to promote statin adherence:
      - GHS01: **84**
      - GHS05: **17**
      - GHS25: **1**
      - GHS90: **41**
      - GT023: **1**
      - GT036: **1**
      - GT038: **1**
      - GT039: **1**
      - GT045: **1**
      - GT046: **2**
      - GT062: **7**
      - GT065: **2**
      - GT089: **1**
      - GT095: **12**
      - GT230: **1**
      - GT400: **21**
• Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
  o This is a monthly report to identify members with a diagnosis of AMI who received beta-blocker treatment for 6 months after discharge and who are non-adherent to beta-blocker therapy
    ▪ For Commercial/Exchange in 2020, 0 letters were sent to members so far.

Completed

• Commercial/Exchange DUR/FWA Program Fliers
  o Last updated 08/2020 next update 02/2021
• Current Provider Letters
  ▪ Congestive Heart Failure DUE
  ▪ Coronary Artery Disease DUE
  ▪ Statin Use in Persons with Diabetes DUE
  ▪ Asthma Med Ratio DUE
  ▪ Opioid Overutilization
  ▪ Severity Report
  ▪ Duplicate Anticoagulant Report
  ▪ Statin Therapy for Patients with Cardiovascular Disease (SPC)
  ▪ Statin Therapy for Patients with Diabetes (SPD)
• Current Member Letters
  ▪ Ending Opioid Authorizations
  ▪ Adherence to Antipsychotics (SAA)
  ▪ Antidepressant Medication Management (AMM)
  ▪ Asthma Medication Ratio (AMR)
  ▪ Medication Management for People with Asthma (MMA)
  ▪ Statin Therapy for Patients with Cardiovascular Disease (SPC)
  ▪ Statin Therapy for Patients with Diabetes (SPD)
  ▪ Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
  ▪ STENT Adherence Report

QUARTERLY CASE AUDIT RESULTS

The Quarterly Case Audit was held on September 4th for 2nd quarter 2020. No recommendations made to changes of formulary at this time. Will continue to look for opportunities to create more drug specific policies at future quarterly case audit meetings.

Meeting adjourned at 4:45 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, November 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 or will be held virtually.