**P&T Committee Meeting Minutes**
**GHP Family Business**
**July 19, 2016**

| **Present:** | **Absent:** |
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| Bret Yarczower, MD, MBA – Chair | Beverly Blaisure, MD |
| Kristen Bender, Pharm.D | Keith Boell, DO |
| Holly Bones, Pharm.D. – via phone | John Bulger, MD, Chief Medical Officer |
| Kimberly Clark, Pharm.D. | Dean Christian, MD |
| Kristi Clarke, Pharm. D. – via phone | Jamie Dodson, RPh |
| Tristram Ford, Pharmacy Student | Michael Evans, Pharm.D., B.S |
| Tricia Heitzman, Pharm.D. | John Flaherty, Pharm.D. |
| Michelle Holt-Macey, Pharm.D. – via phone | Perry Meadows, MD |
| Steven Kheloussi, Pharm.D. | Jonas Pearson, MS, RPh |
| Phillip Krebs, R.EEG T. – via phone | William Seavey, Pharm.D. |
| Lisa Mazonkey, RPh | James Schuster, MD |
| Thomas Morland, MD – via phone | Steve Tracy, Pharm.D. |
| Kristen Scheib, Pharm. D. – via phone | Lori Zaleski, RPh |
| Richard Silbert, MD – via phone | |
| Michael Spishock RPh – via phone | |
| Todd Sponenberg, Pharm.D., RPh | |
| Kevin Szczecina, RPh | |
| Elaine Tino, CRNP – via phone | |

**Call To Order:**
Bret Yarczower called the meeting to order at 1:00 p.m., Tuesday, July 19, 2016.

**Review and Approval of Minutes:**
Dr. Bret Yarczower asked for a motion or approval to accept the May 17, 2016 minutes as written. Kevin Szczecina made a motion to accept the minutes as written and Kimberly Clark seconded the motion. None were opposed.

**DRUG REVIEWS:**

**CABOMETYX** **Steven Kheloussi**
(cabozantinib)

Steven Kheloussi provided a review of Cabometyx to the committee for consideration as a pharmacy benefit. Cabometyx is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.

Formulary alternatives:

Pharmacy Benefit: Afinitor*, Inlyta*, Lenvima*, Nexavar*, Sutent*, Votrient*
*Prior authorization required

**Proposed Clinical Recommendations:** Cabometyx is a pharmacy benefit and should be added to the GHP Family formulary. A prior authorization with the following criteria should apply:

- Prescription written by an oncologist **AND**
- Medical record documentation of use as a single agent for relapse or for surgically unresectable advanced or metastatic renal cell carcinoma with predominant clear-cell histology **AND**
- Medical record documentation of a therapeutic failure on or intolerance to prior anti-angiogenic therapy, including, but not limited to, Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), Afinitor (everolimus), or Torisel (temsirolimus)

It is recommended that the underlined section below be added to the Afinitor policy (1037.0F) for RCC:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Opdivo **OR** Cabometyx

**Clinical Discussion:** FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

Cabometyx (cabozantinib) is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy. NCCN further clarifies its place in therapy with a category 1 recommendation suggesting it be used as a single agent for relapse or for surgically unresectable stage IV disease with predominant clear cell histology that progressed on prior antiangiogenic therapy. Cabometyx is a tyrosine kinase inhibitor (TKI) that is dosed orally once daily. Cabometyx was compared to everolimus (Afinitor) in an open-label, randomized clinical trial and was shown to improve progression free survival (7.4 months versus 3.8 months, respectively) and overall survival (21.4 months versus 16.5 months respectively), while confirmed objective response rates were also higher with Cabometyx (17% versus 3%, respectively). Adverse reactions which occurred in $\geq$ 50% of Cabometyx-treated patients included diarrhea (74%), fatigue (56%), and nausea (50%).

It was recommended that the criteria be clarified to require failure on only one prior anti-angiogenic therapy.

**Clinical Outcome:** Tricia Heitzman made a motion to accept the recommendations as amended. Lisa Mazonkey seconded the motion. None were opposed.

**Proposed Financial Recommendations:** Cabometyx should be added to the GHP Family formulary on the Brand Tier. A quantity limit of one tablet per day should apply. The following additional criteria should apply:

- If the requested dose if 80 mg daily (one 60 mg tablet + one 20 mg tablet daily): Medical record documentation that the patient is using Cabometyx in combination with a strong CYP3A4 inducer, including but not limited to rifampin, phenytoin, carbamazepine, phenobarbital, rifabutin, rifapentine, and St. John's Wort

**AUTHORIZATION DURATION:** Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

**Financial Discussion:** In addition to the combination of one 60 mg tablet + one 20 mg tablet, it's possible that a member may be prescribed two 40 mg tablets. In this circumstance the case should be approved with a GPID for the 40 mg tablet and a quantity limit of two tablets per day. It was also requested that a 30 day supply limit be applied to approvals.

**Financial Outcome:** Kevin Szczecina made a motion to accept the recommendation as amended. Tricia Heitzman seconded the motion. None were opposed.

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**Approved Recommendations**: Cabometyx will be added to the GHP Family formulary on the Brand Tier. The following prior authorization criteria will apply to requests for Cabometyx:

- Prescription written by an oncologist **AND**
- Medical record documentation of use as a single agent for relapse or for surgically unresectable advanced or metastatic renal cell carcinoma with predominant clear-cell histology **AND**
- Medical record documentation of a therapeutic failure on or intolerance to one prior anti-angiogenic therapy, including, but not limited to, Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), Afinitor (everolimus), or Torisel (temsirolimus) **AND**
- If the requested dose if 80 mg daily (one 60 mg tablet + one 20 mg tablet daily): Medical record documentation that the patient is using Cabometyx in combination with a strong CYP3A4 inducer, including but not limited to rifampin, phenytoin, carbamazepine, phenobarbital, rifabutin, rifapentine, and St. John's Wort

**AUTHORIZATION DURATION:** Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

**QUANTITY LIMIT:**

- If approved for 20 mg, 40 mg, or 60 mg daily dose, QL 1 per day, 30 day supply per fill.
- If approved for 80 mg daily, dosed as one 20 mg + one 60 mg tablet – QL 1 per day, 30 day supply per fill, approved both by GPID
- If approved for 80 mg daily, dosed as two 40 mg tablets daily – QL 2 per day, 30 day supply per fill, approved by GPID.

The underlined section below will be added to the Afinitor policy (1037.0F) for RCC:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Opdivo **OR** Cabometyx

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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**NUPLAZID** **Kimberly Clark**
(pimavanserin tartrate)

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Kimberly Clark provided a review of Nuplazid to the committee for consideration as a pharmacy benefit. Nuplazid is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

Formulary alternatives: none

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**Proposed Clinical Recommendations:** It is recommended that Nuplazid be added to the GHP Family formulary with the following prior authorization criteria:

- Medical record documentation that the patient is at least 18 years of age **AND**
- Medical record documentation of diagnosis of Parkinson's disease psychosis (defined by illusions, a false sense of presence, hallucinations, or delusions) **AND**
- Medical record documentation that the diagnosis is established by or in consultation with a neurologist **AND**
- Medical record documentation that the psychosis is not due to other conditions (which may include, but are not limited to, another mental disorder or physiological effects of a substance)

**QUANTITY LIMIT:** 2 tablets per day

**AUTHORIZATION DURATION:** Authorization duration: Approval will be given for an initial duration of three (3) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of Parkinson's disease psychosis on three (3) months of Nuplazid therapy is required.

After the initial three (3) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of Parkinson's disease psychosis while on Nuplazid therapy.

**Clinical Discussion:** FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

Nuplazid is an atypical antipsychotic that is the first and only FDA-approved medication for treatment of hallucinations and delusions associated with Parkinson's disease psychosis. Nuplazid offers small, but significant improvements in score on the PD-adapted Scale for the Assessment of Positive Symptoms (SAPS-PD) as compared to placebo. It also appears to have a milder side effect profile than off-label treatment options (i.e. clozapine). Nuplazid carries a black box warning of increased mortality in elderly

patients with dementia-related psychosis, so careful monitoring of appropriate indication for its use is necessary.

Dr. Silbert stated that in his experience he has seen negative outcomes when antipsychotics other than clozapine are utilized in this patient population. Clozapine has the limitation of requiring extensive monitoring and blood work. He agrees with the recommendations as proposed.

**Clinical Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

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**Proposed Financial Recommendations:** It is recommended that Nuplazid be added to the Brand tier of the GHP Family formulary. No additional authorization criteria should apply.

**Financial Discussion:** No questions or comments.

**Financial Outcome:** Lisa Mazonkey made a motion to accept the recommendation as written. Kristen Bender seconded the motion. None were opposed.

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**Approved Recommendations**: Nuplazid will be added to the brand tier of the GHP Family formulary. The following prior authorization criteria will apply to requests for Nuplazid:

- Medical record documentation that the patient is at least 18 years of age **AND**
- Medical record documentation of diagnosis of Parkinson's disease psychosis (defined by illusions, a false sense of presence, hallucinations, or delusions) **AND**
- Medical record documentation that the diagnosis is established by or in consultation with a neurologist **AND**
- Medical record documentation that the psychosis is not due to other conditions (which may include, but are not limited to, another mental disorder or physiological effects of a substance)

**QUANTITY LIMIT:** 2 tablets per day

**AUTHORIZATION DURATION:** Authorization duration: Approval will be given for an initial duration of three (3) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of Parkinson's disease psychosis on three (3) months of Nuplazid therapy is required.

After the initial three (3) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of Parkinson's disease psychosis while on Nuplazid therapy.

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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**IDELVION** **Steven Kheloussi**
(coagulation factor IX (recombinant), albumin fusion protein (rIX-FP))

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Steven Kheloussi provided a review of Idelvion to the committee for consideration as a pharmacy or medical benefit. Idelvion is indicated in children and adults with hemophilia B (congenital Factor IX deficiency) for:

- On-demand control and prevention of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

Limitations of Use: Idelvion is not indicated for immune tolerance induction in patients with Hemophilia B.

Formulary alternatives: none

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**Proposed Clinical Recommendations:** If Idelvion is NOT being self-administered, it will be a medical benefit and should not require prior authorization. If Idelvion IS being self-administered, it will be a pharmacy benefit. As a pharmacy benefit, it should not be added to the GHP Family formulary at this time and should require a prior authorization to be reviewed under Policy 1084.0F – Antihemophilic Agents with the same existing criteria:

- Medical record documentation of a diagnosis of hemophilia (a documented Factor VIII or Factor IX deficiency) **AND**
- The antihemophilic agent will be for outpatient use

**Clinical Discussion**: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

Idelvion [coagulation Factor IX, (Recombinant), albumin fusion protein (rIX-FP)] is indicated in children and adults with hemophilia B (congenital Factor IX deficiency) for on-demand control and prevention of bleeding episodes, perioperative management of bleeding, and for routine prophylaxis to prevent or reduce the frequency of bleeding episodes. Its prolonged half-life allows for every 14-day dosing for routine prophylaxis in patients > 12 years of age and once weekly dosing for patients < 12 years old compared to the usual twice weekly dosing required with most other Factor IX products. It was shown to be effective in clinical trials in previously treated patients and was well tolerated. The safety profile is similar between this product and the other available recombinant Factor IX products.

**Clinical Outcome:** Tricia Heitzman made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

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**Proposed Financial Recommendations:** Idelvion should not be added to the GHP Family formulary at this time. No additional criteria should apply.

**Financial Discussion:** No comments or questions.

**Financial Outcome:** Lisa Mazonkey made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

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**Approved Recommendations**: Idelvion will not be added to the GHP Family formulary at this time. The following prior authorization criteria will apply to requests for Idelvion:

- Medical record documentation of a diagnosis of hemophilia (a documented Factor VIII or Factor IX deficiency) **AND**
- The antihemophilic agent will be for outpatient use

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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**BRIVIACT** **Kimberly Clark**
(brivaracetam)

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Kimberly Clark provided a review of Briviact to the committee for consideration as a pharmacy or medical benefit. Briviact is indicated as adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy.

Formulary alternatives: carbamazepine, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, primidone, topiramate, zonisamide, Lyrica* (*Prior authorization required)

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**Proposed Clinical Recommendations:** Because Briviact injection would be administered during an inpatient stay, it is considered a medical benefit that should be covered as such without any prior authorization, but should not be added to the GHP Family pharmacy formulary. It is not recommended that Briviact oral tablets or oral solution be added to the GHP Family pharmacy formulary at this time as Briviact does not appear to offer any benefit over the many formulary alternatives. The following policy would apply only to Briviact oral tablets or oral solution, and would not apply to the injectable formulation:

- Medical record documentation of diagnosis of partial-onset seizures **AND**
- Medical record documentation of age greater than or equal to 16 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three formulary alternatives, one of which must be levetiracetam **AND**
- Medical record documentation that Briviact is being used as an adjunctive therapy **AND**
- Medical record documentation that Briviact is NOT being used in combination with levetiracetam

**QUANTITY LIMIT:** 2 tablets per day OR 20 mL/day of oral solution

**Clinical Discussion:** FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

Briviact (brivaracetam) is a Schedule V controlled substance that is indicated as adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy. Its anticonvulsant mechanism is not precisely known, but it is in the same drug class as levetiracetam (Keppra), another commonly used antiepileptic. Many other medications are already available for adjunctive seizure therapy, though they have varying mechanisms and side effect profiles. Briviact offers the advantage of immediate, therapeutic dosing, with no need for a titration period. It offers no advantage when used in combination with levetiracetam.

**Clinical Outcome:** Lisa Mazonkey made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

**Proposed Financial Recommendations:** It is recommended that Briviact not be added to the GHP Family formulary at this time.

**Financial Discussion:** No comments or questions.

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

**Approved Recommendations**: Briviact will not be added to the GHP Family formulary at this time. The following prior authorization criteria will apply to requests for Briviact oral tablets and oral solution:

- Medical record documentation of diagnosis of partial-onset seizures **AND**
- Medical record documentation of age greater than or equal to 16 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three formulary alternatives, one of which must be levetiracetam **AND**
- Medical record documentation that Briviact is being used as an adjunctive therapy **AND**
- Medical record documentation that Briviact is NOT being used in combination with levetiracetam

**QUANTITY LIMIT:** 2 tablets per day OR 20 mL/day of oral solution

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

**ORAL AMPHETAMINE PRODUCTS** **Steven Kheloussi**
(amphetamine)

Steven Kheloussi provided a review of Evekeo, Adzenys XR-ODT, and Dyanavel XR to the committee for consideration as a pharmacy benefit.

Evekeo is indicated for:

- Narcolepsy
- Attention deficit hyperactivity disorder (ADHD) as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for stabilizing effect in children with behavioral syndrome.
- Exogenous obesity as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction for patients refractory to alternative therapy (e.g., repeated diets, group programs, and other drugs). The limited usefulness of amphetamines should be weighed against possible risks inherent in use of the drug.

Adzenys XR-ODT is indicated for the treatment of ADHD in patients 6 years and older.

Dyanavel XR is indicated for the treatment of ADHD.

Formulary alternatives: dexmethylphenidate IR, dextroamphetamine IR/ER, dextroamphetamine/amphetamine IR/ER, guanfacine ER, methamphetamine, methylphenidate IR/ER/CD, Strattera (step therapy required)

**Proposed Clinical Recommendations:** It is recommended that all three agents not be added to the GHP Family formulary. The following prior authorization criteria should apply:

- For Adzenys XR-ODT and Dyanavel XR – Medical record documentation of a diagnosis of ADHD and patient age ≥ 6 years
- For Evekeo
    - Medical record documentation of a diagnosis of ADHD and patient age ≥ 3 years
    - Medical record documentation of a diagnosis of narcolepsy and patient age ≥ 12 years
    - Use for exogenous obesity is considered excluded

**Clinical Discussion:** FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed

Evekeo (immediate-release amphetamine tablets), Dyanavel XR (extended-release amphetamine oral solution), and Adzenys XR-ODT (extended-release amphetamine orally dissolving tablets) are all indicated for the treatment of ADHD. Evekeo is also indicated for short-term use in exogenous obesity and narcolepsy. These products are not interchangeable and are indicated in patients over the age of 6 years (Adzenys XR-ODT and Dyanavel XR), over the age of 3 years (Evekeo for ADHD), or over the age of 12 years (Evekeo for the other indications). Limited safety and efficacy data is available on these agents and guidelines have not been updated to include them to date.

There was discussion that many of these prescriptions for young children are believed to be coming from primary care physicians rather than a child behavioral health specialist. There was a recommendation to consider adding language regarding the prescriber of the medication. It was ultimately decided not to add this language as we do not currently block the formulary agents for this requirement.

**Clinical Outcome:** Lisa Mazonkey made a motion to accept the recommendations as written. Kimberly Clark seconded the motion. None were opposed.

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**Proposed Financial Recommendations:** Adzenys XR-ODT, Evekeo, and Dyanavel XR should not be added to the GHP Family formulary. The following additional criteria should apply:

- For Adzenys XR-ODT and Dyanavel XR – Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to methylphenidate CD (generic Metadate CD) AND amphetamine/dextroamphetamine SR combination
- For Evekeo
    - **For members ≥ 6 years of age being treated for ADHD**: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three of the following formulary alternatives: dexmethylphenidate IR, dextroamphetamine IR, dextroamphetamine/amphetamine IR, or methylphenidate IR
    - **For members ≥ 3 years of age being treated for ADHD:** Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to dextroamphetamine IR and dextroamphetamine/amphetamine IR
    - **For members being treated for narcolepsy:** Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to dextroamphetamine IR, dextroamphetamine/amphetamine IR, **AND** methylphenidate IR

**Financial Discussion:** No questions or comments.

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

**Approved Recommendations**: Adzenys XR-ODT, Evekeo, and Dyanavel XR will not be added to the GHP Family formulary. The following prior authorization criteria will apply to requests for Adzenys XR-ODT, Evekeo, and Dyanavel XR:

Adzenys XR-ODT & Dyanavel XR

- Medical record documentation of a diagnosis of ADHD and patient age ≥ 6 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to methylphenidate CD (generic Metadate CD) AND amphetamine/dextroamphetamine SR combination

Evekeo

ADHD

- Medical record documentation of a diagnosis of ADHD and patient age > 3 years **AND**
- **For members ≥ 6 years of age:** Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three of the following formulary alternatives: dexmethylphenidate IR, dextroamphetamine IR, dextroamphetamine/amphetamine IR, or methylphenidate IR **OR**
- **For members ≥ 3 years of age:** Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to dextroamphetamine IR and dextroamphetamine/amphetamine IR

Narcolepsy

- Medical record documentation of a diagnosis of narcolepsy and patient age > 12 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to dextroamphetamine IR, dextroamphetamine/amphetamine IR, **AND** methylphenidate IR

Use for exogenous obesity is considered excluded

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

**ORAL METHYLPHENIDATE PRODUCTS** **Kimberly Clark**
(methylphenidate hydrochloride)

Kimberly Clark provided a review of Aptensio XR, QuilliChew ER, and Quillivant XR to the committee for consideration as a pharmacy benefit. Aptensio XR, QuilliChew ER, and Quillivant XR are central nervous system (CNS) stimulants indicated for the treatment of attention deficit hyperactivity disorder (ADHD).

Formulary alternatives: dexmethylphenidate IR, dextroamphetamine IR/ER, dextroamphetamine/amphetamine IR/ER, guanfacine ER, methylphenidate IR/ER/CD, Strattera (step therapy required)

**Proposed Clinical Recommendations:** Aptensio XR, QuilliChew ER, and Quillivant XR do not appear to offer any significant clinical advantage over existing formulary alternatives for the treatment of ADHD. It is recommended that these products are not added to the GHP Family formulary at this time. The products will be added to GHP Family policy 94.0 with the following prior authorization criteria:

- There is medical record documentation of a diagnosis of attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD) **AND**

- There is medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Metadate CD **AND** amphetamine/dextroamphetamine SR combination

**Clinical Discussion:** FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

Aptensio XR, QuilliChew ER, and Quillivant XR are all new formulations of the previously available stimulant medication, methylphenidate. While, QuilliChew ER and Quillivant XR provide for previously unavailable formulations, there are several medications for the treatment of ADHD currently available all GHP formulary. Metadate CD capsules, a formulation of methylphenidate, and amphetamine/dextroamphetamine ER capsules may be opened and sprinkled on applesauce for administration for those members unable to swallow capsules/tablets. All warnings and precautions are similar amongst the stimulant medications and these new products do not provide any significant advances in the treatment of ADHD.

The requirement of an age restriction was discussed. Since the formulary products are currently unrestricted it was decided to not include an age restriction in the clinical prior authorization criteria.

**Clinical Outcome:** Tricia Heitzman made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

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**Proposed Financial Recommendations:** It is recommended that Aptensio XR, QuilliChew ER, and Quillivant XR are not added to the GHP Family formulary at this time.

**Financial Discussion:** No comments or questions.

**Financial Outcome:** Todd Sponenberg made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

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**Approved Recommendations**: Aptensio XR, QuilliChew ER, and Quillivant XR will not be added to the GHP Family formulary at this time. The following criteria will apply to prior authorization requests for Aptensio XR, QuilliChew ER, and Quillivant XR:

- There is medical record documentation of a diagnosis of attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD) **AND**
- There is medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Metadate CD **AND** amphetamine/dextroamphetamine SR combination

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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**XURIDEN** **Steven Kheloussi**
(uridine triacetate)

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Steven Kheloussi provided a review of Xuriden to the committee for consideration as a pharmacy benefit. Xuriden is indicated for treatment of hereditary orotic aciduria, also known as uridine monophosphate.

Hereditary orotic aciduria is an extremely rare autosomal recessive disorder with less than 20 cases identified worldwide. Patients with hereditary orotic aciduria are typically diagnosed during infancy and may present with macrocytic hypochromic megaloblastic anemia refractory to iron, folic acid, or B12 therapy, decreased neutrophil and white blood cell counts, and excessive urinary excretion of orotic acid, which may lead to urinary obstruction. Some patients also present with physical and intellectual developmental delays.

Formulary alternatives: none

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**Proposed Clinical Recommendations:** Xuriden is a pharmacy benefit and should not be added to the GHP Family formulary at this time. A prior authorization with the following criteria should apply:

- Medical record documentation of a diagnosis of hereditary orotic aciduria as evidenced by at least one of the following:
    - Assay of the orotate phosphoribosyltransferase and orotidylic acid decarboxylase enzymes in the patient's erythrocytes showing deficiency in both enzymes or deficiency in orotidylic acid decarboxylase alone OR
    - Orotic acid crystals visualized in the urine via microscopy

**AND**

- Medical record documentation of an appropriate dose for the patient's weight*.

*Appropriate dosing for Xuriden is 60 mg/kg or 120 mg/kg once daily. Xuriden is available only in 2 gram, single-use packets. The maximum daily dose should not exceed 8 grams.

**Clinical Discussion:** FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

There was discussion around what was used as a comparator product in clinical trials, and it was determined that it was a uridine compound. Out of all the competitor policies examined only one competitor required failure on the compounded product prior to approval of Xuriden therefore it was decided not to include this criteria.

Additionally there was discussion that these prescriptions should come from a provider experienced in the diagnosis and treatment of hereditary orotic aciduria. This will be added as an additional prior authorization criteria.

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

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**Proposed Financial Recommendations:** Xuriden should not be added to the GHP Family formulary at this time. A quantity limit of four packets per day should apply.

**Financial Discussion:** No comments or questions.

**Financial Outcome:** Lisa Mazonkey made a motion to accept the recommendations as amended. Todd Sponenberg seconded the motion. None were opposed.

**Approved Recommendations**: Xuriden will not be added to the GHP Family formulary at this time. The following prior authorization criteria will apply to requests for Xuriden:

- Medical record documentation of a diagnosis of hereditary orotic aciduria as evidenced by at least one of the following:
    - Assay of the orotate phosphoribosyltransferase and orotidylic acid decarboxylase enzymes in the patient's erythrocytes showing deficiency in both enzymes or deficiency in orotidylic acid decarboxylase alone OR
    - Orotic acid crystals visualized in the urine via microscopy

**AND**

- Medical record documentation of an appropriate dose for the patient's weight* **AND**
- Prescription written by a metabolic specialist, medical geneticist, or other physician with experience in the diagnosis and treatment of inborn errors of metabolism

*Appropriate dosing for Xuriden is 60 mg/kg or 120 mg/kg once daily. Xuriden is available only in 2 gram, single-use packets. The maximum daily dose should not exceed 8 grams.

**QUANTITY LIMIT**: 4 packets per day

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

**ASTAGRAF XL/ENVARSUS XR** **Kimberly Clark**
(tacrolimus)

Kimberly Clark provided a review of Astagraf XL and Envarsus XR to the committee for consideration as a pharmacy benefit. Astagraf XL is indicated for the prophylaxis of organ rejection in kidney transplant patients in combination with other immunosuppressants. Envarsus XR is indicated for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants.

Formulary alternatives: tacrolimus, sirolimus, Rapamune*, Zortress* (*Prior authorization required)

**Proposed Clinical Recommendations:** It is recommended to add Astagraf XL to the GHP Family formulary with no restrictions. It is not recommended to add Envarsus XR to the GHP Family formulary. Astagraf XL is preferred because it is indicated for immediate use in new transplant patients and has appropriate dosing information available to do so. To use Envarsus XR, patients must be converted from immediate-release tacrolimus and be readjusted based on whole blood trough concentrations, requiring extra time and steps to reach a stable dose and regimen.
An exception for coverage of Envarsus XR may be made in individuals who meet the following criteria:

- Prescription must be ordered by a physician experienced in immunosuppressive therapy and management of transplant patients **AND**
- Medical record documentation of kidney transplant **AND**
- Member must be at least 16 years of age or older **AND**
- Medical record documentation of appropriate conversion from immediate-release tacrolimus (using 80% of pre-conversion daily dose of tacrolimus IR) **AND**
- Medical record documentation of rationale for not using Astagraf XL if clinically appropriate

**Clinical Discussion**: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

Envarsus XR tablets and Astagraf XL capsules are extended release formulations of tacrolimus, which allow for once daily dosing for rejection prophylaxis in kidney transplant patients. Studies have shown that both medications have similar efficacy and safety to immediate-release tacrolimus, though no head-to-head comparison trials appear to have been conducted between the two. Tacrolimus is initially dosed based on weight and then adjusted based on whole blood trough concentrations. Both Envarsus XR and Astagraf XL come in three dosages and a typical dose may require multiple tablets/capsules a day, taken all at once. There is a difference in FDA indication for the two drugs as Envarsus XR requires conversion from immediate-release tacrolimus, but Astagraf XL does not. This is reflected in their recommended dosing.

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

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**Proposed Financial Recommendations:** It is recommended that Astagraf XL be added to the brand-non preferred tier of the GHP Family formulary. It is recommended that Envarsus XR not be added to the GHP Family formulary at this time. No additional prior authorization criteria should apply.

**Financial Discussion:** No comments or questions.

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

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**Approved Recommendations**: Astagraf XL will added GHP Family formulary on the brand non-preferred tier. Envarsus XR will not be added to the GHP Family formulary. The following prior authorization criteria will apply to requests for Envarsus XR:

- Prescription must be ordered by a physician experienced in immunosuppressive therapy and management of transplant patients **AND**
- Medical record documentation of kidney transplant **AND**
- Member must be at least 16 years of age or older **AND**
- Medical record documentation of appropriate conversion from immediate-release tacrolimus (using 80% of pre-conversion daily dose of tacrolimus IR) **AND**
- Medical record documentation of rationale for not using Astagraf XL if clinically appropriate

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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**TECENTRIQ** **Steven Kheloussi**
(atezolizumab)

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Steven Kheloussi provided a review of Tecentriq to the committee for consideration as a medical benefit. Tecentriq is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who:

- Have disease progression during or following platinum-containing chemotherapy
- Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Formulary alternatives: none

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**Proposed Clinical Recommendations:** Tecentriq is a medical benefit for GHP Family. A prior authorization with the following criteria should apply:

- Prescription written by an oncologist **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**
- Medical record documentation that the patient has had either:
    - Disease progression during or following platinum-containing chemotherapy **OR**
    - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

**Clinical Discussion:** FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

Tecentriq (atezolizumab) is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or for those who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Tecentriq was granted breakthrough therapy designation, priority review status, and an accelerated approval. In the clinical trial, the overall response rate was 14.8%, while patients with $\geq$ 5% PD-L1 expression had higher overall response rates than those with < 5% PD-L1 expression (26% and 9.5%, respectively). The overall duration of response was not reached, with a range of 2.1+ to 13.8+ months. Tecentriq has recently been added to the NCCN guidelines as a single agent for recurrent or metastatic bladder cancer (primary carcinoma of the urethra, upper genitourinary tract tumors, or urothelial carcinoma of the prostate) as second-line standard agent.

**Clinical Outcome:** Tricia Heitzman made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

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**Proposed Financial Recommendations:** Tecentriq is a medical benefit for GHP Family. The following authorization duration should apply:

> **AUTHORIZATION DURATION**: Initial approval will be for 6 months of less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

**Financial Discussion:** No comments or questions.

**Financial Outcome:** Tricia Heitzman made a motion to accept the recommendations as written. Lisa Mazonkey seconded the motion. None were opposed.

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**Approved Recommendations**: Tecentriq will be considered a medical benefit for GHP Family. The following prior authorization criteria will apply to requests for Tecentriq:

- Prescription written by an oncologist **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**
- Medical record documentation that the patient has had either:
    - Disease progression during or following platinum-containing chemotherapy **OR**
    - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

**AUTHORIZATION DURATION**: Initial approval will be for 6 months of less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

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

**FAST FACTS:**

**COSENTYX** **Steven Kheloussi**
(secukinumab)

**New Indication:** Cosentyx is now indicated for the treatment of adult patients with active:

- Psoriatic Arthritis (PsA); and
- Ankylosing Spondylitis (AS)

Previously Cosentyx was only indicated in plaque psoriasis.

**Clinical discussion:** FDA Approved Indications, Clinical Evidence of Safety and Efficacy, Dosing Schedule, Warnings and Precautions, and Adverse Reactions were discussed.

**Recommendation:** For GHP Family and the medical policy (131.0) the following additional criteria should apply:

For Psoriatic Arthritis:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
  - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Prescription must be written by a rheumatologist or dermatologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* **AND** Enbrel*

**AUTHORIZATION DURATION**: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of psoriatic arthritis on six (6) months of Cosentyx therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of psoriatic arthritis while on Cosentyx therapy.

**Current Quantity Limits:** Requests should be approved by **NDC** currently.

| If requesting a dose of: | In this dosage form: | Approve only this NDC: | With a QL of: |
|---|---|---|---|
| 150 mg every 4 weeks | Prefilled syringe | 00078-0639-98 | 2 mL per 56 days* |
| 300 mg every 4 weeks | Prefilled syringe | 00078-0639-98 | 2 mL per 28 days^ |
| 150 mg every 4 weeks | Sensoready Pen | 00078-0639-41 | 2 mL per 56 days* |
| 300 mg every 4 weeks | Sensoready Pen | 00078-0639-41 | 2 mL per 28 days^ |

* Members who are new to therapy and using the 150 mg dose should receive a one-time 1-week authorization for a QL of 6 mL for 56 days. This is intended to cover the starting dosing of 150 mg at Weeks 0, 1, 2, 3, and 4 plus the following month's dose. For the remainder of the 6 month auth, the QL of 2 mL per 56 days should apply.

^ Members who are new to therapy and using the 300 mg dose should receive a one-time 1-week authorization for a QL of 10 mL for 28 days to cover the starting dosing of 300 mg at Weeks 0, 1, 2, 3, and 4. For the remainder of the 6 month auth, the QL of 2 mL per 28 days should apply.

For Ankylosing Spondylitis

- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Prescription must be written by a rheumatologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Humira* **AND** Enbrel* **AND**
- Medical record documentation that the medication is being dosed as 150 mg every 4 weeks with or without a loading dose of 150 mg at Weeks 0, 1, 2, 3, and 4.

**AUTHORIZATION DURATION**: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of ankylosing spondylitis on six (6) months of Cosentyx therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of ankylosing spondylitis while on Cosentyx therapy.

**Current Quantity Limits:** Requests should be approved by **NDC** currently.

| **If requesting a dose of:** | **In this dosage form:** | **Approve only this NDC:** | **With a QL of:** |
|---|---|---|---|
| 150 mg every 4 weeks | Prefilled syringe | 00078-0639-98 | 2 mL per 56 days* |
| 150 mg every 4 weeks | Sensoready Pen | 00078-0639-41 | 2 mL per 56 days* |

* Members who are new to therapy and using the 150 mg dose should receive a one-time 1-week authorization for a QL of 6 mL for 56 days. This is intended to cover the starting dosing of 150 mg at Weeks 0, 1, 2, 3, and 4 plus the following month's dose. For the remainder of the 6 month auth, the QL of 2 mL per 56 days should apply.

**Discussion**: No comments or questions.

**Outcome:** Tricia Heitzman made a motion to accept the recommendations as written. 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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**TIVICAY** **Steven Kheloussi**
(dolutegravir)

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**New Indication:** Tivicay is now indicated for HIV-1 infection in adults and pediatric patients weighing at least 30 kg.

Previously indicated in adults and pediatric patients aged 12 years of age and older weighing at least 40 kg.

**Recommendation:** No changes are recommended at this time.

**Discussion**: No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

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

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**IMBRUVICA** **Kimberly Clark**
(ibrutinib)

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**New Indication:** Imbruvica is a kinase inhibitor newly indicated for the treatment of patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) and CLL/SLL with 17p deletion.

Previously indicated only for mantle cell lymphoma (MCL) in patients who have received at least one prior therapy and Waldenström's macroglobulinemia.

**Current Formulary Status:**

- GHP Family- Brand tier (PA, QL 3 per day for CLL, 4 per day for MCL)

**Current Prior Authorization Criteria:**
GHP Family Policy:

- Must be prescribed by hematologist/oncologist **AND**
- Medical record documentation of mantle cell lymphoma **OR**
- Medical record documentation of chronic lymphocytic leukemia (CLL) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one prior therapy **OR**
- Medical record documentation of a diagnosis of CLL with 17p deletion **OR**
- Medical record documentation of a diagnosis of Waldenström's macroglobulinemia (WM)

****QUANTITY LIMIT:** 4 capsules per day for mantle cell lymphoma
3 capsules per day for chronic lymphocytic leukemia (CLL) or Waldenström's macroglobulinemia (WM)

**AUTHORIZATION DURATION**: Each treatment period is defined as 6 months. Re-review will occur every 6 months. Imbruvica will no longer be considered medically necessary if there is medical record documentation of disease progression

**Recommendation:** Recommended additions are underlined and deletions are indicated by strikethrough.
GHP Family Policy:

- Must be prescribed by hematologist/oncologist **AND**
- Medical record documentation of mantle cell lymphoma **OR**
- Medical record documentation of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) ~~**AND**~~ **OR**
- ~~Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one prior therapy **OR**~~

- Medical record documentation of a diagnosis of CLL with 17p deletion or SLL with 17p deletion **OR**
- Medical record documentation of a diagnosis of Waldenström's macroglobulinemia (WM)

****QUANTITY LIMIT:** 4 capsules per day for mantle cell lymphoma
3 capsules per day for chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), or Waldenström's macroglobulinemia (WM)

**AUTHORIZATION DURATION**: Each treatment period is defined as 6 months. Re-review will occur every 6 months. Imbruvica will no longer be considered medically necessary if there is medical record documentation of disease progression.

**Discussion**: No comments or questions.

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

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

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**LENVIMA** **Steven Kheloussi**
(lenvatinib)

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**Updated indication:** Lenvima is now indicated in combination with everolimus for the treatment of patients with advanced renal cell carcinoma following one prior anti-angiogenic therapy.

Previously Lenvima was only indicated for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer.

**Current Formulary Status:**
- GHP Family- Brand, PA, QL (3 per day)

**Recommendation:** The following additional criteria should apply:

For RCC:
- Prescription written by an oncologist **AND**
- Medical record documentation of use in combination with Afinitor (everolimus) for surgically unresectable advanced or metastatic renal cell carcinoma with predominant clear-cell histology **AND**
- Medical record documentation of a therapeutic failure on or intolerance to prior anti-angiogenic therapy, including, but not limited to, Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), Afinitor (everolimus), or Torisel (temsirolimus) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Opdivo or Cabometyx

**The quantity limits and authorization duration for all LOB should remain unchanged.**

**Discussion**: It was recommended that the policy be further clarified to indicate failure on one prior anti-angiogenic therapy. The recommendation regarding failure of Opdivo or Cabometyx was based on the following rationale: Cabometyx is a one tablet a day, once daily regimen, as an infusion Opdivo may improve adherence, the combination of Lenvima and Afinitor will incur two specialty copays which may

decrease adherence, and NCCN recommends this combination as category 2A vs. Opdivo and Cabometyx. It was decided at this time to remove this criteria until we are able to consult with system oncologists for their opinion. No other questions or comments.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as amended. Kimberly 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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**OPDIVO** **Steven Kheloussi**
(nivolumab)

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**New Indication:** Opdivo as a single agent is now indicated for the treatment of patients with:

- BRAF V600 wild-type unresectable or metastatic melanoma
  - Previously indicated in combination with ipilimumab, for the treatment of patients with BRAF V600 wild-type unresectable or metastatic melanoma
- BRAF V600 mutation-positive unresectable or metastatic melanoma
  - Previously indicated as a single agent unresectable or metastatic melanoma and disease progression following ipilimumab and if BRAF V600 mutation-positive, a BRAF inhibitor.

Opdivo is now indicated in combination with ipilimumab for the treatment of patients with unresectable or metastatic melanoma.

Opdivo is now indicated for the treatment of patients with classical Hodgkin lymphoma (CHL) that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation brentuximab vedotin.

- This is a new indication that was approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

**Current Formulary Status:**

- GHP Family- NF (medical benefit requiring prior authorization)

**Recommendation:** For the Opdivo medical benefit policy (MBP 126.0) the following additional criteria should apply:

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of classical Hodgkin lymphoma (CHL) that has relapsed or progressed after autologous hematopoietic stem cell transplantation and post-transplantation brentuximab vedotin (Adcetris)

Note – current criteria do not need to be changed to reflect the updated metastatic melanoma indication.

**Discussion**: No questions or comments.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

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

**FANAPT** (iloperidone) **Kimberly Clark**

**Updated indication:** Fanapt is indicated for the treatment of schizophrenia in adults.

Package insert has been updated to include clinical trials supporting long term therapy.

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

- GHP Family- non-formulary requiring prior authorization:
  - There is medical record documentation of a diagnosis of schizophrenia **AND**
  - There is medical record documentation of a contraindication, intolerance or therapeutic failure to all formulary agents (risperidone, olanzapine, quetiapine, aripiprazole and ziprasidone)

**Recommendation:** No changes to existing formulary status or prior authorization criteria are recommended at this time.

**Discussion**: No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Lisa Mazonkey 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.

**CLASS REVIEW:**

**PULMONARY ARTERIAL HYPERTENSION** **Steven Kheloussi**

Steven Kheloussi presented a class review of the agents used to treat pulmonary arterial hypertension to the committee. The review included the following agents:

| Brand | Generic name | Generically Available | Formulation | Available Strengths | Benefit | FDA Approval Date |
|---|---|---|---|---|---|---|
| **Prostacyclin Receptor Agonist** | | | | | | |
| Uptravi | selexipag | N | Oral Tablet | 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, 1600 mcg | Pharmacy | 12/21/2015 |
| **Prostanoids** | | | | | | |
| Orenitram | treprostinil | N | Oral Tablet | 0.125 mg, 0.25 mg, 1 mg, 2.5 mg | Pharmacy | 12/20/2013 |
| Remodulin | treprostinil | N | Injection Solution | 1 mg/mL, 2.5 mg/mL, 5 mg/mL, 10 mg/mL | Rx/Medical | 5/21/2002 |
| Tyvaso | treprostinil | N | Inhalation Solution | 0.6 mg/mL | Pharmacy | 7/30/2009 |
| Flolan | epoprostenol | Y | IV Solution | 0.5 mg, 1.5 mg | Medical | 9/20/1995 |
| Veletri | epoprostenol | Y | IV Solution | 0.5 mg, 1.5 mg | Medical | 6/27/2008 |
| Ventavis | iloprost | N | Inhalation Solution | 10 mcg/mL, 20 mcg/mL | Pharmacy | 12/29/2004 |
| **Soluble guanylate cyclase stimulator** | | | | | | |
| Adempas | riociguat | N | Oral Tablet | 0.5 mg, 1 mg, 1.5 mg, 2 mg, and 2.5 mg tablets | Pharmacy | 10/8/2013 |
| **Endothelin receptor antagonists** | | | | | | |
| Opsumit | macitentan | N | Oral Tablet | 10 mg tablets | Pharmacy | 10/18/2013 |
| Letairis | ambrisentan | N | Oral Tablet | 5 mg, 10 mg tablets | Pharmacy | 6/15/2007 |
| Tracleer | bosentan | N | Oral Tablet | 62.5 mg, 125 mg tablets | Pharmacy | 11/20/2001 |
| **PDE-5 inhibitors** | | | | | | |
| Adcirca | tadalafil | N | Oral Tablet | 20 mg tablets | Pharmacy | 5/22/2009 |
| Revatio | sildenafil | Y | Oral Tablet | 20 mg tablets | Pharmacy | 6/3/2005 |
| Revatio | sildenafil | N | Oral Solution | 10 mg/mL solution | Pharmacy | 11/18/2009 |
| Revatio | sildenafil | Y | IV Solution | 10 mg/12.5 mL | Medical | 8/30/2012 |

**Current Formulary Status**

| | GHP Family |
|---|---|
| **Preferred Generic** | |
| **Generic** | sildenafil*^ |
| **Brand Preferred** | Letairis*^, Tracleer*^ |
| **Brand Non-Preferred** | |
| **Specialty** | |
| **Medical** | Remodulin*, Epoprostenol, Flolan*, Veletri* |

*Prior authorization required, ^Quantity limits apply

**Specialist Feedback:** Dr. Mohammed Mogri and Dr. Debabrata Bandyopadhyay from GHS Pulmonology report the following:

- ERAs of choice
  - Tracleer has fallen out of favor compared to the newer ERAs because it is twice daily (while Opsumit and Letairis are both once daily). Further, Tracleer can cause liver toxicity, requiring serial LFTs while on therapy.
    - This is echoed by the guidelines[2] that state: "Increases in hepatic aminotransferases occurred in approximately 10% of the patients [in the clinical trials] and were found to be dose dependent and reversible after dose reduction or discontinuation. For these reasons liver function testing should be performed monthly in patients receiving bosentan." It is also stated, "The incidence of abnormal LFTs ranges from 0.8 to 3% for Letairis. Monthly liver function assessment is not mandated in the USA."
    - The guidelines[2] also report Opsumit has not shown liver toxicity, but reduction in hemoglobin to levels $\leq$8 g/dL were observed in 4.3% of patients receiving 10 mg of macitentan.
- Switching agents
  - "Switching from one agent to another may be indicated in certain patients especially if they develop side effects to a certain class of drug or are unable to use IV for some reason. Switch is usually not done from one oral to another to increase efficacy."
- CTEPH (Chronic Thromboembolic Pulmonary Hypertension [WHO Group 4 PAH])
  - "Adempas is the only drug studied and the FDA approved for this condition. This should be first line for treatment unless the patient is on nitrates."
    - Adempas is contraindicated with nitrates or nitric oxide donors (e.g., amyl nitrite) in any form. It is also contraindicated with coadministration of PDE inhibitors, including PDE-5 inhibitors or nonspecific PDE inhibitors (e.g., dipyridamole or theophylline).
    - Tracleer has also been studied in CTEPH, but has not shown any beneficial outcomes.[2]

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**Proposed Clinical Recommendations:**

**Sildenafil** – Recommend removing the following bullet point for GHP Family:

- Medical record documentation that sildenafil will not be prescribed in combination with Tracleer (bosentan)

- Evidence is mixed on the combination of sildenafil and Tracleer. One clinical trial found significantly improved hemodynamic parameters and improved functional status,[3] while another found improved 6MWD with the combination, but no improvement in overall survival.[4] An uncited study in the manufacturer labeling states that a randomized, double-blind, placebo controlled study in 103 patients examined the effect of the combination on 6MWD at 12 weeks and found no significant difference in mean change from baseline between the combination and bosentan alone.[5]

- **Rationale**
  - Other criteria are all up to date as sildenafil is an appropriate first line agent and there are numerous options for combination therapy which include sildenafil.

**Tracleer** –

- GHP Family
  - The following bullet point should be removed from the policy: Medical record documentation that Tracleer will not be used in combination with sildenafil
  - The following bullet point should be added to the policy: Prescription written by a cardiologist or a pulmonologist.
- **Rationale**
  - Appropriate first line agent (IA recommendation)
  - A number of other agents have evidence when added on to Bosentan
    - Adempas added on (IB); Uptravi added on (to any ERA or any PDE5 inhibitor) (IB); Tyvaso or Ventavis added on (IIa B); Adcirca added on (IIa C).
  - Should be considered for several initial combination therapies
    - Tracleer (or Opsumit) + PDE5 inhibitor (IIa C); Tracleer + IV epoprostenol +/- sildenafil (IIa C)

**Letairis**

- GHP Family – no changes necessary
- **Rationale**
  - Appropriate first line agent (IA recommendation)
  - But limited/no data for combination therapy with Letairis
    - Adding Letairis or adding to Letairis would fall under “Other double combinations” or “Other triple combinations”, both IIb C recommendations).
    - The only exceptions include:
      - Letairis added to sildenafil (IIb C, same quality recommendation as Tracleer added to sildenafil); and
      - When Uptravi is added to Letairis (IB recommendation), but the latter goes for any ERA and/or any PDE-5 inhibitor.
  - With limited options as second line therapy, better to start with sildenafil and consider Letairis as a second line option.
  - Appropriate first line combination with Adcirca (IB recommendation for FC II and III)

**Opsumit**

- GHP Family – The following bullet point should be removed:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Letairis*
    - A quantity limit of 30/30 should apply.
- **Rationale**
    - Not appropriate as first line therapy (IB recommendation vs other IAs)
    - But the best recommendation of all the ERAs (IB vs IIb Cs) for second line combo therapy added to sildenafil
    - No evidence to suggest Tracleer or Letairis over Opsumit in the second line setting
    - Better strength recommendation as second line combination therapy with sildenafil compared with first line combination therapy with PDE-5 inhibitor (IB vs IIa C)

**Adcirca** –

- No changes for GHP Family.
- **Rationale**
    - Not really appropriate as first line therapy (IB recommendation vs other IAs)
    - Appropriate first line combination with Letairis (IB recommendation for FC II and III)
    - Appropriate second line therapy
        - When Uptravi is added on to Adcirca
        - When Adcirca is added on to Tracleer
    - Recommended against in combination with Adempas (contraindication)

**Adempas** – Sildenafil should be removed as a formulary alternative for PAH (once patients are started on a medication for PAH, it's rare that they are taken off of it). There are also no suitable alternatives for CTEPH.

- GHP Family – Current criteria should be replaced with:
    - Prescription written by a cardiologist or a pulmonologist
    - Medical record documentation of a baseline 6-minute walking distance AND
    - Medical record documentation of WHO functional class II, III, or IV symptoms AND

      **AND**
    - Medical record documentation of a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4), which is inoperable or previously treated surgically.

      **OR**
    - All of the following:
        - Medical record documentation of a diagnosis of WHO Group I pulmonary arterial hypertension
        - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to, or use in combination with Tracleer*
- **Rationale**

- Not really appropriate as first line therapy (IB recommendation vs other IAs)
- But good recommendation (IB) for second line combo therapy added to Tracleer
  - No recommendation for use in combination with other ERAs
- Recommended against in combination added to sildenafil (contraindication)
- Only appropriate agent for CTEPH.
- Not recommended in initial combination therapy
- Ventavis – failure on Tracleer +/- sildenafil
  - Not really appropriate as first line therapy (IB recommendation vs other IAs)
  - Decent recommendation (IIb B) for second line combo therapy added to Tracleer
  - Not recommended for initial combination therapy

**Tyvaso**

- GHP Family – the diagnosis criteria for all LOB should be replaced with:
  - Medical record documentation of a diagnosis of functional class III or IV pulmonary arterial hypertension
- GHP Family – the formulary alternatives bullet points for all LOB should be replaced with:
  - Medical record documentation of a therapeutic failure on, intolerance to, contraindication to or use in combination with sildenafil or Tracleer.
- **Rationale**
  - Not really appropriate as first line therapy (IB recommendation vs other IAs)
  - Decent recommendation (IIb B) for second line combo therapy added to Tracleer or sildenafil
  - Remove QL from Exchange to align our formulary
  - Tyvaso is dosed four times daily, with each 2.9 mL ampule containing "a sufficient volume of medication for all 4 treatment sessions in a single day."

**Remodulin** –

- GHP Family – the formulary alternatives bullet points for all LOB should be replaced with:
  - Medical record documentation of use in combination with, or failure on, intolerance to, contraindication to, or use in combination with sildenafil* **AND** an appropriate second line agent (an endothelin receptor antagonist or Uptravi) used with sildenafil
- Medical policy – Current medical policy language is inaccurate and should be replaced with the following language:
  - Prescription is written by a pulmonologist or cardiologist **AND**
  - Medical record documentation that Remodulin is being administered subcutaneously **AND**
  - Medical record documentation of a diagnosis of functional class II, III, or IV pulmonary arterial hypertension **AND**

- Medical record documentation of use in combination with, or failure on, intolerance to, contraindication to, or use in combination with sildenafil* **AND** an appropriate second line agent (an endothelin receptor antagonist or Uptravi) used with sildenafil

- **Rationale**
  - Not really appropriate as first line therapy (IB (SC) or IIa C (IV) vs other IAs)
  - No data for combination therapy with Remodulin (Adding Remodulin or adding to Remodulin would fall under "Other double combinations" or "Other triple combinations", both IIb C recommendations).
  - Can consider initial combination therapy with Remodulin + ERA or PDE5 inhibitor, but this is the lowest recommendation for initial combination therapy (IIb C)

**Orenitram** – Diagnosis of FC II-IV PAH and failure on, intolerance to, contraindication to Uptravi.

- It is recommended the following criteria be added for GHP Family:
  - Medical record documentation of a therapeutic failure on, intolerance to, contraindication to Uptravi.
- **Rationale**
  - Not appropriate as first line therapy (IIb B vs other IAs)
  - No supporting data for use in initial or sequential combination therapy
  - Opsumit added on to PDE5 inhibitor + ERA showed no additional benefit FREEDOM[6]
    - Current policy does not require failure on any medications as there is no clinical benefit seen if patients are treated with background therapy with the remaining two classes of medications. Uptravi offers a similar MOA with stronger clinical evidence.

**Epoprostenol**

- Medical Policy – It is recommended the following updates be made to the existing language:
  - Medical record documentation of a diagnosis of class II or III pulmonary arterial hypertension with a therapeutic failure on, intolerance to, or contraindication to sildenafil* (generic Revatio) ~~and Ventavis*~~
- **Rationale**
  - Technically indicated for PAH, Group 1. No specific functional classes called out.
  - Not recommended as first line monotherapy, first line combination therapy, or in sequential combination therapy for FC II.
  - Appropriate first line agent for FC III, only IA recommendation for FC IV.
  - Appropriate for initial combination therapy with Tracleer +/- sildenafil (IIa C)
  - Several appropriate options for sequential combination therapy:
    - With sildenafil added on (IB for FC III, IIa B for FC IV).
    - With Tracleer added on (IIb C)

**Uptravi** – Criteria based on current recommendations, need to add a QL

- Criteria are current – policy created in May 2016
- Recommend adding a QL for GHP Family – 60/30

**Clinical Discussion:** Disease state background, treatment guidelines, and specialist feedback were discussed. No comments or questions.

**Clinical Outcome:** Kimberly Clark made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

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**Proposed Financial Recommendations:** No additional recommendations.

**Financial Discussion:** No comments or questions.

**Financial Outcome:** Kim Clark made a motion to accept the recommendations as written. ? 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.

**POLICY UPDATES:**

**MEDICAL BENEFIT POLICY UPDATES** **Tricia Heitzman**

**MBP 115.0 Cyramza (ramucirumab)**

Cyramza (ramucirumab) is a vascular endothelial growth factor receptor 2 (VEGFR2) antagonist that specifically binds VEGF Receptor 2 and blocks binding of VEGFR ligands. Based on changes to NCCN Guidelines, and DHS recommendations the following changes were made to the policy for the indication of 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** ~~clinical justification~~ for use as monotherapy **AND**
  - ~~Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; **AND**~~
  - Absence of Grade 3 or higher gastrointestinal bleeding within the past three months; **AND**
  - Absence of arterial thromboembolic event, including myocardial infarction, unstable angina, transient ischemic attack (TIA) or cerebrovascular accident (CVA), within the past six months

**MBP 83.0 Lumizyme® (alglucosidase alfa)**

Lumizyme® (alglucosidase alfa) is a lysosomal glycogen-specific enzyme indicated for patients with Pompe disease [acid alpha-glucosidase (GAA) deficiency]. Lumizyme® (alglucosidase alfa) provides an exogenous source of GAA allowing conversion of glycogen to energy in heart and muscle cells. Based on DHS recommendations and changes to accepted industry standards for diagnostic testing, as confirmed by Dr. Priya Kishnani the use of dried blood spots in GAA assay testing will be acceptable. Updated criteria are listed below:

- Physician provided documentation of a diagnosis of late-onset (non-infantile) Pompe disease **OR** a diagnosis of infantile-onset Pompe disease supported by:
  - GAA assay performed on dried blood spots, skin fibroblasts or muscle biopsy; **and**
  - Baseline pulmonary function testing (PFT) and muscle strength evaluation; **and**
  - For late-onset Pompe disease only – Genetic testing to identify the specific mutation to confirm the diagnosis of late-onset Pompe disease; **and**
- Physician provided documentation of a consultation with a metabolic specialist and/or biochemical geneticist; and
- Dosing calculation is based on the "Devine formula" which is defined as:
  Men: Ideal Body Weight (in kilograms) = 50 + 2.3 kg per inch over 5 feet.
  Women: Ideal Body Weight (in kilograms) = 45.5 + 2.3 kg per inch over 5 feet.

**MBP 92.0 Off-label Drug Use for Oncologic Indications**

The following changes were made to MBP 92.0 Off-label Drug Use for Oncologic Indications:

Off-label drug use for an oncologic indication is considered to be medically necessary when **all** of the following criteria are met:

1. The drug has been approved by the FDA for at least one indication; **AND**
2. The drug is being prescribed to treat a condition not listed in the product labeling, but for which treatment is medically necessary; **AND**
3. Conventional therapies have been tried and failed, are contraindicated, or do not exist; **AND**

4. The proposed drug use is supported by any one or more of the following:
   - The National Comprehensive Cancer Network Practice Guidelines™ in Oncology category 1 or 2A recommendation; **OR**
   - The National Comprehensive Cancer Network Drug & Biologics Compendium™ category of Evidence and consensus 1 or 2A; **OR**
   - The American Hospital Formulary Service – Drug Information; **OR**
   - Thompson Micromedex DrugDex Compendium (DrugDex®) class I or IIa indication; or
   - Elsevier Gold Standard's Clinical Pharmacology Compendium (Clinical Pharmacology®); ~~**AND**~~

5. ~~Two articles from scientific or medical peer-reviewed journals (excluding case reports, letters, posters or abstracts) which support the proposed off-label use as being effective.~~

~~**LIMITATION:**~~
~~This policy does not address drugs or biologics covered under a pharmacy benefit.~~

**MBP 54.0 Soliris® (eculizumab)**

Soliris® (eculizumab) is approved by the FDA for the treatment of paroxysmal nocturnal hemoglobinuria (PNH). Soliris® works by blocking a part of the immune system called complement. By blocking complement, Soliris® reduces the destruction of red blood cells and improves the symptoms of PNH. The following changes to the Soliris policy are reflective of the 2013 DHS Readiness Review:

**CRITERIA FOR USE: <u>Requires prior Authorization by a Medical Director or Designee</u>**

1. Soliris® is indicated for the reduction of hemolysis in the treatment of paroxysmal nocturnal hemoglobinuria (PNH) when all of the following criteria are met:

- Physician provided documentation of flow cytometry confirming diagnosis AND
- Physician provided documentation of Soliris being prescribed by a hematologist AND
- Physician provided documentation of failure on, contraindication to or intolerance to one corticosteroid (e.g., prednisone), ~~prednisone~~ and one androgenic hormone~~s~~ ~~such as~~ (e.g., Danazol) AND
- ~~Physician provided documentation of the insured individual not being a candidate for stem cell transplantation~~
- Physician provided documentation of the insured individual being vaccinated with the meningococcal vaccine AND
- ~~Physician provided documentation of the insured individual having persistent hemolysis that requires transfusions at least every 2 weeks to maintain a Hgb of at least 9 AND there is a significant adverse impact on the insured individual's health related to these transfusions (i.e. development of red cell antibodies, dystonias)~~
- Physician documentation of one of the following:
  - member is transfusion-dependent (i.e., has at least 1 transfusion in the 24 months prior to initiation of eculizumab due to documented hemoglobin less than 7 g/dL in persons without anemic symptoms or less than 9 g/dL in persons with symptoms from anemia) prior to initiation of eculizumab treatment; **or**
  - there is a significant adverse impact on the insured individual's health such as end organ damage or thrombosis without other cause.

**MBP 65.0 Torisel™ (temsirolimus)**

Torisel™ (temsirolimus) is an mTOR kinase inhibitor. It is metabolized to sirolimus and suppresses the production of proteins that control progression through cell cycle and angiogenesis. Torisel is indicated for the treatment of advanced renal cell carcinoma. A limitation existed on the old policy that stated that "Geisinger Health Plan considers conditions other than those listed under Indications to be Experimental, Investigational or Unproven and NOT Medically Necessary". Since it is GHP standard of practice to utilize and accept indications recommended in industry compendia such as NCCN Guidelines, which may not be listed in this policy the language of the limitation was removed from the policy.

**MBP 85.0 Cinryze™ (C1 esterase inhibitor, human)**

Cinryze™ is a C1 Esterase Inhibitor indicated for routine prophylaxis against angioedema attacks in adult and adolescent patients with Hereditary Angioedema. To better align with our current policies for acute treatment, a history of laryngeal attacks was added to the criteria assessing severity in the policy criteria. Criteria were updated as follows:

- Member is 13 years of age or older; and
- Prescription is written by an allergist, immunologist, hematologist or dermatologist; and
- Medication is being used as prophylactic therapy for HAE attacks; and
- Diagnosis of hereditary angioedema has been established and supported by physician provided documentation of:
    - Recurrent, self-limiting non-inflammatory subcutaneous angioedema without urticaria , lasting more than 12 hours; or
    - Laryngeal edema; or
    - Recurrent, self-remitting abdominal pain lasting more than 6 hours, without clear organic etiology

AND

- the presence of specific abnormalities in complement proteins, in the setting of a suggestive clinical history of episodic angioedema without urticaria; supported by
    - Medical record documentation of 2 or more sets of complement studies, separated by one month or more, showing consistent results of
        - Low C4 levels and
        - Less than 50% of the lower limit of normal C1-INH antigenic protein levels OR
        - Less than 50% of the lower limit of normal C1-INH function levels

AND

- Physician provided documentation of failure on, intolerance to, or contraindication to danazol; AND
- Physician provided documentation of history of more than one (1) severe event per month OR a history of laryngeal attacks

**MBP 51.0 Vivitrol® (naltrexone) injectable- Prior Authorization Removed**

Vivitrol® (naltrexone) is FDA approved for the treatment of alcohol dependence in insured individuals who are able to abstain from alcohol in the outpatient setting prior to initiation of treatment with Vivitrol®. Vivitrol is also indicated for the prevention of relapse to opioid dependence, following opioid detoxification. Based on the high number of appealed and overturned cases, often due to not receiving sufficient information on the initial request, and the low risk of abuse as compared to other therapeutic alternatives, it was recommended that the Prior Authorization requirement for Vivitrol be removed and the policy retired.

**Discussion**: No comments or questions.

**Outcome:** Lisa Mazonkey made a motion to accept the recommendations as modified. 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.

**ALOXI** **Tricia Heitzman**
(palonosetron)

**Indication:** Aloxi is a selective 5-HT3 receptor antagonist, blocking serotonin, both on vagal nerve terminals in the periphery and centrally in the chemoreceptor trigger zone. It is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses in patients treated with moderately emetogenic cancer chemotherapy in adults; prevention of acute nausea and vomiting associated with initial and repeat courses in patients treated with highly emetogenic cancer chemotherapy in adults; prevention of acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy (including highly emetogenic chemotherapy) in pediatric patients 1 month to younger than 17 years.

**Current Prior Authorization Criteria:**

- Medical record documentation that Aloxi is being used for prevention of chemotherapy induced nausea or vomiting from low, minimally, or moderately emetogenic cancer chemotherapy for members who have a treatment failure or contraindication to Granisetron (Kytril) or Ondansetron (Zofran). Treatment failure is defined as an allergy, intolerable side effects, significant drug-drug interactions, or lack of efficacy; **OR**
- Medical record documentation that Aloxi is being used for prevention of acute nausea or vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy.

**Guideline Recommendations:** The following recommendations for treatment of moderately emetogenic intravenous cancer chemotherapy list palonosetron as the preferred 5-HT3 receptor antagonist:

MODERATE EMETIC RISK INTRAVENOUS CHEMOTHERAPY - ACUTE AND DELAYED EMESIS PREVENTION[f,g]

| DAY 1: Select option A, B, or C (order does not imply preference)<br>Start before chemotherapy:[h] | DAYS 2 and 3: |
|---|---|
| A:<br>Serotonin (5-HT3) antagonist + steroid (category 1) ± NK1 antagonist[i,j] (netupitant, see option B)<br>• Serotonin (5-HT3) antagonist (Select one):[j]<br>‣ Dolasetron 100 mg PO once<br>‣ Granisetron 2 mg PO once, or 0.01 mg/kg (max 1 mg) IV once, or 3.1 mg/24-h transdermal patch applied 24–48 h prior to first dose of chemotherapy<br>‣ Ondansetron 16–24 mg PO once or 8–16 mg IV once<br>‣ Palonosetron 0.25 mg IV once (preferred)<br>AND<br>• Steroid[j]<br>‣ Dexamethasone 12 mg[m] PO/IV once<br>WITH/WITHOUT<br>• NK1 antagonist: [j,r]<br>‣ Aprepitant 125 mg PO once<br>‣ Fosaprepitant 150 mg IV once<br>‣ Rolapitant 180 mg PO once[s] (category 1) | A:<br>If no NK1 antagonist given on day 1:<br>• Serotonin (5-HT3) antagonist monotherapy [j,t] (Select one):<br>‣ Dolasetron 100 mg PO daily on days 2, 3<br>‣ Granisetron 1–2 mg PO daily or 1 mg PO BID or 0.01 mg/kg (maximum 1 mg) IV daily on days 2, 3<br>‣ Ondansetron 8 mg PO BID or 16 mg PO daily or 8–16 mg IV daily on days 2, 3<br>OR<br>• Steroid monotherapy[j]:<br>‣ Dexamethasone 8 mg[m] PO/IV daily on days 2, 3<br>If NK1 antagonist given on day 1:<br>• If aprepitant given day 1, then<br>‣ Aprepitant 80 mg PO daily on days 2, 3 ± dexamethasone 8 mg PO/IV daily on days 2, 3<br>• If fosaprepitant given day 1, then<br>‣ No further NK1 antagonist is needed on days 2, 3 ± dexamethasone on days 2, 3<br>• If rolapitant given day 1, then<br>‣ No further NK1 antagonist is needed on days 2, 3 ± dexamethasone on days 2, 3 |
| B:<br>Netupitant-containing regimen:[i,j,n]<br>‣ Netupitant 300 mg/palonosetron 0.5 mg PO once[r]<br>‣ Dexamethasone 12 mg[m] PO/IV once | B:<br>‣ ± Dexamethasone 8 mg[m] PO/IV daily on days 2, 3 |
| C:<br>Olanzapine-containing regimen:[i,j,p]<br>‣ Olanzapine 10 mg PO<br>‣ Palonosetron 0.25 mg IV once<br>‣ Dexamethasone 20 mg[m] IV once | C:<br>‣ Olanzapine 10 mg PO daily days 2, 3 |

**Recommendations:** To align with current FDA indications as well as NCCN Guidelines it is recommended to remove the requirement for failure of therapeutic alternatives prior to receiving palonosetron in patients receiving Moderately Emetogenic chemotherapy. The following policy changes are recommended:

**PREVENTION OF ACUTE NAUSEA AND VOMITING**

- Medical record documentation that Aloxi is being used for prevention of chemotherapy induced nausea or vomiting from low, or minimally, ~~or moderately~~ emetogenic cancer chemotherapy for members who have a treatment failure or contraindication to Granisetron (Kytril) or Ondansetron (Zofran). Treatment failure is defined as an allergy, intolerable side effects, significant drug-drug interactions, or lack of efficacy; **OR**
- Medical record documentation that Aloxi is being used for prevention of acute nausea or vomiting associated with initial and repeat courses of moderately or highly emetogenic cancer chemotherapy.

The following antineoplastic agents are considered MODERATELY emetogenic (not a complete list):

- Aldesleukin >12-15 million IU/$m^2$
- Amifostine >300 mg/$m^2$
- Arsenic trioxide
- Azacitidine
- Bendamustine
- Busulfan
- Carboplatin
- Carmustine $\leq$ 250 mg/$m^2$
- Clofarabine
- Cyclophosphamide $\leq$ 1500mg/$m^2$
- Cytarabine >200mg/$m^2$
- Dactinomycin
- Daunorubicin
- Dinutuximab
- Doxorubicin <60 mg/$m^2$
- Epirubicin $\leq$ 90 mg/$m^2$
- Idarubicin
- Ifosfamide <2 g/$m^2$ per dose
- Interferon alfa $\geq$ 10 million IU/$m^2$
- Irinotecan
- Melphalan
- Methotrexate $\geq$250 mg/$m^2$
- Oxaliplatin
- Temozolomide
- Trabectedin

The following antineoplastic agents are considered HIGHLY emetogenic (not a complete list):

- AC combination defined as either doxorubicin or epirubicin with cyclophosphamide
- Carmustine at doses >250mg/$m^2$
- Cisplatin
- Cyclophosphamide at doses >1500 mg/$m^2$
- Dacarbazine
- Doxorubicin at doses $\geq$ 60mg/$m^2$
- Epirubicin at doses >90mg/$m^2$
- Ifosfamide at doses $\geq$2g/$m^2$
- Mechlorethamine
- Streptozotocin

**Discussion**: No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Lisa Mazonkey 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.

**PCSK9 INHIBITORS** **Steven Kheloussi**

The GHP Family General PCSK9 Inhibitors policy (1304.0F) should be updated to the following:

**ADDITIONAL DEFINITIONS:**

1. ***Formulary*** – a continually updated list of prescription medications that represents the current covered drugs under the Plan.
2. ***Non-formulary products*** – those medications that are not included in the Formulary.
3. ***Healthcare provider*** – a person who is licensed, certified or otherwise regulated to provide health care services under the laws of the Commonwealth of Pennsylvania (i.e., physician, physician's assistant, certified registered nurse practitioner).
4. ***NCQA*** – National Committee for Quality Assurance.
5. ***Medically Necessary or Medical Necessity*** – covered services rendered by a provider that the Health Plan determines are:
   A. Appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
   B. Provided for the diagnosis, or the direct care and treatment of the Member's condition, illness, disease or injury;
   C. In accordance with current standards of medical practice;
   D. Not primarily for the convenience of the Member, or the Member's Provider; and
   E. The most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.
6. Therapeutic failure to statins, Zetia, fibrates, and/or bile acid sequestrants – inability to reach target LDL goals (<100 mg/dL for primary prevention in HeFH or HoFH or <70 mg/dL for ASCVD or secondary prevention in HeFH or HoFH) despite a ≥ 3 month trial with the patient taking ≥ 90% of the prescribed doses.
7. Intolerance to statins – increased LFT's, intolerable myalgia (muscle symptoms without creatinine kinase [CK] elevations) or myopathy (muscle symptoms with CK elevations), or myositis (elevations in CK without muscle symptoms), which persists after two retrials with a different dose or different dosing strategy (i.e. every other day administration) of alternative moderate- or high-intensity statin.
8. Contraindication to statins – active liver disease, previous history of rhabdomyolysis, or hypersensitivity

**PROCEDURE:**

An exception for coverage of PCSK9 Inhibitors may be made for members who meet the following criteria:

- Medical record documentation of use for an FDA approved indication (based on FDA approved indications)
  - If indicated and being used for homozygous familial hypercholesterolemia:
    - Medical record documentation of genetic testing showing at least one LDL receptor-defective mutation **OR**
    - Diagnosis made based on a history of an untreated LDL-C > 500 mg/dL AND either xanthoma before 10 years of age OR evidence of HeFH in both parents **OR**
  - If indicated and being used for heterozygous familial hypercholesterolemia (HeFH):

        - Genetic testing to confirm a mutation in the LDL receptor, PCSK9, or ApoB gene **OR**
        - Medical record documentation of definite HeFH (score ≥ 8) on the diagnostic criteria scoring system (Table 1) as defined by the ESC/EAS guidelines and the World Health Organization (WHO) **OR**
    - If indicated, medical record documentation of a diagnosis clinical atherosclerotic cardiovascular disease, including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **AND**
- Prescription must be written by a cardiologist or lipidologist **AND**
- Medical record documentation of a baseline LDL drawn within 3 months of the start of PCSK9 therapy showing:
    - LDL > 100 if the patient has a diagnosis of HeFH or HoFH and is using the requested agent for primary prevention OR
    - LDL > 70 if the patient has a diagnosis of ASCVD or either HeFH or HoFH and is using the requested agent for secondary prevention **AND**
- Medical record documentation that the patient is ≥ 18 years of age (based on FDA approved age) **AND**
- One of the following:
    - Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) high-intensity statin therapy with atorvastatin 40 mg or 80 mg or rosuvastatin 20 mg or 40 mg, or the highest tolerable dose AND **OR**
    - Medical record documentation of intolerance to atorvastatin **AND** rosuvastatin **AND** current use or intolerance to a lower dose of rosuvastatin or atorvastatin or an alternative statin **OR**
    - Medical record documentation of a contraindication to statin therapy **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to either a bile acid sequestrant or fibrate or medical record documentation of an LDL ≥ 100 **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Zetia **AND**
- Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies **AND**
- Medical record documentation of an inability to achieve and maintain an LDL cholesterol level at or below goal (< 100 mg/dL for primary prevention in HeFH or HoFH or < 70 mg/dL for ASCVD or secondary prevention in HeFH or HoFH) with diet, exercise, and at least 12 weeks of combination therapy of statin with Zetia and either a bile acid sequestrant or fibrate if appropriate with the patient taking ≥ 90% of the prescribed doses of each medication **AND**
- Medical record documentation of a therapeutic failure on Repatha AND Praluent **AND**
- Medical record documentation that the requested medication is not being used in combination with another PCSK9 inhibitor, Juxtapid, or Kynamro

***NOTE:** Adherence calculations must be supported by claims data or physician attestation if no claims history is available (i.e., if the patient is new to the plan or did not use insurance for their statin prescriptions).

**QUANTITY LIMIT:** based on FDA approved dosing

**AUTHORIZATION DURATION:** Initial authorizations for PCSK9 Inhibitors will be approved for a period of 6 months. Reauthorizations will be for a period of 12 months each provided the following criteria are met:

- Medical record documentation of an up to date LDL cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor **AND**
- Medical record documentation that the patient is not experiencing any significant adverse events related to therapy **AND**
- Claims history and attestation from the provider showing the patient is adherent to PCSK9 therapy **AND**
- Claims history or attestation from the provider that the patient is staying adherent to (filling at least 90% of doses) statin therapy **AND**
- Medical record documentation that the requested agent continues to not be used in combination with another PCSK9 inhibitor, Juxtapid, or Kynamro.

Table 1. Diagnostic criteria for the clinical diagnosis of HeFH (WHO)

| | Criteria | Score |
|---|---|---|
| **Family history** | First-degree relative known with premature CAD* and/or first-degree relative with LDL-C >95th percentile | 1 |
| | First-degree relative with Tx and/or children <18 with LDL-C >95th centile | 2 |
| **Clinical history** | Patient has premature CAD* | 2 |
| | Patient has premature cerebral/peripheral vascular disease | 1 |
| **Physical examination** | Tx | 6 |
| | Arcus cornealis below the age of 45 years | 4 |
| **LDL-C** | >8.5 mmol/L (more than ~330 mg/dL) | 8 |
| | 6.5-8.4 mmol/L (~250-329 mg/dL) | 5 |
| | 5.0-6.4 mmol/L (~190-249 mg/dL) | 3 |
| | 4.0-4.9 mmol/L (~155-189 mg/dL) | 1 |
| **Definite FH** | | Score >8 |
| **Probable FH** | | Score 6-8 |
| **Possible FH** | | Score 3-5 |
| **No diagnosis** | | Score <3 |

If an exception is made, the requested PCSK9 Inhibitor will be paid for under the member's prescription drug benefit.

Reviewer should refer to the process and procedure in Pharmacy Policy 4.0F (Geisinger Health Plan (GHP) Formulary Exception) for additional information.

**FORMULARY ALTERNATIVES:**
atorvastatin, rosuvastatin, Zetia, cholestyramine, Prevalitge, colestipol, fenofibrate, fenofibric acid, gemfibrozil

**Discussion**: No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

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

## POLICY UPDATES — Kimberly Clark

### SUBOXONE/ZUBSOLV/BUNAVAIL

Renewal authorizations for members receiving a buprenorphine containing product currently occur after the initial 3 months of therapy and then every 6 months from that point forward. The below statistics demonstrate that our overall approval rate of these requests is extremely high, indicating that there may not be great value in such frequent reviews:

Suboxone, buprenorphine/naloxone, and buprenorphine renewal requests: 1/1/16 – 6/20/16

| LOB | Approval Rate | Denial Rate |
|---|---|---|
| GHP Family | 90% | 10% |
| GHP Family | 86% | 14% |
| Geisinger Gold | 96% | 4% |
| **Total** | **89.4%** | **10.6%** |

**Recommendation:** Based on the high percentage of approvals, it is recommended that the renewal authorization duration for all buprenorphine containing products is extended from 6 months to 12 months.

**Discussion:** No comments or questions.

**Outcome:** Steven Kheloussi made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

### OLOPATADINE OPHTHALMIC SOLUTION

Olopatadine 0.1% (generic Patanol) has recently become available as an option for the treatment of allergic conjunctivitis. Other available olopatadine containing products include Pataday 0.2% and Pazeo 0.7%. Olopatadine 0.1% differs from Pataday and Pazeo in that it requires twice daily administration, while Pataday and Pazeo require once daily application.

| Drug | Cost per 30 day supply |
|---|---|
| Olopatadine 0.1% | $40.00 |
| Pataday | $189.84 |
| Pazeo | $179.10 |

**Recommendation:** It is recommended that olopatadine 0.1% ophthalmic solution is added to the GHP Family and Marketplace formulary to provide members with an alternative therapy for the treatment of allergic conjunctivitis.

- GHP Family – generic tier

**Discussion:** No comments or questions.

**Outcome:** Kristen Bender made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

**LINEZOLID**

Zyvox tablets have recently become available generically. Taking into consideration that in many hospital systems the prescribing of linezolid is limited to infectious disease physicians only and the availability of a generic product, it is recommended the generic linezolid tablets are added to all prescription drug formulary with the following limitations:

- GHP Family – generic tier, QL of 2 tablets per day, 28 day supply per fill, maximum of 56 day supply within a 180 window.

The existing prior authorization policy should remain in place for linezolid oral suspension requests. Language should be added to this policy for the review of quantity limit exception requests beyond 8 weeks of therapy in 180 days:

- Medical record documentation of an infectious disease consultation documenting continued need of linezolid therapy

**AUTHORIZATION DURATION:** 28 days

**Discussion:** No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Kristen Bender seconded the motion. None were opposed.

**ABSORICA/AMNESTEEM**

Failure of Amnesteem is required prior to approval of Absorica for GHP Family members, but Amnesteem has recently been discontinued by the manufacturer.

**Recommendation:** It is recommended that the GHP Family Absorica policy (1306.0F) be updated to remove failure of Amnesteem from policy criteria and also from the formulary alternatives. It is also recommended that Amnesteem is removed from the existing GHP Family isotretinoin policy (1305.0F)

**Discussion:** No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

**XELJANZ XR**

A once-daily, extended-release formulation of Xeljanz has recently become available. The extended-release formulary shares the same indication as the non-extended-release formulation.

**Recommendation:** Based on the availability of Xeljanz XR it is recommended that the existing policy is updated to include a quantity limit applicable to this formulation. All other clinical criteria will remain in place for both Xeljanz and Xeljanz XR.

- Quantity limit: 1 tablet per day, 30 day supply per fill

**Discussion:** No comments or questions.

**Outcome:** Steven Kheloussi made a motion to accept the recommendations as written. Lisa Mazonkey seconded the motion. None were opposed.

**AUVI-Q**

In November 2015, all lots of Auvi-Q were voluntarily recalled after it was discovered that the product did not consistently deliver an accurate dose of epinephrine. Further communication has since been received from the manufacturer of Auvi-Q stating that they do not plan to bring Auvi-Q back onto the US drug market.

**Recommendation:** It is recommended that Auvi-Q is removed from the formulary.

**Discussion:** No comments or questions.

**Outcome:** Steven Kheloussi made a motion to accept the recommendations as written. Lisa Mazonkey 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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**STELARA** **Steven Kheloussi**
(ustekinumab)

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**Background:** Stelara is a biologic agent for psoriatic arthritis and plaque psoriasis. It is available in two strengths – 45 mg/0.5 mL and 90 mg/1 mL prefilled syringes.

**Dosing**:

- Plaque psoriasis
  - Patients weighing over 100 kg should receive 90 mg every 12 weeks
  - Patients weighing ≤ 100 kg should receive 45 mg every 12 weeks
- Psoriatic arthritis
  - 45 mg every 12 weeks
  - For patients with co-existent moderate-to-severe plaque psoriasis weighing > 100 kg, the recommended dose is 90 mg every 12 weeks.

**Cost**

| Drug | AWP per mL | AWP per 12 weeks |
|---|---|---|
| Stelara 45 mg/0.5 mL | $21,216.52 | $10,608.26 |
| Stelara 90 mg/1 mL | $21,216.48 | $21,216.48 |

**Recommendation**: The Stelara medical and GHP Family formulary should be updated to include the following:

- For plaque psoriasis:
  - Medical record documentation that the prescribed dosing is appropriate for patient's weight
- For psoriatic arthritis:
  - Medical record documentation that the patient is going to receive a dose of 45 mg every 12 weeks **OR** medical record documentation that the patient has a co-existing diagnosis of moderate-to-severe plaque psoriasis and weighs > 100 kg.

Additionally, approved requests for Stelara should be approved by GPID.

**Discussion:** No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Lisa Mazonkey 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** **Kevin Szczecina**
(ruxolitinib)

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**Background:** Jakafi is a kinase inhibitor that selectively inhibits Janus-associated kinase 1 (JAK1) and JAK2. JAK1 and JAK2 mediate signaling of cytokine and growth factors responsible for hematopoiesis and immune function; JAK-mediated signaling involves recruitment of signal transducers and activators of transcription (STATs) to cytokine receptors, which leads to modulation of gene expression. In myelofibrosis and polycythemia vera, JAK1/2 activity is dysregulated; ruxolitinib modulates the affected JAK1/2 activity.

It is indicated for the treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis and also the treatment of polycythemia vera with an inadequate response to or intolerance to hydroxyurea. There is a different dosing regimen for those with a platelet count of 50 to less than 100 x $10^9$/L. This regimen is missing from Policy 1053.0F. There are also additional factors that can be used to define intermediate or high risk myelofibrosis listed in the DIPSS-Plus prognostic system that are not included in the policies.

**Current Prior Authorization Criteria:**

- Must be prescribed by hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis **AND**
- Medical record documentation of platelet count ≥ 100 x $10^9$/L **AND**
- Medical record documentation of splenomegaly as measured by CT, MRI, or ultrasound **AND**
- Medical record documentation of a baseline Total Symptom Score as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF)

**NOTE:** Intermediate or High Risk Myelofibrosis is defined by having at least 2 of the following factors:

- ✓ Age > 65 years
- ✓ WBC > 25 x $10^9$/L
- ✓ Hemoglobin < 10 g/dL
- ✓ Blood Blasts ≥ 1%
- ✓ Presence of Constitutional Symptoms (weight loss, fever, excessive sweats, etc.)

**AUTHORIZATION DURATION:** Each treatment period will be defined as six (6) months. Re-review with occur every six (6) months. Jakafi** will no longer be covered if medical record documentation does not show:

- ✓ Medical record documentation of platelet count ≥ 50 x $10^9$/L **AND**

- ✓ The member has achieved a reduction from pretreatment baseline of at least 35% in spleen volume as measured by CT, MRI, or ultrasound **OR**
- ✓ The member has achieved a 50% or greater reduction in the Total Symptom Score from baseline as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF)

**Recommendation**: It is recommended that the prior authorization criteria are updated as follows (changes underlined):

- Must be prescribed by hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis **AND**
- Medical record documentation of platelet count ≥ 50 x $10^9$/L **AND**
- Medical record documentation of splenomegaly as measured by CT, MRI, or ultrasound **AND**
- Medical record documentation of a baseline Total Symptom Score as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF)

**NOTE:** Intermediate or High Risk Myelofibrosis is defined by having at least 2 of the following factors:

- ✓ Age > 65 years
- ✓ WBC > 25 x $10^9$/L
- ✓ Hemoglobin < 10 g/dL
- ✓ Blood Blasts ≥ 1%
- ✓ Presence of Constitutional Symptoms (weight loss, fever, excessive sweats, etc.)
- ✓ Transfusion dependency
- ✓ Platelets < 100 x $10^9$/L
- ✓ Unfavorable karyotype

**AUTHORIZATION DURATION:** Each treatment period will be defined as six (6) months. Re-review with occur every six (6) months. Jakafi** will no longer be covered if medical record documentation does **not** show:

- ✓ Medical record documentation of platelet count ≥ 50 x $10^9$/L if baseline count was ≥ 100 x $10^9$/L **OR** platelet count ≥ 25 x $10^9$/L if baseline count was ≥ 50 to < 100 x $10^9$/L **AND**
- ✓ The member has achieved a reduction from pretreatment baseline of at least 35% in spleen volume as measured by CT, MRI, or ultrasound **OR**
- ✓ The member has achieved a 50% or greater reduction in the Total Symptom Score from baseline as measured by the modified Myelofibrosis Symptom Assessment Form (MFSAF)

**Discussion:** No comments or questions.

**Outcome:** Tricia Heitzman made a motion to accept the recommendations as written. Lisa Mazonkey 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.

**INVEGA SUSTENNA** **Steven Kheloussi**
(paliperidone)

**Background:** Invega Sustenna's dosing instructions are as follows:
- One 234 mg injection on Day 1
- One 156 mg injection on Day 8
- Then monthly maintenance doses

Our current quantity limits are one syringe per 28 days.

**Recommendation:** It is recommended that the QL be updated to:
- QL of two syringes for a 1 week authorization, then a QL of 1 syringe per 28 days thereafter.

**Discussion:** Based on the way the authorization must be entered for Invega Sustenna approvals, it is recommended that the quantity limit be operationalized as follows:
- Medical benefit:
    - Rx Count of 1 approved by GPID for 234 mg, QL 1
    - Rx Count of 1 approved by GPID for 156 mg, QL 1
    - Open-ended authorization for QL 1 syringe per month, request to be approved by GPID for the prescribed strength.

**Outcome:** Lisa Mazonkey made a motion to accept the recommendations as amended. 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.

**HEPATITIS C POLICY UPDATES** **Kristi Clarke**

**HARVONI**

**Recommendation:** It is recommended that Harvoni be added to the GHP Family formulary.

**Discussion:** No comments or questions.

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

**VIEKIRA PAK**

**Background:** Recent safety concerns over the use of Viekira in cirrhosis have resulted in a formulary change
- FDA labeling, Warnings and Precautions: Hepatic Decompensation and Hepatic Failure in Patient with Cirrhosis: Hepatic decompensation and hepatic failure, including liver transplantation or fatal outcomes, have been reported mostly in patients with advanced cirrhosis. Monitor for clinical signs and symptoms of hepatic decompensation

**Recommendation:** It is recommended that Viekira Pak be removed from the GHP Family formulary.

**Discussion:** No comments or questions.

**Outcome:** Lisa Mazonkey made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

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

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**Gleevec** **Kevin Szczecina**
(imatinib mesylate)

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**Background:** Gleevec is a tyrosine kinase inhibitor indicated for Acute Lymphoblastic Leukemia, Aggressive Systemic Mastocytosis, Chronic Myeloid Leukemia, Deramtofibrosarcoma Protuberans, Gastrointestinal Stromal Tumors, Hypereosinophilic Syndrome and/or Chronic Eosinophilic Leukemia, and Myleosysplastic/Myeloproliferative Diseases. Included in the GIST indication is that Gleevec can be used for the adjuvant treatment of Kit (CD117) - positive GIST following complete gross resection

**Recommendation:** It is recommended that the indication for the use of Gleevec for adjuvant treatment of Kit (CD117) - positive GIST following complete gross resection be added to the policy.

**Discussion:** No questions or comments

**Outcome:** Kim Clark made a motion to accept the recommendations as presented. Steve Kheloussi 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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**Rebif and Avonex** **Kevin Szczecina**
(interferon beta-1A)

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**Background:** Rebif and Avonex are interferons indicated for the treatment of relapsing forms of multiple sclerosis. However, both policies included criterion for the use in secondary progressive MS with current relapses.

**Recommendation:** It is recommended that this non-FDA approved use be removed from both policies

**Discussion:** No questions or comments

**Outcome:** Kim Clark made a motion to accept the recommendations as presented. Kristen Bender 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.

**GHP Family Formulary Update** **Kevin Szczecina**

**Background:** The following medications have been identified as having high prior authorization approval rates. Recommended changes are noted:

| Medication | Proposed Change |
|---|---|
| aripiprazole | Remove PA requirement for members age 18 years and older |
| Formulary stimulants | Remove PA requirement for members age 22 years and older |

**Recommendation:** In an effort to increase member satisfaction and decrease prior authorization volume it is recommended the above changes be accepted. All other edits and quantity limits will remain in place

**Discussion:** No questions or comments

**Outcome:** Kim Clark made a motion to accept the recommendations as presented. Stephen Kheloussi 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.

**ELECTRONIC VOTES:**

**GILOTRIF** **Kimberly Clark**
(afatinib)

Gilotrif was recently approved for the treatment of patients with metastatic, squamous non-small cell lung cancer (NSCLC) progressing after platinum-based chemotherapy. This new indication was submitted to the P&T committee for electronic vote on 5/20/2016. The vote was approved on 5/26/2016 with 19 committee members voting to approve, 0 committee members opposed.

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

Meeting adjourned at 3:52 pm.

**Future Scheduled Meetings**

September 20, 2016 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.

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