

**P&T Committee Meeting Minutes**  
**Medicaid**  
**July 16, 2019**

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<p><b>Present:</b> Bret Yarczower, MD, MBA – Chair Kristen Bender, PharmD – via phone Rajneel Chohan Pharm.D. Alyssa Cilia, RPh – via phone Kimberly Clark, Pharm.D. Jason Howay, Pharm.D. – via phone Keith Hunsicker, Pharm.D. Kelli Hunsicker, Pharm.D. – via phone Steven Kheloussi, Pharm.D. – via phone Phillip Krebs, R.EEG T. – via phone Jamie Miller, RPh Aubrielle Prater Pharm.D. Kimberly Reichard Pharm.D. Kristen Scheib, Pharm.D. – via phone William Seavey, Pharm.D. – via phone Richard Silbert, MD – via phone Michael Spishock, RPh – via phone Todd Sponenberg, Pharm.D. Kevin Szczecina, RPh Kelly Yelenic Pharm.D. Austin Paisley, Pharmacy student Vincenzo Parente, Pharmacy student Lucas Whittaker, Pharmacy student</p>	<p><b>Absent:</b> Kenneth Bertka, MD Beverly Blaisure, MD Holly Bones, Pharm.D. Kim Castelnovo Dean Christian, MD Michael Evans, RPh Tricia Heitzman, Pharm.D. Perry Meadows, MD Steven Moscola, RPh Jonas Pearson, RPh Angela Scarantino Jill Stone, Pharm.D.</p>
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**Call to Order:**

Dr. Bret Yarczower called the meeting to order at 1:04 p.m., Tuesday, July 16, 2019.

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**Review and Approval of Minutes:**

Dr. Bret Yarczower asked for a motion or approval to accept the May 21, 2019 minutes as written. Kevin Szczecina accepted the motion and Todd Sponenberg seconded the motion. None were opposed.

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## DRUG REVIEWS

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### CABLIVI (caplacizumab-yhdp)

**Review:** Cablivi is a von Willebrand factor (vWF)- directed antibody fragment indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy. Cablivi is a selective, humanized, bivalent anti-vWF nanobody. Cablivi targets the A1-domain of vWF, and inhibits the interaction between vWF and platelets, thereby reducing both vWF-mediated platelet adhesion, platelet consumption, and microthrombi formation. Cablivi (caplacizumab-yhdp) is the first FDA-approved agent for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP) when used in combination with plasma exchange (PEX) and immunosuppressive therapy.

Cablivi is supplied as a 11 mg single use vial kit. Cablivi should be administered upon initiation of PEX therapy (before and after), during daily PEX (once daily), and then continued once daily for 30 days following the last daily PEX. The first dose should be administered by a healthcare provider as a bolus intravenous injection. Subsequent doses may be administered subcutaneously in the abdomen by the patient or caregiver after proper training. After initial treatment course, if sign(s) of persistent underlying disease such as suppressed ADAMTS13 activity levels remain present, treatment may be extended for a maximum of 28 days. It should be discontinued if the patient experiences more than 2 recurrences of aTTP, while on Cablivi.

HERCULES is a phase 3, multicenter, randomized, double-blind, placebo-controlled trial that enrolled a total of 145 adults. Patients with aTTP were randomized to receive either Cablivi (n = 72) or placebo (n = 73) during PEX and for 30 days thereafter. Patients in both groups also received standard of care aTTP treatment: PEX and immunosuppressive therapy (e.g. glucocorticoids, Rituxan). Cablivi or placebo treatment could be extended beyond 30 days based on a number of risk factors for TTP recurrence, including persistent and severe ADAMTS13 deficiency, up to a maximum of 28 days. Study treatment was stopped when ADAMTS13 activity showed a sustained upward trend of > 10%. Patients included in the trial were  $\geq 18$  years, had a clinical diagnosis of TTP (thrombocytopenia and microscopic evidence of red blood cell fragmentation), and required initiation of daily PEX and received 1 PEX treatment prior to randomization. At baseline, 81% of patients in Cablivi and 89% in placebo had ADAMTS13 activity < 10%. The primary outcome was the time to platelet count response (platelet count  $\geq 150,000/\mu\text{L}$ ) followed by discontinuation of daily plasma exchange within 5 days. Time to platelet count response was shorter among patients treated with Cablivi, compared to placebo. Median time (50<sup>th</sup> percentile) to platelet normalization was 2.69 days in Cablivi versus 2.88 days in placebo. Additionally, treatment with Cablivi resulted in a lower number of patients with TTP-related death, recurrence of TTP, or at least one treatment-emergent major thromboembolic event (a composite endpoint) during the treatment period. Exacerbations (within 30-day post PEX) occurred in 4% of Cablivi patients and 38% of placebo patients. Relapse (>30 days after end of PEX) occurred in 8% of patients receiving Cablivi and none of placebo patients. Mean days of PEX, mean volume of PEX, mean days of hospitalizations were lower for those receiving Cablivi. Also, patients receiving Cablivi spent fewer days in the ICU.

Cablivi does not carry any black box warnings but does have contraindications for a previous hypersensitivity reaction to Cablivi or any of the excipients, and warnings and precautions for bleeding. Concomitant use of anticoagulants with Cablivi may increase the risk of bleeding, hence close monitoring for bleeding is recommended. The most common adverse reactions occurring in more than 15% of patients included epistaxis, headache and gingival bleeding. There may be an increased risk of bleeding in the fetus, neonate, and pregnant women. The safety and effectiveness of Cablivi in pediatric patients have not been established.

The American Society of Apheresis consensus conference in 2012 published treatment recommendations for TTP. PEX should be started in patients who present with unexplained microangiopathic hemolytic anemia (Coombs' negative anemia) and thrombocytopenia (platelet count <  $100 \times 10^9/\text{L}$ ), in the absence of oliguric renal insufficiency. The routine use of corticosteroids for the treatment of newly diagnosed TTP is supported by evidence. In patients experiencing exacerbations, relapses, or refractory disease despite aggressive PEX, Rituxan is recommended in these patients. There was no recommendations made on the use of cyclosporine, splenectomy, and antiplatelets. Rituxan should be considered in patients with recurrent episodes of aTTP.

Gary Lewis, hematology/oncology pharmacist at Geisinger, said that typically if aTTP is suspected, providers will just start therapy without getting ADAMST13 testing. ADAMST13 testing takes about 3-4 days to get results. He mentioned that PEX and corticosteroids are used initially. Rituxan would be considered as a 3<sup>rd</sup> line agent prior to Cablivi. Cablivi would be considered last line agent at this time. Typically, PEX is given inpatient for about a week. After that, providers try to move PEX to every other day dosing at an outpatient clinic. 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 questions or comments. Keith Hunsicker made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

**Financial Discussion:** No questions or comments. Jamie Miller made a motion to accept the recommendations as presented. Kelly Yelenic seconded the motion. None were opposed.

**Outcome:** Cablivi will be covered as a pharmacy benefit requiring prior authorization. It will be added to the formulary on the brand tier. The following prior authorization criteria will apply:

Currently on PEX Therapy:

- Prescription written by or in consultation with a hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) **AND**
- Medical record documentation that Cablivi will be used in combination with daily plasma exchange and immunosuppressive therapy (e.g. glucocorticoids, rituximab) **AND**
- Medical record documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi

Completed PEX:

- Prescription written by or in consultation with a hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) **AND**
- Medical record documentation that the member previously received daily plasma exchange, immunosuppressive therapy, and Cablivi within the inpatient setting **AND**
- Medical record documentation of the date of the last plasma exchange **AND**
  - Medical record documentation of one of the following:
    - The date of plasma exchange is within 30 days of the request date **OR**
    - If the date of plasma exchange is > 30 days of the request date, medical record documentation sign(s) of persistent underlying disease (e.g. suppressed ADAMTS13 activity levels remain present) and medical record documentation that the member has not exceeded the maximum treatment duration of Cablivi (30 days post PEX and up to 28 days of extended treatment) **AND**
- Medical record documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi

**AUTHORIZATION DURATION:** Initial approval will be for 30 days or less if the reviewing provider feels it is medically necessary. Subsequent approvals will be for an additional 30 days or less if the reviewing provider feels it is medically necessary.

**REAUTHORIZATION CRITERIA:**

#### Currently on PEX

- Medical record documentation that the member is still receiving daily plasma exchange therapy and Cablivi will be used in combination with plasma exchange and immunosuppressive therapy (e.g. glucocorticoids, rituximab) **AND**
- Medical record documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi

#### Completed PEX within 30 days

- Medical record documentation that the member previously received daily plasma exchange and immunosuppressive therapy **AND**
- Medical record documentation of the date of last plasma exchange **AND**
- The date of plasma exchange is within 30 days of the request date **AND**
- Medical record documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi

#### Completed PEX >30 days

- Medical record documentation sign(s) of persistent underlying disease (e.g. suppressed ADAMTS13 activity levels remain present) **AND**
- Medical record documentation of the date of last plasma exchange **AND**
- Medical record documentation that the member has not exceeded the maximum treatment duration of Cablivi (30 days post PEX and up to 28 days of extended treatment) **AND**
- Medical record documentation that the member has not experienced more than two recurrences of aTTP while on Cablivi

**QUANTITY LIMIT:** 1 kit per day

**NOTE:** Cablivi should be administered upon initiation of PEX therapy, during daily PEX, and continued daily for 30 days following last daily PEX. If necessary, treatment can be extended for a maximum of 28 days.

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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#### **BALVERSA (erdafitinib)**

**Review:** Balversa (erdafitinib) is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has susceptible FGFR3 or FGFR2 genetic alterations and progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. Balversa is dosed 8 mg (two 4 mg tablets) orally once daily without regard to food and can be increased to 9 mg (three 3 mg tablets) once daily based on tolerability. The oral route of administration provides an important benefit over other agents with a similar role in therapy, namely the PD-L1 inhibitors that are all dosed IV. The most important adverse events with this agent are ocular disorders, hyperphosphatemia, and embryofetal toxicity. In a clinical study, there was a 32.2% overall response rate to Balversa, including 2.3% a complete response rate and a 29.9% partial response rate. The NCCN guidelines recommend Balversa as an alternative preferred regimen only for patients with susceptible FGFR3 or FGFR2 genetic alternations after platinum-containing chemotherapy. This is the only agent that targets FGFR3 or FGFR2 susceptible mutations.

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

**Clinical Discussion:** While presenting the criteria, Steven Kheloussi recommended adding a criteria requiring the member to be 18 years of age or older. No comments or questions. Jamie Miller made a motion to accept the recommendations as amended. Kevin Szczecina seconded the motion. None were opposed.

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

**Outcome:** Balversa will be covered as a pharmacy benefit requiring prior authorization. Balversa will be added to the formulary on the Brand tier. The following prior authorization criteria will apply:

- Medical record documentation that the patient is at least 18 years of age **AND**
- Medical record documentation that Balversa is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**
- Medical record documentation of an FGFR3 or FGFR2 genetic alteration determined using an FDA-approved test\* **AND**
- Medical record documentation of failure on platinum-containing chemotherapy

**QUANTITY LIMIT:**

- 3 mg tablets – 3 tablets per day
- 4 mg tablets – 2 tablets per day
- 5 mg tablets – 1 tablet per day

**MAX DAYS SUPPLY:** 28 days

**PHARMACIST NOTE TO CSR:** Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

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

**\*NOTE:** – The FDA-approved test is the *therascreen*® FGFR RGQ RT-PCR Kit<sup>1</sup>

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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## ZOLGENSMA (onasemnogene abeparvovec-xioi)

**Review:** Zolgensma is a recombinant adenovirus-associated vector-based gene therapy indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene. The safety and effectiveness of repeat administrations of Zolgensma have not been evaluated, and the use of Zolgensma in patients with advanced SMA has not been evaluated. Zolgensma works by delivering a copy of the gene encoding the human SMN protein, resulting in cell transduction and expression of SMN protein. Zolgensma is administered as a one-time IV infusion.

In clinical trials, Zolgensma achieved positive survival and permanent ventilation outcomes, motor milestone achievement outcomes, and motor function outcomes (among other outcomes). These outcomes were achieved in a manner that differed significantly from the natural history of the disease. While there are not clinical trials directly powered to compare Zolgensma to Spinraza, post-hoc analyses have indicated that Zolgensma may result in faster and numerically larger motor function outcomes than Spinraza. Zolgensma is very well tolerated by patients with the exception acute serious liver injury, which is a black box warning for the medication. To combat this adverse reaction, systemic corticosteroids should be administered prior to dosing with Zolgensma and for at least 30 days after Zolgensma administration.

Dr. Brandsema and Dr. Maguire have very favorable opinions of both Zolgensma and Spinraza. To date, the outcomes with Zolgensma are impressive, and the main shortcomings of Zolgensma is the unknown durability of the drug and the difficult follow up on these patients. Dr. Brandsema indicated that Zolgensma should not yet be considered a “one-time cure” until more information about Zolgensma is known. Dr. Brandsema indicated that SMA subtypes do not have much of a role in the treatment of SMA anymore and advocates against the inclusion of SMN2 copy criteria in drug policies. He also indicated that gene modifications (such as the c.859G>C modification mentioned in the trials’ inclusion/exclusion criteria) are not testable clinically and should not be included in policy criteria. Dr. Brandsema indicated that the use of both Spinraza and Zolgensma have not been studied and there is no evidence to support that the combination is safe and more effective than the use of an individual treatment; however, he has used the combination post-clinical trials when the drugs were sponsored by the manufacturers. Dr. Maguire indicates that he plans to discontinue Spinraza prior to dosing Zolgensma in eligible patients.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. Zolgensma has not been studied and therefore is not approved for use in the adult population.

**Clinical Discussion:** Dr. Yarczower made a comment that it appears they are pushing for earlier treatment, and that Pennsylvania is adding this test to the newborn screening requirements. Kimberly Clark asked why there is a hard stop for 2 years of age and older. Reviewer stated that this medication was only studied in newborns. Jamie Miller made a motion to accept the recommendations as presented. Aubrielle Prater seconded the motion. None were opposed

**Financial Discussion:** No comments or questions. Aubrielle Prater made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

**Outcome:** Zolgensma will be covered as a medical benefit requiring prior authorization. The following prior authorization criteria will apply:

- Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
    - Homozygous exon 7 gene deletion **OR**
    - Homozygous exon 7 conversion mutation **OR**
    - Compound heterozygous exon 7 mutation
- OR**
- Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies

**AND**

- Prescription is being prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation that the patient will be less than 2 years of age at the time of dosing **AND**
- Medical record documentation that patient does not have anti-AAV9 antibody titers >1:50 as determined by ELISA (within two weeks of the anticipated infusion date) **AND**
- Medical record documentation that patient is not permanent ventilator-dependent **AND**
- Medical record documentation that patient has not received a prior dose of Zolgensma **AND**
- Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Spinraza) with Zolgensma (Note: Any current authorizations for SMN modifying therapy will be terminated upon Zolgensma approval)

**AUTHORIZATION DURATION:** 30 days (to receive the one-time infusion) or the date equivalent to the patient age of 2 years (whichever is less).

**QUANTITY LIMIT:** One (1) Zolgensma infusion per lifetime

**Other Recommendations: Spinraza (nusinersen)**

With the introduction of Zolgensma to the market, treatment with Spinraza may not be appropriate in all patients. The use of concomitant Zolgensma + Spinraza has not been studied and there is no evidence to suggest that this combination is safe or effective. For that reason, Spinraza should be discontinued if Zolgensma is to be given, and Spinraza should not be given if Zolgensma was previously given. It is recommended that the Spinraza policy be adjusted to account for these changes.

**Recommendations:** No changes are recommended to the formulary placement of Spinraza at this time. It is recommended that the prior authorization criteria are updated as follows.

- Prescription is being prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
  - Homozygous exon 7 gene deletion **OR**
  - Homozygous exon 7 conversion mutation **OR**
  - Compound heterozygous exon 7 mutation

**OR**

- Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies.

**AND**

- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Zolgensma)

**AUTHORIZATION DURATION:** If determined to be medically necessary, Spinraza should be approved for an initial authorization duration of 12 months. Subsequent authorizations of Spinraza will be determined

medically necessary and should be approved for an authorization duration of 12 months when the following criteria are met:

- Medical record documentation that member is compliant with prescribed nusinersen regimen **AND**
- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Zolgensma)

**Clinical Discussion:** Kimberly Clark asked what we would do if someone “failed” Zolgensma. Reviewer stated that this would be handled on a case by case basis and reviewed for medical necessity. Kelly Yelenic made a recommendation to accept the recommendations as presented. Jamie Miller seconded the motion. None were opposed.

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

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### **SYMJEPI (epinephrine)**

**Review:** Symjepi is a new epinephrine pen indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis reactions to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.<sup>1</sup> There are four other products available containing epinephrine as the active ingredient including epinephrine, EpiPen, Auvi-Q, and generically available AdrenaClick. Symjepi is dosed as 0.15 mg/0.3 mL for individuals weighing between 15 and 30 kg, and 0.3 mg/0.3 mL for patients weighing over 30 kg. At the time of this review, only the 0.3 mg/0.3 mL strength is available on the market. In a simulated study, no errors occurred with the Symjepi device while there were four errors with the EpiPen trainer, showing that the Symjepi pen may be an easier device for patients to use. Due to the presence of an exposed needle before injection and need for manual covering after injection, Symjepi has the potential to cause inadvertent needle sticks. Also, Symjepi may be more complicated for users to inject the correct quantity since the user has to make sure the plunger of the device is all the way down as well as making sure the solution window is partially covered or blocked. It is, however, the smallest device on the market and requires the needle to remain in place for only 2 seconds after administration, like Auvi-Q.

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

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

**Financial Discussion:** Dr. Silbert questioned the availability of epinephrine auto-injectors. The reviewer indicated the intention of the note to the reviewer was to approve requests in the event the member is unable to obtain a different epinephrine product. Kevin Szczecina made a motion to accept the recommendations as presented. Keith Hunsicker seconded the motion. None were opposed.

**Outcome:** Symjepi will be covered as a pharmacy benefit requiring prior authorization. Symjepi will not be added to the formulary. The following prior authorization criteria will apply:

- Medical record documentation that the patient has shown the inability to properly use the generic EpiPen device

**QUANTITY LIMIT:** 2 pens per fill



**NOTE TO REVIEWER** – In the event that the preferred alternative is unavailable at the time of the request, exception can be made to approve the use of Symjepi for an appropriate length of time as designated by the reviewer (end of contract year).

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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## **DIACOMIT (stiripentol)**

**Review:** Diacomit is the second agent approved for use as adjunct treatment in the management of Dravet Syndrome, a rare epileptic syndrome usually manifesting in the first year of life and characterized by refractory epilepsy with multiple seizure types and encephalopathic features that present or worsen after onset. Diacomit is not indicated for use as monotherapy and should be used in combination with first line agents clobazam (labeled) or valproate (off-label). Diacomit works by modulating both benzodiazepine-sensitive and benzodiazepine-insensitive GABA<sub>A</sub> receptors, enhancing the effect on GABA neurotransmission and mediating tonic inhibition. It is also an inhibitor of CYB450 activity, indirectly increasing the blood concentrations of other antiepileptics.

The efficacy of Diacomit was shown in two randomized, double-blind placebo-controlled trials investigating the efficacy of Diacomit in the adjunct treatment of Dravet syndrome in patients 3-18 years old who had at least four generalized clonic or tonic-clonic seizures per month and had been receiving treatment with valproate and clobazam. Patients had a one-month baseline period where they received valproate and clobazam at protocol doses, followed by a two-month double-blind period where patients were had Diacomit or placebo added to their current treatments.

In STICLO-France, 41 patients were randomized 2:1 to receive either Diacomit or placebo as adjunct treatment. The baseline characteristics, including type and number of seizures per month, were comparable between the two groups. Patients recorded the frequency of generalized clonic or tonic-clonic seizures during the two months of the double-blind period of the clinical trial. The primary efficacy endpoint was the percentage of responders, defined as patients who had a greater than 50% decrease in the frequency of seizures during month 2 of the double-blind period compared to baseline. Patients with episodes of status epilepticus or an increase by more than 50% in the frequency of seizures during the baseline period or days 0-20 of the double-blind period were considered non-responders. The responder rate was significantly higher in patients treated with Diacomit than placebo. The secondary outcomes measured showed that patients treated with Diacomit had a significantly greater reduction in the number of seizures when compared to the placebo. Nine patients in the Diacomit group reported being seizure free during the second month of the double-blind period, while all patients in the placebo group reported at least one seizure.

STICLO-Italy had a similar design to the first trial and 23 patients were randomized 1:1 to receive adjunct treatment with Diacomit or placebo. During the second trial, diazepam was occasionally proved to patients throughout the study for seizures with no report on dose or frequency. The responder rate was significantly higher in the patients treated with Diacomit compared to placebo. The secondary outcomes measured showed a significant decrease in the number of seizures during the first month of the double-blind period in the patients treated with Diacomit. During the second month, there was a decrease in the number of seizures in both treatment groups and although there was a greater decrease in the number of seizures in the Diacomit treatment group, the difference in the number of reported seizures was not statistically significant. Three patients in the Diacomit group reported being seizure-free during the second month of the double-blind period. Similar to the first trial, all patients in the placebo group reported at least one seizure.

Adverse events reported with Diacomit are somnolence, decreased appetite and weight loss, neutropenia, thrombocytopenia, and suicidal thoughts or behavior. Other adverse events reported were agitation, ataxia, hypotonia, nausea, tremor, dysarthria, and insomnia. The safety and efficacy of Diacomit has been established in pediatric patients aged 2 to 18 years of age for treatment of Dravet syndrome in patients taking clobazam.

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

**Clinical Discussion:** No comments or questions. Kimberly Clark made a motion to accept the recommendations as presented. Todd Sponenberg seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Todd Sponenberg made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

**Outcome:** Diacomit will be covered as a pharmacy benefit requiring prior authorization. Diacomit will be added to the formulary on the Brand tier. The following prior authorization criteria will apply:

- Medical record documentation of age 2 or older **AND**
- Medical record documentation that Diacomit is prescribed by a neurologist **AND**
- Medical record documentation of diagnosis of Dravet syndrome **AND**
- Medical record documentation that Diacomit is to be used in combination with clobazam

**Other Recommendations:** It is recommended that clobazam be added to the Generic tier.

**Discussion:** No comments or questions. Todd Sponenberg made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

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

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## **PIQRAY (alpelisib)**

**Review:** Piqray is indicated in combination with fulvestrant for the treatment of postmenopausal women and men with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen. The SOLAR-1 trial investigated the impact of Piqray + fulvestrant versus placebo + fulvestrant on progression free survival. The median progression-free survival rate was 11.0 months for the Piqray + fulvestrant group (95% CI, 7.5 to 14.5) compared to 5.7 months for the placebo + fulvestrant group (95% CI, 3.7 to 7.4), leading to a hazard ratio for progression or death of 0.65 (95% CI, 0.50 to 0.85; P<0.001). While this was significant in patients with the PIK3CA mutation, the same outcome was not found to be statistically significant for patients without the PIK3CA mutation. Warnings include severe hypersensitivity reactions, severe cutaneous reactions, hyperglycemia, pneumonitis, diarrhea, and embryofetal toxicity. NCCN guidelines have recently been updated to include Piqray as a category I recommendation for postmenopausal women who test positive for the PIK3CA mutation.

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

**Clinical Discussion:** No comments or questions. Kevin Szczecina made a motion to accept the recommendations as presented. Rajneel Chohan seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Kimberly Clark made a motion to accept the recommendations as presented. Keith Hunsicker seconded the motion. None were opposed

**Outcome:** Piqray will be covered as a pharmacy benefit requiring prior authorization. Piqray will be added to the formulary on the Brand tier. The following prior authorization criteria will apply:

- Prescription written by an oncologist **AND**
- Medical record documentation that the patient is a male or a postmenopausal female **AND**
- Medical record documentation of a diagnosis of advanced or metastatic breast cancer that is hormone receptor-positive, HER2-negative (HR+/HER2-) **AND**
- Medical record documentation of a PIK3CA mutation determined using an FDA-approved test\* **AND**
- Medical record documentation that the patient is at least 18 years of age **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to prior endocrine therapy^ **AND**
- Medical record documentation that Piqray is being prescribed in combination with fulvestrant

\*NOTE: The FDA-approved test is the *therascreen*® PIK3CA RGQ PCR Kit.

^NOTE: Examples of endocrine therapy include: exemestane, letrozole, anastrozole, tamoxifen, and toremifene

**QUANTITY LIMIT:**

- 300 mg or 250 mg daily dose: 2 tablets per day
- 200 mg daily dose: 1 tablet per day

**MAX DAYS SUPPLY:** 28 days

**PHARMACIST NOTE TO CSR:** Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

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

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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**POLIVY (polatuzumab vedotin-piiq)**

**Review:** Polivy is indicated in combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, after at least two prior therapies. Polivy is a novel antibody drug conjugate (ADC), and the first chemoimmunotherapy to be approved for use in diffuse large B-cell lymphoma (DLBCL). ADC agents are designed to target cancer cells and spare healthy cells, theoretically minimizing systemic adverse effects, as they combine the specificity of monoclonal antibodies to deliver cytotoxic agents directly to cancer cells. The recommended dose of Polivy is 1.8 mg/kg

administered as an intravenous infusion once every 21 days for 6 cycles in combination with bendamustine and rituximab product. Polivy is given on Day 1, Rituxan is given on Day 1, and bendamustine is given on day 1 and 2.

Polivy was approved based on results from the phase 1b/2 pivotal trial. This was an open-label, multicenter clinical trial that included 80 patients with relapsed or refractory DLBCL who had received at least one prior regimen and were not candidates for autologous hematopoietic stem cell transplant (HSCT) at study entry. Patients were randomized in a 1:1 manner to receive either Polivy plus bendamustine and rituximab (BR) or BR only for six 21-day cycles. Most patients (98%) had DLBCL not otherwise specified. Patients treated with Polivy + BR demonstrated higher CR rates (40%) compared with standard of care BR (18%). In the patients who achieved a partial or complete response in the Polivy arm, 64% had a DOR of at least 6 months, and 48% had a DOR of at least 12 months. While in the BR arm, of the 10 patients who achieved a PR or CR, 30% had a DOR lasting at least 6 months, and 20% had a DOR lasting at least 12 months. Further analysis demonstrated that Polivy + BR demonstrated an improved median overall survival compared to the BR arm. Polivy treated patients also had an improved progression-free survival.

While Polivy does not bear any black box warnings or contraindications, it has a number of warnings and precautions: peripheral neuropathy, infusion-related reactions, myelosuppression, serious and opportunistic infections, progressive multifocal leukoencephalopathy (PML), tumor lysis syndrome, hepatotoxicity, and embryo-fetal toxicity. Peripheral neuropathy is a cumulative effect and may notably occur as early as the first treatment cycle. In recipients of Polivy plus BR, adverse reactions in  $\geq 20\%$  of patients included neutropenia, thrombocytopenia, anemia, peripheral neuropathy, fatigue, diarrhea, pyrexia, decreased appetite, and pneumonia. Polivy should be avoided in patients with moderate or severe hepatic impairment (bilirubin  $> 1.5 \times \text{ULN}$ ), due to increased risk of adverse reactions. The safety and effectiveness have not been established in pediatric patients.

Per NCCN, Polivy is recommended for use in DLBCL in combination with bendamustine and rituximab as second-line or subsequent therapy for partial response, no response, relapsed, progressive or refractory disease after  $\geq 2$  prior therapies in non-candidates for transplant.

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

**Clinical Discussion:** No comments or questions. Kevin Szczecina made a motion to accept the recommendations as presented. Todd Sponenberg seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Kelly Yelenic made a motion to accept the recommendations as presented. Todd Sponenberg seconded the motion. None were opposed.

**Outcome:** Polivy will be covered as a medical benefit requiring prior authorization. The following prior authorization criteria will apply:

- Prescription written by an oncologist/hematologist **AND**
- Medical record documentation of age  $\geq 18$  years **AND**
- Medical record documentation of relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified **AND**
- Medical record documentation that Polivy will be used in combination with bendamustine and rituximab **AND**
- Medical record documentation Polivy will be used as subsequent therapy after a trial of  $\geq 2$  prior therapies

**AUTHORIZATION DURATION:** 6 months

Authorization for Polivy should not exceed the FDA-approved treatment duration of 6, 21 day cycles. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

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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## **DEXYCU (dexamethasone)**

**Review:** Dexycu is an intracameral injection of a 5 mcL droplet that forms a tension-based sphere which releases 517 mcg of dexamethasone over 21 days. It is indicated for the treatment of ocular inflammation following cataract surgery.

The efficacy of Dexycu was shown in a randomized placebo-controlled trial comparing intracameral injections of 342 mcg and 517 mcg of dexamethasone to placebo. The primary endpoint measuring anterior chamber cell clearing (ACC score of 0) showed a significantly higher proportion of patients treated with Dexycu had ACC clearing at post-operative Day 8 compared to placebo. Secondary end points showed a significantly higher proportion of patients treated with Dexycu had ACC clearing at all time points after post-operative day 1, anterior chamber flare clearing (ACF score of 0) at post-operative day 8, and both ACC and ACF scores of 0 at post-operative day 8. The proportion of patients requiring rescue medications for the treatment of inflammation was significantly lower in the Dexycu treatment arm.

A second phase 3 study evaluating the safety of Dexycu compared to prednisolone 1.0% drops showed that the treatments were safe and similarly effective after reducing inflammation following cataract surgery. The most frequent adverse events reported in clinical trials were increased intraocular pressure, corneal edema, and iritis. Other adverse events reported were consistent with the known safety profile of other ophthalmic corticosteroids. No overall differences observed between older and younger patients.

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

**Clinical Discussion:** No comments or questions. Kimberly Clark made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Kelly Yelenic made a motion to accept the recommendations as presented. Aubrielle Prater seconded the motion. None were opposed.

**Outcome:** Dexycu will be covered as a medical benefit that does not require prior authorization.

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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**DEXTENZA (dexamethasone ophthalmic insert)**

**Review:** Dextenza, dexamethasone 0.4 mg ophthalmic insert, is a rod-shaped polyethylene glycol-based hydrogel depot inserted post-operatively that provides a sustained and tapered release of dexamethasone over 30 days for the treatment of ocular pain and inflammation following cataract surgery. The PEG hydrogel slowly softens over time until it is cleared through the nasolacrimal duct without the need for removal, but saline irrigation or manual expression can be performed if removal is necessary. Dextenza also contains a fluorescein dye so the depot can be illuminated with a blue light source and yellow filter to confirm proper placement of the depot.

The efficacy of Dextenza was shown in three clinical trials comparing Dextenza ophthalmic insert to placebo upon completion of cataract surgery. All three trials showed a significantly higher proportion of patients treated with Dextenza were pain-free by post-operative day 8 compared to placebo. Two out of three trials showed a significantly higher proportion of patients treated with Dextenza had an absence of anterior chamber cells at post-operative day 14. Secondary endpoints measuring ocular pain and anterior chamber cell and flare scores at all other visits showed that the Dextenza treatment groups had complete resolution of ocular pain as early as day 1 and inflammation as early as day 4. In all three studies, the proportion of patients requiring use of rescue medications to treat pain or inflammation was significantly lower in all Dextenza treatment arms.

The safety of Dextenza was evaluated in four clinical trials and the most commonly reported adverse events were anterior chamber inflammation including iritis and iridocyclitis and an increase in intraocular pressure. The other adverse events reported were consistent with the known safety profile of other ophthalmic corticosteroids.

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

**Clinical Discussion:** No comments or questions. Keith Hunsicker made a motion to accept the recommendations as presented. Kimberly Clark seconded the motion. None were opposed.

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

**Outcome:** Dextenza will be covered as a medical benefit that does not require prior authorization.

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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**INVELTYS (loteprednol etabonate)**

**Review:** Inveltys is a loteprednol etabonate 1% ophthalmic suspension which contains nanoparticles of the corticosteroid designed for better ocular penetration and longer presence on the ocular surface, allowing it to be dosed twice daily compared to many topical corticosteroids which are frequently prescribed four times daily. Inveltys is indicated for the treatment of post-operative inflammation and pain following ocular surgery.

The efficacy of Inveltys was investigated in two trials comparing Inveltys 1% suspension dosed twice daily to placebo. Both trials demonstrated a significant difference favoring Inveltys 1% suspension for all primary and secondary endpoints with a greater number of patients achieving complete resolution of both anterior chamber cells and ocular pain by day 8 and maintained through day 15, complete resolution of pain at day 4 maintained through day 15, and complete resolution of anterior chamber cells and ocular pain at day 15.

Adverse events reported during clinical trials were events commonly observed with corticosteroid use and the safety profile is similar to the known safety profile of loteprednol. The most common adverse events reported were eye pain and posterior capsular opacification.

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

**Clinical Discussion:** No comments or questions. Kelly Yelenic made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Rajneel Chohan made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

**Outcome:** Inveltys will be covered as a pharmacy benefit and will not be added to the formulary. The following prior authorization criteria will apply:

- Medical record documentation of use for post-operative inflammation and pain following ocular surgery  
**AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

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

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## **LOTEMAX SM (loteprednol)**

**Review:** Lotemax SM is a 0.38% gel formulation of loteprednol formulated with submicron drug particles designed to improve penetration and exposure of loteprednol into the aqueous humor, iris, ciliary body, and cornea after a single dose topical installation. It is indicated for the treatment of post-operative inflammation and pain following ocular surgery.

The efficacy of Lotemax SM was investigated in a total of 742 patients during two double-masked, vehicle-controlled, parallel-group studies comparing the efficacy of Lotemax SM 0.38% gel to placebo. The pooled data from the clinical trials showed that a significantly higher proportion of patients treated with Lotemax SM had complete anterior chamber cell clearance and resolution of ocular pain by day 8 following ocular surgery. A significant number of patients treated with Lotemax SM had complete resolution of ocular pain by post-operative day 3. There was also a significantly lower proportion of patients treated with Lotemax SM who required the use of anti-inflammatory rescue medications compared to placebo.

The safety profile is similar to other topical ophthalmic corticosteroids and the known safety profile of loteprednol with no new or unexpected safety concerns emerging in clinical trials. The most common adverse events reported during clinical trial were eye pain, photophobia, and foreign body sensation.

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

**Clinical Discussion:** No comments or questions. Kimberly Clark made a motion to accept the recommendations as presented. Aubrielle Prater seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Kimberly Clark made a motion to accept the recommendations as presented. Kelly Yelenic seconded the motion. None were opposed.

**Outcome:** Lotemax SM will be covered as a pharmacy benefit and will not be added to the formulary. The following prior authorization criteria will apply:

- Medical record documentation of use for post-operative inflammation and pain following ocular surgery  
**AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**Other Recommendations:** It is recommended that the following prior authorization criteria be added to all Lotemax and loteprednol products that are non-formulary:

- Medical record documentation of use for post-operative inflammation and pain following ocular surgery  
**AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

**FORMULARY ALTERNATIVES:**

Dexamethasone sodium phosphate 0.1% drops, fluorometholone 0.1% drops, prednisolone acetate 1 % drops, prednisolone sodium phosphate 1 % drops, Maxidex, FML S.O.P.

**Discussion:** The additional indication for loteprednol 0.05% for ophthalmic inflammatory conditions was questioned as it isn't currently addressed in the policy. It was determined that the additional indication should be added to the policy for loteprednol 0.05% only and that the existing formulary alternative recommendations are still appropriate. Keith Hunsicker made a motion to accept the recommendations as amended. Rajneel Chohan seconded the motion. None were opposed.

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

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**KRINTAFEL (tafenoquine)**

**Review:** Krintafel (tafenoquine) is an 8-aminoquinoline antimalarial orphan drug that is active against pre-erythrocytic, erythrocytic, and gametocytes of the *Plasmodium* species, specifically indicated for the radical cure (prevention of relapse) of *Plasmodium vivax* infections in patients aged 16 and older who are receiving appropriate antimalarial therapy for an acute *P. vivax* infection. Krintafel is considered an adjunctive therapy to either chloroquine or hydroxychloroquine, as well as adjunctive therapy to quinine for chloroquine-resistant *P. vivax* in Papua New Guinea and Indonesia. Primaquine can be used in place of Krintafel for adjunctive therapy.

The efficacy of Krintafel was shown through three randomized, double-blinded, placebo-controlled studies. Trial one studied men and women aged 16 and older with microscopically confirmed *P. vivax* infections, each patient was treated with chloroquine for 3 days and then randomly assigned by a computer-generated schedule (1:1:1:1:1) to receive either a single dose tafenoquine 50 mg, tafenoquine 100 mg, tafenoquine 300 mg, tafenoquine 600 mg, primaquine 15 mg for 14 days, or chloroquine alone. Trial two was similar to trial one in design, patient population, and results. Each patient was treated with chloroquine for 3 days and then were randomly assigned using a computer-generated schedule (2:1:1) to receive either a single dose of tafenoquine 300 mg, primaquine 15 mg for 14 days, or placebo. The primary endpoints for both trials was the percentage of patients who were free from recurrence at 6 months after the initial dose. Results were consistent between the studies showing there to be a significant decrease in percentage of patients experiencing a recurring *P. vivax* infection in patients taking



tafenoquine 300 mg versus placebo and chloroquine alone, each with a number needed to treat of 3 patients. The second study showed that primaquine 15 mg was significantly effective as well with the same number needed to treat. The third study was designed to compare efficacy of the tafenoquine 300 mg regimen to the primaquine 15 mg for 14 days regimen. Patients were randomly assigned in a 2:1 ratio to either a single dose of tafenoquine 300 mg or primaquine 15 mg for 14 days. Kaplan-Meier estimates of freedom from recurrence at 6 months in the intention-to-treat analysis were 72.7% for the tafenoquine group and 75.1% for the primaquine group. Noninferiority of tafenoquine to primaquine could not be shown.

There are no black box warnings for Krintafel but its use is contraindicated in patients with an unknown G6PD status, patients with a G6PD deficiency, and patients breastfeeding an infant that has a G6PD deficiency or unknown status, and patients that experience hypersensitivity to tafenoquine, other 8-aminoquinolines, or any component of the formulation. The most common adverse events (> 10%) reported during clinical trials were headache, dizziness, pruritus, and upper abdominal pain. A meta-analysis from Cochrane review found that both headache and chills were significant adverse events that occurred in patients taking chloroquine with tafenoquine 300 mg as compared to chloroquine alone. All patients must be tested for G6PD deficiency prior to the prescribing of Krintafel. Krintafel should be administered with food for absorption.

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

**Clinical Discussion:** No comments or questions. Kevin Szczecina made a motion to accept the recommendations as presented. Todd Sponenberg seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Kevin Szczecina made a motion to accept the recommendations as presented. Aubrielle Prater seconded the motion.

**Outcome:** Krintafel will be covered as a pharmacy benefit that does not require prior authorization. Krintafel will be added to the formulary on the brand tier with the following quantity limit:

**QUANTITY LIMIT:** Two (2) tablets/six (6) months

**Additional Recommendations:** It is recommended that Primaquine be added to the formulary on the brand tier with a quantity limit of 14 tablets per 6 months.

**Outcome:** No comments or questions. Kevin Szczecina made a motion to accept the recommendations as presented. Kelly Yelenic seconded the motion.

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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## **MOTTEGRITY (prucalopride)**

**Review:** Motegrity is a serotonin-4 (5-HT<sub>4</sub>) receptor agonist indicated for the treatment of chronic idiopathic constipation (CIC) in adults. It is dosed as one 2 mg tablet once daily but must be dose reduced to one 1 mg tablet once daily in those with severe renal impairment. Suicidal thoughts (n=1) and attempts (n=3), including completed suicides (n=2), have been reported following treatment with Motegrity. The primary endpoint for all trials was the percentage of subjects with an average of  $\geq 3$  spontaneous complete bowel movements per week and was found to be statistically significant in each of the five 12-week trials. The primary outcome was not met at 12- or 24-weeks in the 24-week trial. Motegrity can be an alternative to other prescription medications, linaclotide (Linzess), plecanatide (Trulance), and lubiprostone (Amitiza) for the indication of CIC as it provides a novel mechanism of

action. However, suicidal thoughts and behaviors have not been seen with these alternatives. Dose adjustments are needed for renal impairment in Motegrity as compared to the need for dose adjustment in hepatic impairment for lubiprostone, and no required dosage adjustment for linaclotide and plecanatide.

For geriatric members, elderly patients were started on 1 mg Motegrity and titrated up in some studies. Dose adjustments may be necessary based on renal function

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

**Clinical Discussion:** No comments or questions. Kim Clark made a motion to accept the recommendations as presented. Kelly Yelenic seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Jamie Miller made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

**Outcome:** Motegrity is a pharmacy benefit and should not be added to the formulary at this time. The following prior authorization criteria should apply:

- Medical record documentation of a diagnosis of chronic idiopathic constipation **AND**
- Medical record documentation that the patient is at least 18 years of age **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Amitiza\* and Linzess\*.

(\*prior authorization required)

**Quantity Limit:** 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.

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## FAST FACTS

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### VENCLEXTA (venetoclax)

**Updated Indication:** Venclexta is now indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Also, Venclexta is still indicated in combination with azacitadine or decitabine or low-dose cytarabine for the treatment of newly-diagnosed AML in adults who are aged 75 years or older, or who have comorbidities that preclude the use of intensive induction chemotherapy.

**Recommendations:** There is no change recommended to formulary placement. However, it is recommended to update the **CLL/SLL** prior authorization criteria to the following.

#### **CLL or SLL**

- Medical record documentation that Venclexta is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

There will be no changes to quantity limits or authorization durations. However, the following language can be removed from all the policies “NOTE: The FDA approved test for detection of 17-p deletion in patients to be treated with Venclexta is the Vysis CLL Fish Probe Kit”.

**Discussion:** No comments or questions

**Outcome:** Kim Clark made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

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

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## **DUPIXENT (dupilumab)**

**Updated Indication:** Dupixent is now indicated for the treatment of patients aged 12 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

Previously, Dupixent was only indicated for the treatment of adult patients with atopic dermatitis.

Dupixent also maintains the indication as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.

**Recommendations:** No changes are recommended to the formulary placement of Dupixent. It is recommended that the atopic dermatitis criteria are updated to account for the updated indication as noted below.

- Medical record documentation that Dupixent is prescribed by or in consultation with an allergist, dermatologist, or immunologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of moderate to severe atopic dermatitis **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure\* on an adequate trial of at least one medium (or greater) potency\*\* topical corticosteroid 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 15 years of age **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on an adequate trial of tacrolimus ointment **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on an adequate trial of Eucrisa (crisaborole)\* **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on an adequate trial of phototherapy (UVA/UVB treatment)

\*Prior authorization required

**Discussion:** No comments or questions.

**Outcome:** No comments or questions. Kevin Szczecina made a motion to accept the recommendations as presented. Kim Clark seconded the motion. None were opposed.

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

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**AVYCAZ (ceftazidime and avibactam)**

**Updated Indication:** Avycaz is now indicated for both complicated urinary tract infections (cUTIs) including pyelonephritis and complicated intra-abdominal infections (cIAIs) when used in combination with metronidazole, in pediatric patients 3 months and older.

Previously, Avycaz was only indicated to treat adults with those indications as well as hospital-acquired and ventilator-acquired pneumonia.

**Recommendation: Recommendation:** It is recommended that current age criteria are removed from the medical benefit policy based on the updated indications:

Avycaz (ceftazidime/avibactam) will be considered medically necessary when all of the following criteria are met:

- Prescribed by or in consultation with an infectious disease specialist **AND**
- Medical record documentation of one of the following:
  - A diagnosis of complicated intra-abdominal infection caused by caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Enterobacter cloacae*, *Klebsiella oxytoca*, *Citrobacter freundii* complex and *Pseudomonas aeruginosa* **OR**
  - A diagnosis of complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Citrobacter freundii* complex, *Proteus mirabilis*, and *Pseudomonas aeruginosa* **OR**
  - A diagnosis of Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP) caused by the following susceptible microorganisms: *Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa* and, *Serratia marcescens*

**AND**

- Medical record documentation of a creatinine clearance > 50 mL/min **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

**AUTHORIZATION DURATION:** Approval will be given for a duration of 14 days.

**LIMITATIONS:** a quantity limit of 3 vials per day should apply, with total duration of treatment not exceeding 14 days.

**Discussion:** No comments or questions.

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

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

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**BAVENCIO (avelumab)**

**Updated Indication:** Bavencio is now indicated in combination with axitinib for the first-line treatment of patients with advanced renal cell carcinoma.

In addition to the newly approved indication, Bavencio maintains previously approved indications for metastatic merkel cell carcinoma and locally advanced or metastatic urothelial carcinoma.

**Current Formulary Status/Prior Authorization Criteria:** Medical benefit requiring PA

**Recommendations: Recommendations:** No changes are recommended to the formulary placement of Bavencio at this time. It is recommended that the policy is updated to account for the new indication as outlined below.

#### **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

**Discussion:** No comments or questions.

**Outcome:** Todd Sponenberg made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

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

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#### **KADCYLA (ado-trastuzumab emtansine)**

**Updated Indication:** Kadcyla is a HER2-targeted antibody and microtubule inhibitor conjugate indicated, as a single agent, for the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.

Kadcyla was previously only indicated for the treatment of patients with HER2-positive, metastatic breast cancer who have previously received trastuzumab and a taxane separately or in combination and had either received prior therapy for metastatic disease or developed disease recurrence during or within six months of completing adjuvant therapy.

**Current Formulary Status/Prior Authorization Criteria:** Medical benefit requiring a prior authorization.

**Recommendations:** There are no changes recommended to the formulary status of Kadcyla. It is recommended that the current policy be updated to include the new indications and recommended duration of therapy as outlined below.

Kadcyla (ado-trastuzumab emtansine) will be considered medically necessary when all of the following criteria are met:

#### **For Treatment of Early Breast Cancer:**

- Prescribed by hematologist/oncologist **AND**
- Physician supplied documentation of HER2-positive early breast cancer **AND**
- Physician supplied documentation of neoadjuvant treatment with trastuzumab and a taxane **AND**

- Physician supplied documentation of residual invasive disease detected in the surgical specimen of the breast or axillary nodes after completion of neoadjuvant therapy.

**AUTHORIZATION DURATION:** Approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Kadcyla for the treatment of early breast cancer should not exceed the FDA-approved treatment duration of 14 cycles. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

**For Treatment of Metastatic Breast Cancer:**

- Prescribed by a hematologist/oncologist **AND**
- Physician supplied documentation of a diagnosis of HER2-positive, metastatic breast cancer **AND**
- Physician supplied documentation of previous treatment with trastuzumab (Herceptin) and a taxane (Paclitaxel or Docetaxel) separately or in combination and one of the following:
  - Received prior therapy for metastatic disease **OR**
  - Developed disease recurrence during or within six months of completing adjuvant

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

**Discussion:** No comments or questions.

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

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

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**VFEND (voriconazole)**

**Updated Indication:**

Vfend is indicated for the treatment of adults and pediatric patients 2 years of age and older with:

- Invasive aspergillosis
- Candidemia in non-neutropenics and the following *Candida* infections: disseminated infections of the skin and infections in the abdomen, kidney, bladder wall, and wounds
- Esophageal candidiasis
- Serious fungal infections caused by *Scedosporium apiospermum* (asexual form of *Pseudallescheria boydii*) and *Fusarium* species including *Fusarium solani*, in patients intolerant of, or refractory to, other therapy

Specimens for fungal culture and other relevant laboratory studies (including histopathology) should be obtained prior to therapy to isolate and identify the causative organism (s). Therapy may be started prior to the results, however once the results are available, antifungal therapy should be adjusted accordingly.

Previously, Vfend was only indicated in patients 12 years of age and older.

**Current Formulary Status/Prior Authorization Criteria:** Voriconazole (generic Vfend) tablets and oral suspension are pharmacy benefits available at the generic tier. Voriconazole (generic Vfend) vial medical benefit. Voriconazole vial is available at the Brand Non-Preferred tier. Voriconazole does not require a prior authorization.

**Recommendation:** There is no change to formulary status at this time

**Discussion:** No comments or questions.

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

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

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### **XULTOPHY (insulin degludec and liraglutide)**

**Updated Indication:** Xultophy is now indicated for patients with type 2 diabetes mellitus that are naïve to basal insulin or a GLP-1 agonist. Previously, Xultophy was only indicated for patients with type 2 diabetes mellitus that were currently on a basal insulin or a GLP-1 agonist. This new indication now allows patients that may have been started on either a basal insulin, a GLP-1 agonist, or both, the option of starting both as a single injection.

**Recommendations:** There are no changes recommended to the current formulary status or quantity limits based on the updated indication. It is recommended that the criteria are clarified that prior use must include a long-acting basal insulin product.

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

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of one formulary GLP-1 agonist OR one formulary long-acting basal insulin product, within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate.
- OR**
- If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to a GLP-1 agonist **OR** a long-acting basal insulin product.

**QUANTITY LIMIT:** 0.5 ml/day

**Discussion:** No comments or questions.

**Outcome:** Aubrielle Prater made a motion to accept the recommendations as presented. Keith Hunsicker seconded the motion. None were opposed.

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

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**SOLIQUA (insulin glargine and lixisenatide)**

**Updated Indication:** Soliqua is now indicated for patients with type 2 diabetes mellitus that are naïve to basal insulin or a GLP-1 agonist. Previously, Soliqua was only indicated for patients with type 2 diabetes mellitus that were currently on a basal insulin or a GLP-1 agonist. This new indication now allows patients that may have been started on either a basal insulin, a GLP-1 agonist, or both, the option of starting both as a single injection.

**Current Formulary Status/Prior Authorization Criteria:** Nonformulary

**Recommendation:** There is no change to formulary status at this time. Recommended to update QL to 0.6 mL per day.

**Discussion:** No comments or questions.

**Outcome:** Kelly Yelenic made a motion to accept the recommendations as presented. Keith Hunsicker seconded the motion. None were opposed.

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

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**TIBSOVO (ivosidenib)**

**Updated Indication:** Tibsovo is now indicated for the treatment of acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by and FDA-approved test in adult patients with newly-diagnosed AML who are  $\geq 75$  years old or who have comorbidities that preclude the use of intensive induction chemotherapy.

**Note:** Information on FDA-approved tests for the detection of IDH1 mutations in AML is available at <http://www.fda.gov/CompanionDiagnostics>.

**Current Formulary Status/Prior Authorization Criteria:** Tibsovo is a pharmacy benefit available on the Brand tier. Tibsovo requires a prior authorization with the following criteria.

- Prescription written by an oncologist/hematologist AND
- Medical record documentation of the member being  $\geq 18$  years AND
- Medical record documentation of relapsed or refractory acute myeloid leukemia AND
- Medical record documentation of an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA approved test

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

Newly Diagnosed AML

- Prescription written by an oncologist/hematologist AND
- Medical record documentation of newly diagnosed acute myeloid leukemia AND
- Medical record documentation of one of the following:
  - Medical record documentation of the member being  $\geq 75$  years OR



- Medical record documentation that the member is at least 18 years AND has comorbidities\* that preclude the use of intensive induction chemotherapy AND
- Medical record documentation of an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA approved test

#### Relapsed or Refractory AML

- Prescription written by an oncologist/hematologist AND
- Medical record documentation of the member being  $\geq 18$  years AND
- Medical record documentation of relapsed or refractory acute myeloid leukemia AND
- Medical record documentation of an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA approved test

\*In the clinical trials, comorbidities that precluded the use of intensive induction chemotherapy included at least one of the following criteria: baseline ECOG performance status of  $\geq 2$ , severe cardiac or pulmonary disease, hepatic impairment with bilirubin  $> 1.5 \times \text{ULN}$ , or creatinine clearance  $< 45 \text{ mL/min}$ .

There will be no changes to quantity limits or authorization durations.

**Discussion:** No comments or questions.

**Outcome:** Keith Hunsicker made a motion to accept the recommendations as presented. Todd Sponenberg seconded the motion. None were opposed.

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

#### **CYRAMZA (ramucirumab)**

**Updated Indication:** Cyramza is now indicated as a single agent for the treatment of hepatocellular carcinoma in patients who have an alpha fetoprotein (AFP) of  $\geq 400 \text{ ng/mL}$  and have been treated with sorafenib.

Previously approved indications for Cyramza include gastric cancer, colorectal cancer, and non-small cell lung cancer.

**Current Formulary Status/Prior Authorization Criteria:** Medical benefit requiring PA

**Recommendation: Recommendations:** No changes are recommended to the formulary placement of Cyramza. It is recommended that the following changes are made to the policy to account for the updated indication and to align with other oncology products.

1. Advanced or metastatic gastric or gastro-esophageal junction adenocarcinoma:
  - Prescription is written by an oncologist; **AND**
  - Medical record documentation of:
    - Advanced or metastatic gastric or gastro-esophageal junction adenocarcinoma with disease progression on or after prior fluoropyrimidine or platinum containing chemotherapy; **AND**
    - Medical record documentation of use in combination with paclitaxel **OR** for use as monotherapy **A**
2. NSCLC:
  - Prescription is written by an oncologist **AND**

- Medical record documentation of metastatic non-small cell lung cancer with disease progression on or after platinum-based chemotherapy **AND**
  - Patients with EGFR or ALK genomic tumor aberrations must provide medical record documentation of disease progression on FDA-approved therapy for these aberrations prior to receiving Cyramza **AND**
  - Medical record documentation of use in combination with docetaxel
3. Metastatic Colon or Rectal Cancer:
- Prescription is written by an oncologist **AND**
  - Medical record documentation of metastatic colon or rectal cancer with disease progression on or after FOLFOX, CapeOX or a regimen not previously containing irinotecan **AND**
  - Medical record documentation of use in combination with irinotecan or FOLFIRI (fluorouracil, leucovorin, and irinotecan)
4. Hepatocellular Carcinoma (HCC):
- Prescription is written by an oncologist **AND**
  - Medical record documentation of a diagnosis of hepatocellular carcinoma **AND**
  - Medical record documentation of an alpha fetoprotein (AFP) level of  $\geq 400\text{ng/mL}$  **AND**
  - Medical record documentation of disease progression on or after treatment with sorafenib (Nexavar) or an intolerance to sorafenib (Nexavar)

**Discussion:** No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as presented. Aubrielle Prater seconded the motion. None were opposed.

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

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## **JAKAFI (ruxolitinib)**

**Updated Indication:** Jakafi is now indicated for steroid-refractory acute graft-versus- host disease in adult and pediatric patients 12 years and older.

Note: Previously, Jakafi was only indicated for adult patients with intermediate/high-risk myelofibrosis (including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis) and polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea.

**Current Formulary Status/Prior Authorization Criteria:** Jakafi is a pharmacy benefit available at the Brand tier and requires a prior authorization

**Recommendation:** There is no change recommended to formulary placement however, it is recommended to update the prior authorization criteria to include a section for GVHD.

### GVHD

- Medical record documentation that Jakafi is prescribed by a hematologist/oncologist or transplant specialist **AND**
- Medical record documentation of age  $\geq 12$  years **AND**
- Medical record documentation of steroid refractory acute graft-versus- host disease (GVHD)

**Discussion:** Keith Hunsicker asked if immunologist should be added as a prescriber requirement. It was decided to just monitor and bring back to group if needed. No further comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as presented. Kelly Yelenic seconded the motion. None were opposed.

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

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## **KEYTRUDA (pembrolizumab)**

**Updated Indication:** Keytruda is now indicated under accelerated approval for the treatment of patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy.

Previously, Keytruda did not maintain any indications for SCLC.

Keytruda is also now indicated for the treatment of Head and Neck Squamous Cell Cancer (HNSCC):

- In combination with platinum and fluorouracil (FU) for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC.
- As a single agent for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 (CPS  $\geq 1$ ) as determined by an FDA-approved test.

Previously Keytruda was only indicated for recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy. Keytruda maintains this indication.

Keytruda maintains its other FDA approved indications for melanoma, RCC, cHL, PMBCL, HCC, MCC, urothelial carcinoma, MSI-H/dMMR cancer, gastric cancer, and cervical cancer.

**Current Formulary Status/Prior Authorization Criteria:** Specialty Tier requiring PA or medical benefit requiring PA

**Recommendation: Recommendations:** No changes are recommended to the formulary status of Keytruda at this time. It is recommended that the current policy be updated to account for the new indications as outlined below.

### MBP 119.0

#### **Small Cell Lung Cancer (SCLC)**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is  $\geq 18$  years of age **AND**
- Medical record documentation of a diagnosis of metastatic small cell lung cancer (SCLC) **AND**
- Medical record documentation of disease progression on or after two lines of therapy, one of which must be platinum-based chemotherapy

#### **Head and Neck Squamous Cell Carcinoma**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is  $\geq 18$  years of age **AND**
- Medical record documentation of one of the following:
  - A diagnosis of Head and Neck Squamous Cell Carcinoma that is recurrent or metastatic **AND**
  - Disease progression on or after platinum-containing chemotherapy **AND**

- Keytruda is being used as a single agent.

**OR**

- A diagnosis of metastatic or unresectable, recurrent Head and Neck Squamous Cell Carcinoma **AND**
- Keytruda is being used as a first-line treatment **AND**
- Keytruda is being used as a single agent **AND**
- Tumors express PD-L1 [Combined Positive Score (CPS)  $\geq$  1] as determined by an FDA-approved test

**OR**

- A diagnosis of metastatic or unresectable, recurrent Head and Neck Squamous Cell Carcinoma **AND**
- Keytruda is being used as a first-line treatment **AND**
- Keytruda is being administered in combination with platinum chemotherapy and fluorouracil (FU)

**Discussion:** No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as presented. Rajneel Chohan seconded the motion. None were opposed.

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

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### **EMGALITY (galcanezumab-gnlm)**

**Updated Indication:** Emgality is indicated in adults for the treatment of episodic cluster headache.

**Updated Dosing for New Indication:** The recommended dose for episodic cluster headache is 300 mg (administered as 3 consecutive injections of 100 mg each) at the onset of the cluster period, then monthly until the end of the cluster period.

**Current Formulary Status/Prior Authorization Criteria:** Emgality is non-formulary and the following prior authorization criteria applies.

**Recommendation:** There are no changes to formulary status but it is recommended to add the following prior authorization criteria to the current policy to reflect the new indication.

#### Episodic Cluster Headache

- Medical record documentation that Emgality is prescribed by or in consultation with a neurologist or headache specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of episodic cluster headache, based on the ICHD-III diagnostic criteria **AND**
- Medical record documentation of baseline cluster headache attack frequency (e.g. weekly headache attack frequency) **AND**
- Medical record documentation the member is currently experiencing a cluster headache period (period of recurrent attacks) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to verapamil.

#### **ICHD-III Diagnostic Criteria:**

### **Diagnosis of Cluster Headache**

At least 5 attacks fulfilling the following criteria:

- Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes (when untreated)

*During part (but less than half) of the active time-course attacks may be less severe and/or of shorter or longer duration.*

#### **One or both of the following:**

- At least one of the following symptoms or signs, ipsilateral to the headache:
  - Conjunctival injection and/or lacrimation
  - Nasal congestion and/or rhinorrhea
  - Eyelid edema
  - Forehead and facial sweating
  - Miosis and/or ptosis
- A sense of restlessness or agitation

Occurring with a frequency between one every other day and 8 per day

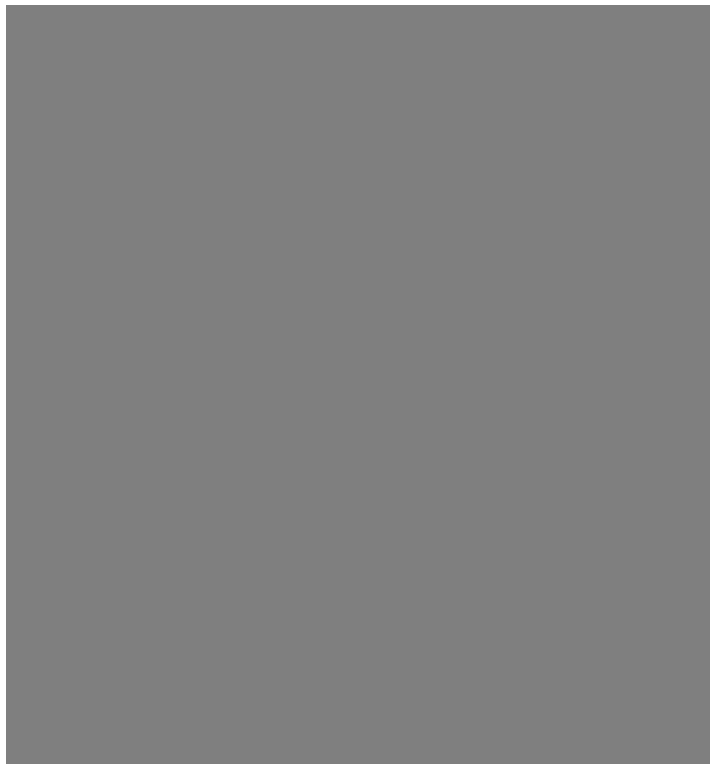
*During part (but less than half) of the active time-course attacks may be less frequent*

Not better accounted for by another ICHD-3 another ICHD-3 diagnosis

### **Diagnosis of Episodic Cluster Headache**

Diagnosis of Cluster Headache fulfilling occurring in bouts (cluster periods) the following criteria:

At least two cluster periods lasting from 7 days to 1 year (when untreated) and separated by pain-free remission periods of  $\geq 3$  months.



**Authorization Duration:** Initial approval will be for six (6) months and subsequent approvals will be for six (6) months. Requests for continuation of coverage will be approved for members who meet the following criteria:

- Medical record documentation of a diagnosis of episodic cluster headache, based on the ICHD-III diagnostic criteria AND
- Medical record documentation the member is currently experiencing a cluster headache period (period of recurrent attacks) AND
- Medical record documentation of continued or sustained reduction in cluster headache attack frequency

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

**Emgality (100 mg/mL syringe): 3 mL per 30 days**

**Discussion:** No comments or questions.

**Outcome:** Keith Hunsicker made a motion to accept the recommendations as presented. Todd Sponenberg seconded the motion. None were opposed.

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

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**BIKTARVY (bictegravir sodium/emtricitabine/tenofovir alafenamide fumarate)**

**Updated Indication:**

Biktarvy is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 25 kg who have 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 Biktarvy.

**Current Formulary Status/Prior Authorization Criteria:** Brand Tier with quantity limit of 1 tablet/day.

**Recommendation:** There is no change to formualry status.

**Discussion:** No comments or questions.

**Outcome:** Todd Sponenberg made a motion to accept the recommendations as presented. Aubrielle Prater seconded the motion. None were opposed.

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

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**VRAYLAR (cariprazine)**

**Updated Indication:** Vraylar is now indicated for the treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults.

Previously, Vraylar was only indicated for the treatment of schizophrenia and acute treatment of manic/mixed episodes associated with bipolar I disorder in adults.

**Current Formulary Status/Prior Authorization Criteria:** Vraylar is a pharmacy benefit and is non-formulary with a quantity limit.

**Recommendation:** There is no change recommended to formulary placement however it is recommended to update the prior authorization criteria to the following.

- Medical record documentation that member is 18 years of age or older AND
- Medical record documentation of a diagnosis of schizophrenia or acute treatment of manic or mixed episodes associated with bipolar I disorder AND
- Medical record documentation of a therapeutic failure on two formulary alternatives (aripiprazole, olanzapine, quetiapine, ziprasidone, or risperidone)

OR

- Medical record documentation that Vraylar is being used for the treatment of depressive episodes associated with bipolar I disorder (bipolar depression) AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to quetiapine

**Formulary Alternatives:**

For Schizophrenia: olanzapine, risperidone, quetiapine, ziprasidone, aripiprazole  
For Bipolar depression: quetiapine, olanzapine/fluoxetineRemove

Remove “Approve by GPID” from the policy.

**Discussion:** No comments or questions.

**Outcome:** Kim Clark made a motion to accept the recommendations as presented. Rajneel Chohan seconded the motion. None were opposed.

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

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### **REVLIMID (lenalidomide)**

**Updated Indication:** Revlimid, in combination with a rituximab product, is now indicated for the treatment of adult patients with previously treated follicular lymphoma (FL) and previously treated marginal zone lymphoma (MZL).

Revlimid maintains its previous indications of multiple myeloma, myelodysplastic syndromes, and mantle cell lymphoma. Revlimid also maintains its limitation of use: Revlimid is not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials.

**Current Formulary Status/Prior Authorization Criteria:** Brand Tier requiring PA.

**Recommendation: Recommendations:** No changes are recommended to the formulary placement of Revlimid however it is recommended that the applicable policies are updated to account for the new indications.

**OR**

For Follicular Lymphoma

- Medical record documentation of a diagnosis of follicular lymphoma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior therapy **AND**
- Medical record documentation that Revlimid is being given in combination with a rituximab product

**OR**

For Marginal Zone Lymphoma

- Medical record documentation of a diagnosis of marginal zone lymphoma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one prior therapy **AND**
- Medical record documentation that Revlimid is being given in combination with a rituximab product

**Discussion:** No comments or questions.

**Outcome:** Kelly Yelenic made a motion to accept the recommendations as presented. Todd Sponenberg seconded the motion. None were opposed.

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

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### **OSPHENA (ospemifene)**

**Updated Indication:** Ospshena is now indicated for the treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.

Previously, Ospshena was only indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

**Current Formulary Status/Prior Authorization Criteria:** Ospshena is pharmacy benefit and is non-formulary

**Recommendation:** There is no change to formulary status however it is recommended to create a policy for reviewing coverage determination requests:

- Medical record documentation of a diagnosis of menopause AND
- Medical record documentation that the member is experiencing at least one of the following symptoms of vulvar and vaginal atrophy:
  - Moderate to severe dyspareunia
  - Moderate to severe vaginal dryness AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) formulary topical estradiol/conjugated estrogen products (e.g. cream, tablet, ring)

Quantity limit: one tablet daily

**Discussion:** No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as presented. Kelly Yelenic seconded the motion. None were opposed.

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

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## UPDATES

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### MONUROL (Fosfomycin)

Cystitis is an infection of the urinary tract and can be complicated or uncomplicated. Cystitis is one of the most common infections that requires antibacterial treatment in otherwise healthy women. While all antibiotic therapies are based on pathogen specific susceptibility, there are three general treatment regimens recommended as first line for the treatment of uncomplicated cystitis by the Infectious Disease Society of America (IDSA). The IDSA recommends nitrofurantoin monohydrate/macrocrystals 100 mg twice daily for 5 days, trimethoprim-sulfamethoxazole 160/800 mg twice daily for 3 days, or fosfomycin trometamol 3g as a single dose. Fosfomycin has started to gain some traction with dosing regimens other than the FDA approved one. Throughout several studies fosfomycin has shown to have activity against *P. aeruginosa*, ESBL, and several other multidrug resistant organisms. Due to its broad spectrum of activity, some trials have been done supporting the use of fosfomycin in ESBL related cystitis infections. One retrospective study showed a 94.3% clinical cure rate and a microbiological success rate of 78.5% along with relapse rates of 0% and reinfection rates of 10.7%. They were able to achieve these results using 3g of fosfomycin every other night for 3 doses. The article goes on to explain that ciprofloxacin is one of the most commonly used agents for treatment of UTIs but that it increases one's risk for acquiring an ESBL infection as well as for the bacteria to develop resistance. It also supports the idea that fosfomycin (80.5%) can be used for complicated cystitis since it showed comparable microbiological success rates



to imipenem/cilastin (81%) and meropenem (90%). It should be noted that one statement reads, “The fact that the microbiological cure rate in our study is about 15% lower than other studies performed with one dose of FT [fosfomycin tromethamine] supports the need for three or more doses of FT in this patient group.” This study was completed in 2007. A Canadian review article on fosfomycin looked at in vitro activities of oral antibiotics that cover *E. coli* isolated from urine from 2010-2013. In Table 1, results on the susceptibility of each pathogen to each medication is shown. In Table 2, results of resistance to each pathogen to each medication is shown. Despite a greater ease of treatment regimen, fosfomycin remains far more expensive than equally effective alternative treatment options of cystitis. Fosfomycin is a first line agent in the treatment of uncomplicated cystitis as per the FDA, but studies have shown that it also may have some use in complicated cystitis and pathogen specific infections. Due to fosfomycin having a broad spectrum of bacterial coverage, it may be useful in multidrug resistant organisms at a dosing regimen with a longer duration than FDA approved at 3g of fosfomycin every 48-72 hours for 3 doses. Nitrofurantoin has similar coverage with equal if not better effectiveness barring some specific multidrug resistant organisms. Fosfomycin should be reserved for patients that have contraindications to, intolerance to, or therapeutic failure of nitrofurantoin and sulfamethoxazole-trimethoprim, or in patients that have an ESBL-producing infection, or in patients that have a multidrug resistant lower urinary tract infection.

**Recommendations:** Approval of coverage for fosfomycin should be done on a case to case basis as the evidence to support its use outside of the FDA approved dosing is limited and there are cheaper, just as effective medications on our formulary for the treatment of uncomplicated cystitis.

**Policy Recommendations:**

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

- Medical record documentation of use for treatment of uncomplicated cystitis **AND**
- Medical record documentation of therapeutic failure on, intolerance to, contraindication to, or bacterial resistance to nitrofurantoin **AND** sulfamethoxazole-trimethoprim

**QUANTITY LIMIT:** 1 dose

**AUTHORIZATION DURATION:** once, Rx count of 1

**OR** It may be medically acceptable to use Fosfomycin for the following:

- Medical record documentation of use for treatment of uncomplicated cystitis **AND**
- Medical record documentation of ESBL-producing bacteria or multidrug resistant bacteria **AND**
- Medical record documentation of susceptibility to fosfomycin **AND**
- Medical record documentation of culture and sensitivity showing the patient’s infection is not susceptible to alternative oral antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity

**QUANTITY LIMIT:** 3 doses

**AUTHORIZATION DURATION:** 9 days, Rx count of 1

**NOTE:** There is little to no evidence supporting use of fosfomycin as prophylaxis.

**Discussion:** No comments or questions.

**Outcome:** Keith Hunsicker made a motion to accept the recommendations as presented. Aubrielle Prater seconded the motion. None were opposed.

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

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## **XIFAXAN (rifaximin) – off label use for small bowel bacterial overgrowth**

**Summary:** Small intestinal bacterial overgrowth (SIBO) is aptly named as it is described as excessive bacterial growth occurring in the small intestine. This primarily occurs in the lower end of the small intestine as the higher end is naturally more sterile due to bile acid and normal peristalsis. The two main causes of SIBO are anatomical differences and motility disorders but can occur without any specific contributing factor. Patients with SIBO typically present with bloating, diarrhea, abdominal discomfort, or flatulence but could also present with more severe symptoms like malabsorption, weight loss, or hypoalbuminemia. Obtaining bacterial cultures for SIBO can be impractical as an invasive procedure would need to be done to access the bacteria. Since cultures are difficult to obtain, diagnosis is done through a hydrogen breath test (HBT). There are two different types of SIBO, hydrogen-predominant bacterial overgrowth and methane-predominant bacterial overgrowth. The hydrogen breath test is also the only other objective way to determine effective treatment/eradication of the bacteria via a negative result following treatment. Resolution of symptoms related to SIBO may occur prior to the end of treatment. Antibiotics are considered standard treatment for small intestinal bacterial overgrowth; however, the choice of which antibiotic should be used is heavily debated but empiric therapy is needed due to limited ability to obtain cultures. Although it is not FDA indicated for it, rifaximin, a semi-synthetic derivative of rifamycin, is one of the most commonly prescribed medications for the treatment of hydrogen predominant SIBO. It was modified to decrease the amount of gastrointestinal absorption while maintaining the same level of antibacterial activity. According to one study, rifaximin fulfills all characteristics set by DuPont and Ericsson for optimal use in treatment of gastrointestinal infections which has led many physicians to prescribe this medication for years despite minimal available evidence of its support.

The current antibiotic of choice, dosage, and duration of treatment for SIBO is undetermined. Antibiotics that have been studied include tetracycline, norfloxacin, amoxicillin-clavulanate, metronidazole, ciprofloxacin, neomycin, cephalexin, trimethoprim-sulfamethoxazole, levofloxacin, and gentamicin. Most review articles and medical society recommendations will not state any specific antibiotic as first line but note that the most evidence is shown for rifaximin with less adverse events as compared to other antibiotics that are used. UpToDate lists rifaximin 1650 mg/day for 14 days as the recommended treatment of hydrogen predominant bacterial overgrowth. Generally, long-term treatment of SIBO with broad-spectrum antibiotics is not recommended. Studies show that rifaximin is about equally effective as metronidazole and ciprofloxacin.

Small intestinal bacterial overgrowth is an increasingly more common, complex disease state that is often underdiagnosed. Antibiotics are the mainstay of therapy for patients suffering from SIBO, but there is no definitive first line agent for treatment. It would be ideal to obtain cultures, but due to the nature of where the bacteria are located, the process would be invasive with the potential for complications and more risk than benefit so broad-spectrum antibiotics are used. Diagnosis is done through hydrogen breath testing. The most common medications used for treatment are rifaximin (Xifaxan), metronidazole, ciprofloxacin, neomycin, and tetracycline. Rifaximin is effective at treating SIBO evidenced by normalization of breath tests after an initial abnormal result despite the lack of an FDA indication for this disease state. Rifaximin was not associated with any serious or significant adverse events with comparable efficacy to common alternative agents and dosing regimens. It does appear to be beneficial for patients that have irritable bowel syndrome along with SIBO.

**Recommendations:** There is significant evidence to support the use of rifaximin (Xifaxan) in patients with hydrogen-predominant small intestinal bacterial overgrowth, especially in patients with irritable bowel syndrome. It is the most studied medication for SIBO and should be dosed at 1650 mg/day for 14 days if used for this indication.

**Policy Recommendations:** It is recommended that criteria for review of small intestinal bacterial overgrowth are added as follows:

It may be medically acceptable to approve Xifaxan for use in the following situations:

**Small Intestinal Bacterial Overgrowth**

- Medical record documentation of a diagnosis of small intestinal bacterial overgrowth **AND**
- Medical record documentation that the bacteria is hydrogen predominant as evidenced by a hydrogen breath test

**QUANTITY LIMIT:** 3 tablets daily

**AUTHORIZATION DURATION:** 14 days, Rx count of 1

**FORMULARY ALTERNATIVES:**

Small intestinal bacterial overgrowth: ciprofloxacin, metronidazole, neomycin, amoxicillin-clavulanate

**Discussion:** No comments or questions.

**Outcome:** Aubrielle Prater made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

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

**Recommendation** – it is recommended that the following minimum and maximum days-supply be adopted

Drug Name	Dosage	Recommended Restriction
Abilify Maintena	<ul style="list-style-type: none"> <li>• 400 mg per month (no sooner than 26 days after previous injection) or 300 mg per month</li> </ul>	<ul style="list-style-type: none"> <li>• Max Qty Supply: 1</li> <li>• Min Day Supply: 28</li> </ul>
Aristada	(based on current oral aripiprazole dose)	<u>441 mg:</u>
	<ul style="list-style-type: none"> <li>• 441 mg per month</li> <li>• 662 mg per month</li> <li>• 882 mg per month or every 6 weeks</li> <li>• 1,064 mg every 2 months</li> </ul>	<ul style="list-style-type: none"> <li>• Max Qty Supply: 1.6</li> <li>• Min Day Supply: 28</li> </ul> <u>662 mg:</u> <ul style="list-style-type: none"> <li>• Max Qty Supply: 2.4</li> <li>• Min Day Supply: 28</li> </ul>
		<u>882 mg:</u>
		<ul style="list-style-type: none"> <li>• Max Qty Supply: 3.2</li> <li>• Min Day Supply: 28</li> </ul>
		<u>1064 mg:</u>
		<ul style="list-style-type: none"> <li>• Max Qty Supply: 3.9</li> <li>• Min Day Supply: 56</li> </ul>
Botox/Dysport/Xeomin/	Depends on indication, subsequent doses can be given every 42, 84, 90 days.	• Max Day Supply: 90 days
Myobloc	Patients may use for more than 1	

indication so hard to define a Min Day supply.

Entyvio

- 300 mg IV at 0, 2, 6 weeks and then every 8 weeks

For subsequent auths only:

- Max Quantity: 1
- Max Day Supply: 56
- Min Day Supply: 56

Fasenra

- 30 mcg every 4 weeks and then once every 8 weeks

Initial:

- Max Qty Supply: 1
- Max Day Supply: 28
- Min Day Supply: 28

Remainder/Subsequent auths:

- Max Qty Supply: 1
- Max Day Supply: 56
- Min Day Supply: 56

Ilaris

(weight-based)

CAPS

- 150 mg or 2 mg/kg every 8 weeks (max 600 mg or 8 mg/kg)

CAPS:

- Max Day Supply: 56
- Min Day Supply: 56

FMF

- 150 mg or 2 mg/kg every 4 weeks (max 300 mg or 4 mg/kg)

All other indications:

- Max Day Supply: 28
- Min Day Supply: 28

HIDS/MKD

- 150 mg or 2 mg/kg every 4 weeks (max 300 mg or 4 mg/kg)

TRAPS:

- 150 mg or 2 mg/kg every 4 weeks (max 300 mg or 4 mg/kg)

SJIA:

- 4 mg/kg every 4 weeks

Ilumya

- 100 mg subcutaneously at weeks 0, 4, and then every 12 weeks thereafter

For subsequent auths only:

- Max Quantity: 1
- Max Day Supply: 84
- Min Day Supply: 84

Inflectra, Remicade, Renflexis	(weight-based)	<u>For subsequent auths only:</u>
	<ul style="list-style-type: none"> <li>• Induction IV regimen at 0,2, 6 weeks</li> <li>• Maintenance dose is administered every 6 or 8 weeks based on indication. For RA, dose can be increased to every 4 weeks.</li> </ul>	<ul style="list-style-type: none"> <li>• Max Day Supply: 56</li> <li>• Min Day Supply: 28</li> </ul>
Invega Sustenna	<ul style="list-style-type: none"> <li>• Initial: 234 mg on day 1, 156 mg 1 week later</li> <li>• Maintenance: 39 to 234 mg every month</li> </ul>	For the <i>open-ended</i> auth: <ul style="list-style-type: none"> <li>• Max Qty Supply: 1 syringe (billed in mL)</li> <li>• Min Day Supply: 28</li> </ul>
Invega Trinza	(based on Invega Sustenna dose) <ul style="list-style-type: none"> <li>• 273 to 819 mg every 3 months</li> </ul>	<ul style="list-style-type: none"> <li>• Max Qty Supply: 1 syringe (billed in mL)</li> <li>• Min Day Supply: 84</li> </ul>
Ocrevus	<ul style="list-style-type: none"> <li>• 300 mg on day 1, 300 mg 2 weeks later, then 600 mg every 6 months (starting 6 months after 1<sup>st</sup> dose).</li> </ul>	<u>For Subsequent auths only:</u> <ul style="list-style-type: none"> <li>• Max Qty Supply: 20</li> <li>• Max Day Supply: 180</li> <li>• Min Day Supply: 180</li> </ul>
Onpatro	<ul style="list-style-type: none"> <li>• 0.3 mg/kg once every 3 weeks (maximum 30 mg)</li> </ul>	<ul style="list-style-type: none"> <li>• Max Qty Supply: 15</li> <li>• Max Day Supply: 21</li> <li>• Min Day Supply: 21</li> </ul>
Perseris	<ul style="list-style-type: none"> <li>• 90 mg or 120 mg once monthly</li> </ul>	<ul style="list-style-type: none"> <li>• Max Qty Supply: 1</li> <li>• Min Day Supply: 28</li> </ul>
Prolia	<ul style="list-style-type: none"> <li>• 60 mg every 6 months</li> </ul>	<ul style="list-style-type: none"> <li>• Max Qty Supply: 1</li> <li>• Max Day Supply: 180</li> <li>• Min Day Supply: 180</li> </ul>
Risperdal Consta	<ul style="list-style-type: none"> <li>• 25 mg to 50 mg IM every 2 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• Max Qty Supply: 2</li> <li>• Min Day Supply: 28</li> </ul>
Simponi Aria	(weight-based) <ul style="list-style-type: none"> <li>• IV at weeks 0,4, and then every 8 weeks</li> </ul>	<u>For subsequent auths only:</u> <ul style="list-style-type: none"> <li>• Max Day Supply: 56 days</li> <li>• Min Day Supply: 56</li> </ul>
Spinraza	<ul style="list-style-type: none"> <li>• 12 mg once every 14 days for 3 doses, then once 30 days after 3<sup>rd</sup> dose then 12 mg every 4 months</li> </ul>	<u>For subsequent auths only:</u> <ul style="list-style-type: none"> <li>• Max Qty Supply: 5</li> <li>• Max Day Supply: 120</li> <li>• Min Day Supply: 120</li> </ul>
Supprelin LA	<ul style="list-style-type: none"> <li>• 50 mg implant every 12 months</li> </ul>	<ul style="list-style-type: none"> <li>• Max Qty Supply: 1</li> <li>• Max Day Supply: 365</li> </ul>

- |                  |   |   |
|------------------|---|---|
| Zyprexa Relprevv | (based on current oral olanzapine dose)   | <ul style="list-style-type: none"> <li>• Min Day Supply: 365</li> </ul>   |
|                  | <ul style="list-style-type: none"> <li>• 150 mg every 2 weeks</li> <li>• 210 mg every 2 weeks</li> <li>• 300 mg every 2 weeks or every 4 weeks</li> <li>• 405 mg every 4 weeks</li> </ul> | <u>210 mg &amp; 300 mg:</u> <ul style="list-style-type: none"> <li>• Max Qty Supply: 2</li> <li>• Min Day Supply: 28</li> </ul> |
|                  |   | <u>405 mg:</u> <ul style="list-style-type: none"> <li>• Max Qty Supply: 1</li> <li>• Min Day Supply: 28</li> </ul>              |

<b>Drug Name</b>	<b>Dosage</b>	<b>Recommended Restriction</b>
Actemra	<ul style="list-style-type: none"> <li>• 162 mg SubQ once weekly</li> </ul>	<p>Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).</p> <ul style="list-style-type: none"> <li>• Max Qty Supply: 3.6</li> <li>• Min Day Supply: 28</li> <li>• Max Day Supply: 28</li> </ul>
Arcalyst	<ul style="list-style-type: none"> <li>• Initial: 320 mg SubQ given as two separate injections on the same day at 2 different sites</li> <li>• Maintenance (1 week following loading dose): 160 mg SubQ once weekly</li> </ul>	<p><u>Initial 3 month auth:</u></p> <p>One-time 1-week auth</p> <ul style="list-style-type: none"> <li>• Max Qty Supply: 4</li> <li>• Max Day Supply: 21</li> <li>• Min Day Supply: 21</li> </ul> <p>For the remainder of the 3 month auth duration:</p> <ul style="list-style-type: none"> <li>• Max Qty Supply: 4</li> <li>• Max Day Supply: 28</li> <li>• Min Day Supply: 28</li> </ul> <p><u>Subsequent:</u></p> <ul style="list-style-type: none"> <li>• Max Qty: 4</li> <li>• Max Day Supply: 28</li> <li>• Min Day Supply: 28</li> </ul>

Benlysta	<ul style="list-style-type: none"> <li>• 200 mg SubQ once weekly</li> </ul>	<p>Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).</p> <ul style="list-style-type: none"> <li>• Max Qty Supply: 4</li> <li>• Max Day Supply: 28</li> <li>• Min Day Supply: 28</li> </ul>
Cimzia	<ul style="list-style-type: none"> <li>• Initial: 400 mg SubQ, repeat dose 2 and 4 weeks after initial dose</li> <li>• Maintenance: 200 mg every 2 weeks or 400 mg every 4 weeks</li> </ul>	<p><u>Initial 6 month auth:</u> One-time 1-week auth</p> <ul style="list-style-type: none"> <li>• Max Qty Supply: 3</li> <li>• Max Day Supply: 28</li> <li>• Min Day Supply: 28</li> </ul> <p>For the remainder of the 6 month auth duration:</p> <ul style="list-style-type: none"> <li>• Max Qty Supply: 1</li> <li>• Max Day Supply: 28</li> <li>• Min Day Supply: 28</li> </ul> <p><u>Subsequent:</u></p> <ul style="list-style-type: none"> <li>• Max Qty: 1</li> <li>• Max Day Supply: 28</li> <li>• Min Day Supply: 28</li> </ul>
Cotellic (20 mg tablets)	<ul style="list-style-type: none"> <li>• 60 mg PO once daily on days 1 to 21 of each 28-day treatment cycle</li> <li>• For dose adjustments: 40 mg once daily or 20 mg once daily</li> </ul>	<p>Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).</p> <ul style="list-style-type: none"> <li>• Max Qty: 63</li> <li>• Max Day Supply: 28</li> <li>• Min Day Supply: 28</li> </ul>
Enbrel	<b>RA, AS, PsA, Pediatric PP, JIA</b>	<b>RA, AS, PsA, Pediatric PP, JIA</b>

- 50 mg SubQ once weekly

25 mg vial

- Max Qty Supply: 8
- Max Day Supply: 28
- Min Day Supply: 28

### **Plaque Psoriasis**

- Initial: 50 mg twice weekly for 3 months
- Maintenance: 50 mg once weekly

25 mg syringe

- Max Qty Supply: 4.08 mL
- Max Day Supply: 28
- Min Day Supply: 28

50 mg syringe/pen

- Max Qty Supply: 3.92 mL
- Max Day Supply: 28
- Min Day Supply: 28

### **Plaque Psoriasis**

#### Initial 6 month auth:

25 mg vial

One-time 3-month auth

- Max Qty Supply: 16
- Max Day Supply: 28
- Min Day Supply: 28

For the remainder of the 6 month auth duration:

- Max Qty Supply: 8
- Max Day Supply: 28
- Min Day Supply: 28

#### Subsequent:

- Max Qty: 8



- Max Day Supply: 28
- Min Day Supply: 28

25 mg syringe

One-time 3-month auth

- Max Qty Supply: 8.16 mL
- Max Day Supply: 28
- Min Day Supply: 28

For the remainder of the 6 month auth duration:

- Max Qty Supply: 4.08 mL
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty: 4.08 mL
- Max Day Supply: 28
- Min Day Supply: 28

50 mg syringe/pen

One-time 3-month auth

- Max Qty Supply: 7.84 mL
- Max Day Supply: 28
- Min Day Supply: 28

For the remainder of the 6 month auth duration:

- Max Qty Supply: 3.92 mL
- Max Day Supply: 28
- Min Day Supply: 28

		<p><u>Subsequent:</u></p> <ul style="list-style-type: none"> <li>• Max Qty: 3.92 mL</li> <li>• Max Day Supply: 28</li> <li>• Min Day Supply: 28</li> </ul>
Farydak	<ul style="list-style-type: none"> <li>• 20 mg PO once every other day for 3 doses each week during weeks 1 and 2 of a 21-day treatment cycle for up to 8 cycles, treatment may continue for an additional 8 cycles if patient seeing benefit and acceptable tox</li> </ul>	<p>Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).</p> <ul style="list-style-type: none"> <li>• Max Qty Supply: 6</li> <li>• Max Day Supply: 21</li> <li>• Min Day Supply: 21</li> </ul>
Forteo	<ul style="list-style-type: none"> <li>• 20 mcg SubQ once daily for up to 2 years</li> </ul>	<p>Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).</p> <p>600 mcg/2.4 mL Subcutaneous Solution</p> <ul style="list-style-type: none"> <li>• Max Qty Supply: 2.4 mL</li> <li>• Max Day Supply: 30</li> <li>• Min Day Supply: 30</li> </ul>
Galafold	<ul style="list-style-type: none"> <li>• 123 mg PO once every other day</li> </ul>	<p>Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).</p> <ul style="list-style-type: none"> <li>• Max Qty Supply: 14</li> <li>• Max Day Supply: 28</li> <li>• Min Day Supply: 28</li> </ul>
Humira	<p><b>Ankylosing Spondylitis:</b></p> <ul style="list-style-type: none"> <li>• 40mg SubQ every other week</li> </ul> <p><b>Crohn's:</b></p>	<p><b>Ankylosing Spondylitis</b></p> <p><u>Initial 6 month auth:</u></p> <ul style="list-style-type: none"> <li>• Max Qty Supply: 2</li> <li>• Max Day Supply: 28</li> </ul>

- Initial: 160mg SubQ as a single dose or split over two consecutive days, then 80mg on day 15
- Maintenance (4 wks after initial dose): 80mg SubQ once weekly or once every other week

- Min Day Supply: 28

Subsequent:

- Max Qty: 2
- Max Day Supply: 28
- Min Day Supply: 28

Children aged  $\geq 6$  years Moderate-severe; refractory Chron's

**Crohn's**

Biweekly Dosing

(17 to <40 kg)

Initial 6 month auth:

- Initial: 80mg SubQ divided in 2 injections on day 1, then 40mg on day 15
- Maintenance (4 wks after initial dose): 20mg SubQ every other week, if still having flares at 12 weeks, switch to weekly dosing

One-time 1-week auth

- Max Qty Supply: 3
- Max Day Supply: 28
- Min Day Supply: 28

For the remainder of the 6 month auth duration:

( $\geq 40$ kg)

- Initial: 160mg divided in 4 injections on day 1 (or 2 injections per day over 2 consecutive days), then 80mg SubQ divided in 2 injections on day 15
- Maintenance (4 wks after initial dose): 40mg SubQ every other week, if still having flares at 12 weeks, switch to weekly dosing

- Max Qty Supply: 2
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty: 2
- Max Day Supply: 28
- Min Day Supply: 28

**Hidradenitis suppurativa:**

Children aged  $\geq 6$

- Initial: 160mg SubQ as a single dose or split over two consecutive days, then 80mg on day 15
- Maintenance (4 wks after initial dose): 40mg SubQ once weekly

Moderate-severe; refractory Chron's

17 to <40 kg:

Initial 6 month auth:

One-time 1-week auth

- Max Qty Supply: 3

Children aged  $\geq$  12 years

(30 to <60 kg)

- Initial: 80mg SubQ on day 1
- Maintenance (1 week after initial dose): 40mg SubQ once every other week

( $\geq$ 60kg)

- Initial: 160mg injections on day 1 (or split over 2 consecutive days), then 80mg SubQ on day 15
- Maintenance (4 wks after initial dose): 40mg SubQ once weekly

**Plaque Psoriasis:**

- Initial: 80mg SubQ as a single dose
- Maintenance (1 week after initial dose): 40mg SubQ once every other week

**Psoriatic Arthritis:**

- 40 mg SubQ every other week

**Rheumatoid Arthritis:**

- 40 mg SubQ every other week, 40 mg SubQ every week if patient not taking methotrexate

**Ulcerative Colitis:**

- Initial: 160mg SubQ as a single dose or split over two consecutive days, then 80mg on day 15

- Max Day Supply: 28

- Min Day Supply: 28

For the remainder of the 6 month auth duration:

- Max Qty Supply: 2

- Max Day Supply: 28

- Min Day Supply: 28

Subsequent:

- Max Qty: 4

- Max Day Supply: 28

- Min Day Supply: 28

$\geq$ 40 kg:

Initial 6 month auth:

One-time 1-week auth

- Max Qty Supply: 6

- Max Day Supply: 28

- Min Day Supply: 28

For the remainder of the 6 month auth duration:

- Max Qty Supply: 2

- Max Day Supply: 28

- Min Day Supply: 28

Subsequent:

- Max Qty: 2

- Max Day Supply: 28

- Min Day Supply: 28

Weekly Dosing

- Maintenance (4 wks after initial dose): 40mg SubQ once every other week

Children aged  $\geq$  6 years Moderate-severe; refractory ulcerative colitis

Children and adolescents

- Initial: 100 mg/m<sup>2</sup> SubQ on day 1 (max 160mg/dose), then 50mg/m<sup>2</sup> on day 15 (max 80mg/dose)
- Maintenance: 25 mg/m<sup>2</sup> SubQ once every other week (max 40mg/dose)

**Uveitis:**

- Initial: 80mg SubQ as a single dose
- Maintenance (1 week after initial dose): 40mg SubQ once every other week

Children  $\geq$  2 years

Fixed Dosing

- (10 to <15 kg): 10mg SubQ once every other week
- (15 to <30 kg): 20mg SubQ once every other week
- ( $\geq$ 30 kg): 40mg SubQ once every other week

Children  $\geq$  4 years

Initial 6 month auth:

- Max Qty Supply: 4
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty: 4
- Max Day Supply: 28
- Min Day Supply: 28

**Hidradenitis Suppurativa**

Initial 6 month auth:

One-time 1-week auth

- Max Qty Supply: 3 (80mg 3 pack pen kit)
- Max Qty Supply: 6 (40mg 6 pack pen kit)
- Max Day Supply: 28
- Min Day Supply: 28

For the remainder of the 6 month auth duration:

- Max Qty Supply: 4
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty: 4
- Max Day Supply: 28
- Min Day Supply: 28

Children aged  $\geq$  12

Body surface area (BSA)-directed dosing

- 24 or 40 mg/m<sup>2</sup> SubQ once every other week, max dose 40mg/dose

**Juvenile idiopathic arthritis (JIA):**

Fixed dosing

Children 2 to <4 years

- (10 to <15 kg): 10mg SubQ once every other week
- (15 to <30 kg): 20mg SubQ once every other week

Children ≥4 years

- (15 to <30 kg): 20mg SubQ once every other week
- (≥30 kg): 40mg SubQ once every other week

Body surface area (BSA)-directed dosing

- Children 2 to <4 years:  
24mg/m<sup>2</sup>/dose SubQ every other week; maximum dose 20 mg/dose
- Children 4 to 17 years:  
24mg/m<sup>2</sup>/dose SubQ every other week; maximum dose 40 mg/dose

30-60 kg:

Initial 6 month auth: One-time 1-week auth

- Max Qty Supply: 3 (80mg-40mg 3 pack pen kit)
- Max Qty Supply: 4 (40mg 4 pack pen kit)

For the remainder of the 6 month auth duration:

- Max Qty Supply: 2
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty Supply: 2
- Max Day Supply: 28
- Min Day Supply: 28

≥60 kg:

Initial 6 month auth:

One-time 1-week auth

- Max Qty Supply: 3 (80mg 3 pack pen kit)
- Max Qty Supply: 6 (40mg 6 pack pen kit)
- Max Day Supply: 28
- Min Day Supply: 28

For the remainder of the 6 month auth duration:

- Max Qty Supply: 4
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty: 4
- Max Day Supply: 28
- Min Day Supply: 28

**Plaque Psoriasis**

Initial 6 month auth: One-time 1-week auth

- Max Qty Supply: 3 (80mg-40mg 3 pack pen kit)
- Max Qty Supply: 4 (40mg 4 pack pen kit)
- Max Day Supply: 28
- Min Day Supply: 28

For the remainder of the 6 month auth duration:

- Max Qty Supply: 2
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty Supply: 2
- Max Day Supply: 28
- Min Day Supply: 28

**Psoriatic Arthritis**

Initial 6 month auth:

- Max Qty Supply: 2
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty: 2
- Max Day Supply: 28
- Min Day Supply: 28

### **Rheumatoid Arthritis**

Biweekly Dosing

Initial 6 month auth:

- Max Qty Supply: 2
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty: 2
- Max Day Supply: 28
- Min Day Supply: 28

Weekly Dosing

Initial 6 month auth:

- Max Qty Supply: 4
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty: 4
- Max Day Supply: 28
- Min Day Supply: 28

### **Ulcerative Colitis**

Initial 6 month auth:

One-time 1-week auth



- Max Qty Supply: 3 (80mg 3 pack pen kit)
- Max Qty Supply: 6 (40 mg 6 pack pen kit)
- Max Day Supply: 28
- Min Day Supply: 28

For the remainder of the 6 month auth duration:

- Max Qty Supply: 2
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty: 2
- Max Day Supply: 28
- Min Day Supply: 28

**Uveitis**

Initial 6 month auth: One-time 1-week auth

- Max Qty Supply: 3 (80mg-40mg 3 pack pen kit)
- Max Qty Supply: 4 (40mg 4 pack pen kit)
- Max Dap Supply: 28
- Min Day Supply: 28

For the remainder of the 6 month auth duration:

- Max Qty Supply: 2
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty Supply: 2
- Max Day Supply: 28
- Min Day Supply: 28

Children  $\geq$  2 years

Initial 6 month auth:

- Max Qty Supply: 2
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty Supply: 2
- Max Day Supply: 28
- Min Day Supply: 28

**Juvenile idiopathic arthritis (JIA)**

Initial 6 month auth:

- Max Qty Supply: 2
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty: 2
- Max Day Supply: 28
- Min Day Supply: 28

Ibrance

- 125 mg PO once daily for 21 days, then 7 days off, repeat every 28 days

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

- Max Qty Supply: 21
- Max Day Supply: 28

Kevzara

- 200 mg SubQ once every 2 weeks
- When ALT > 5 ULN, 150 mg once every 2 weeks.

- Min Day Supply: 28

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

- Max Qty Supply: 2.28 mL
- Max Day Supply: 28
- Min Day Supply: 28

Kisqali/Kisqali Femara Co-Pack

- 600 mg oral once daily for 21 days, then 7 days off.
- If concomitant use with a strong CYP3A4 inhibitor cannot be avoided, decrease dose to 400 mg once daily
- If eGFR 15 to <30 mL/minute/1.73 m<sup>2</sup>, reduce dose to 200 mg once daily

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

Kisqali 200 mg Dose:

- Max Qty Supply: 21
- Min Day Supply: 28
- Max Day Supply: 28

Kisqali 400 mg Dose:

- Max Qty Supply: 42
- Min Day Supply: 28
- Max Day Supply: 28

Kisqali 600 mg Dose:

- Max Qty Supply: 63
- Min Day Supply: 28
- Max Day Supply: 28

Kisqali Femara Co-Pack 200 mg Dose:

- Max Qty Supply: 49

- Min Day Supply: 28
- Max Day Supply: 28

Kisqali Femara Co-Pack 400 mg Dose:

- Max Qty Supply: 70
- Min Day Supply: 28
- Max Day Supply: 28

Kisqali Femara Co-Pack 600 mg Dose:

- Max Qty Supply: 91
- Min Day Supply: 28
- Max Day Supply: 28

Kynamro

- 200 mg SubQ once weekly

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

- Max Qty Supply: 4
- Max Day Supply: 28
- Min Day Supply: 28

Lonsurf

- 35 mg/m<sup>2</sup> PO twice daily on days 1-5, and 8-12, of a 28-day cycle (max 80 mg of trifluridine per dose)

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

15-6.14 mg Tablet

- Max Qty Supply: 100
- Min Day Supply: 28
- Max Day Supply: 28

20-8.19 mg Tablet

Mavyret	<ul style="list-style-type: none"> <li>• Three tablets PO once daily for either 8, 12, or 16 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• Max Qty Supply: 80</li> <li>• Min Day Supply: 28</li> <li>• Max Day Supply: 28</li> </ul> <p>Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).</p>
Ninlaro	<ul style="list-style-type: none"> <li>• 4 mg PO once weekly on days 1, 8, and 15 of 28-day treatment cycle</li> </ul>	<ul style="list-style-type: none"> <li>• Max Qty Supply: 84</li> <li>• Max Day Supply: 28</li> <li>• Min Day Supply: 28</li> </ul> <p>Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).</p>
Orencia	<ul style="list-style-type: none"> <li>• 125 mg SubQ once weekly</li> </ul> <p><b>Juvenile idiopathic arthritis</b></p> <p>Children <math>\geq 2</math> and <math>\leq 17</math> years</p> <ul style="list-style-type: none"> <li>• 10 to &lt;25 kg: 50 mg SubQ once weekly</li> <li>• <math>\geq 25</math> to &lt;50 kg: 87.5 mg SubQ once weekly</li> <li>• <math>\geq 50</math> kg: 125 mg SubQ once weekly</li> </ul>	<p>Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).</p> <p>ClickJet/125 mg/mL syringe</p> <ul style="list-style-type: none"> <li>• Max Qty Supply: 4</li> <li>• Max Day Supply: 28</li> <li>• Min Day Supply: 28</li> </ul> <p>50 mg/0.4 mL syringe</p> <ul style="list-style-type: none"> <li>• Max Qty Supply: 1.6</li> <li>• Max Day Supply: 28</li> <li>• Min Day Supply: 28</li> </ul>

Praluent	<ul style="list-style-type: none"> <li>75 mg SubQ every 2 weeks, may increase to a max dose of 150 mg SubQ every 2 weeks</li> </ul>	87.5 mg/0.7 mL Syringe	<ul style="list-style-type: none"> <li>Max Qty Supply: 2.8</li> <li>Max Day Supply: 28</li> <li>Min Day Supply: 28</li> </ul>
		Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).	<ul style="list-style-type: none"> <li>Max Qty Supply: 2</li> <li>Max Day Supply: 28</li> <li>Min Day Supply: 28</li> </ul>
Repatha/ Repatha Pushtronex/Repatha SureClick	<p><b>Homozygous FH</b></p> <ul style="list-style-type: none"> <li>420 mg SubQ once monthly</li> </ul> <p><b>Primary Hyperlipidemia, prevention of cardiovascular events in patients with established cardiovascular disease</b></p> <ul style="list-style-type: none"> <li>140 mg SubQ every 2 weeks or 420 mg SubQ once monthly</li> </ul>	Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).	<p><u>Repatha Pushtronex</u></p> <ul style="list-style-type: none"> <li>Max Qty Supply: 3.5</li> <li>Max Day Supply: 28</li> <li>Min Day Supply: 28</li> </ul>
		<u>Repatha</u>	<ul style="list-style-type: none"> <li>Max Qty Supply: 2</li> <li>Max Day Supply: 28</li> <li>Min Day Supply: 28</li> </ul>
		<u>Repatha SureClick</u>	<ul style="list-style-type: none"> <li>Max Qty Supply: 2</li> <li>Max Day Supply: 28</li> <li>Min Day Supply: 28</li> </ul>
Revlimid	<b>Mantle Cell Lymphoma/Multiple Myeloma</b>	Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box	

- 25 mg PO once daily for 21 days of a 28-day treatment cycle (no QLs need to be entered within the authorization).
- (adjustment for thrombocytopenia in MCL) When platelets return to  $\geq 50,000/\text{mm}^3$ : Resume treatment at 5 mg below previous dose; do not dose below 5 mg daily
- (adjustment for neutropenia in MCL) When ANC returns to  $\geq 1,000/\text{mm}^3$ : Resume treatment at 5 mg below previous dose; do not dose below 5 mg daily

Revlimid 20 mg caps:

- Max Qty Supply: 21
- Min Day Supply: 28
- Max Day Supply: 28

Revlimid 25 mg caps:

- Max Qty Supply: 21
- Min Day Supply: 28
- Max Day Supply: 28

**Multiple Myeloma, maintenance (following autologous stem cell transplant) / Myelodysplastic syndrome with deletion 5q**

- 10 mg orally once daily, if tolerated can increase to 15 mg once daily after 3 28-day cycles
- If CrCl is 30-60 mL/min: 5 mg once daily
- If CrCl < 30 mL/min: 2.5 mg once daily
- If eGFR 15 to < 30 mL/minute/1.73 m<sup>2</sup>, reduce dose to 200 mg once daily

Rydapt

**Acute myeloid leukemia (AML), FLT3-positive**

- Induction: 50 mg twice daily on days 8 to 21 of each induction cycle (in combination with daunorubicin and cytarabine); administer a second induction cycle if there is definitive evidence of (clinically significant) residual leukemia
- Consolidation: 50 mg twice daily on days 8 to 21 of each 28-day consolidation cycle (in combination with high-dose cytarabine) for 4 consolidation cycles

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

**Acute myeloid leukemia (AML), FLT3-positive**

- Max Qty Supply: 56
- Min Day Supply: 28
- Max Day Supply: 28

**Mast cell leukemia:**

- 100 mg twice daily until disease progression or unacceptable toxicity

**Systemic mastocytosis (aggressive systemic mastocytosis or systemic mastocytosis with associated hematological neoplasm)**

- Oral: 100 mg twice daily until disease progression or unacceptable toxicity

Simponi

**Ankylosing spondylitis, PsA, RA**

- 50 mg SubQ once a month

**Ulcerative Colitis**

- Initial: 200 mg SubQ, then 100 mg SubQ at week 2
- Maintenance: 100 mg SubQ once monthly

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

**Ankylosing spondylitis, PsA, RA**

50 mg/0.5 mL Syringe

- Max Qty Supply: 0.5 mL
- Min Day Supply: 28
- Max Day Supply: 28

**Ulcerative Colitis**

100 mg/1 mL Syringe

Initial 6 month auth:

One-time 1-week auth

- Max Qty Supply: 3 mL
- Max Day Supply: 28
- Min Day Supply: 28

For the remainder of the 6 month auth duration:

- Max Qty Supply: 1 mL
- Max Day Supply: 28



- Min Day Supply: 28

Subsequent:

- Max Qty: 1 mL
- Max Day Supply: 28
- Min Day Supply: 28

Stivarga

- 160 mg once daily for the first 21 days of each 28-day cycles

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

- Max Qty: 84
- Max Day Supply: 28
- Min Day Supply: 28

Sutent

**Gastrointestinal stromal tumor (GIST), Renal cell cancer (adjuvant treatment), advanced renal cell cancer**

- 50 mg PO once daily for 4 weeks of a 6-week treatment cycle (4 weeks on, 2 weeks off)

**Advanced Pancreatic neuroendocrine tumors (PNET)**

- 37.5 mg PO once daily, maximum daily dose used in clinical trials was 50 mg

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

**Gastrointestinal stromal tumor (GIST), Renal cell cancer (adjuvant treatment), advanced renal cell cancer**

- Max Qty: 28
- Max Day Supply: 42
- Min Day Supply: 42

Takhzyro

- 300 mg SubQ every 2 weeks

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

- Max Qty: 4
- Max Day Supply: 28

Taltz  
Autoinjector/Syringe

**Plaque Psoriasis:**

- 160mg SubQ once, then 80mg SubQ at weeks 2, 4, 6, 10, and 12, then 80mg SubQ every 4 weeks

**Psoriatic Arthritis**

- 160mg SubQ once, then 80mg SubQ every 4 weeks

- Min Day Supply: 28

**Plaque Psoriasis**

Initial 6 month auth:

One- time 3-month auth

- Max Qty Supply: 8 mL
- Max Day Supply: 84

For the remainder of the 6 month auth duration:

- Max Qty: 1 mL
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty: 1 mL
- Max Day Supply: 28
- Min Day Supply: 28

**Psoriatic Arthritis**

Initial 6 month auth:

One- time 1-week auth

- Max Qty: 3 mL
- Max Day Supply: 28
- Min Day Supply: 28

For the remainder of the 6 month auth duration:

- Max Qty Supply: 1 mL
- Max Day Supply: 28
- Min Day Supply: 28

Subsequent:

- Max Qty Supply: 1 mL
- Max Day Supply: 28
- Min Day Supply: 28

Tymlos

- 80 mcg SubQ once daily (Lifetime therapy duration should not exceed 2 years)

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

3120 mcg/1.56 mL Pen

- Max Qty Supply: 1.56 mL
- Max Day Supply: 30
- Min Day Supply: 30

Tyvaso

- Initial: Inhale 18 mcg by mouth, three inhalations, 4 times/day
- Maintenance: Inhale 54 mcg by mouth, nine inhalation, 4 times/day

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

0.6 mg/mL (2.9 mL) inhalation

- Max Qty: 81.2
- Max Day Supply: 28
- Min Day Supply: 28

**Discussion:** No comments or questions.

**Outcome:** Keith Hunsicker made a motion to accept the recommendations as presented. Kim Clark seconded the motion. None were opposed.

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

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## **QUARTERLY CASE AUDIT RESULTS**

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The Quarterly Case Audit was held on June 6<sup>th</sup>, 2019. No changes are recommended at this time. We will be looking into creating policies for Humulin R U-500, carisoprodol, and the rosacea class of medications sometime in the future to allow for consistency among reviewers. We will continue to look for opportunities to create more drug specific policies at future quarterly case audit meetings.

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**DUR REPORT**

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The 2017-2018 GHP Family DUR Report was submitted to the Department of Human Services on May 21, 2019. The report and attachments can be found in the drug review presented to the committee.

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Meeting adjourned at 4:05 pm.

**Future Scheduled Meetings**

The next bi-monthly scheduled meeting will be held on Tuesday, September 17, 2019 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.