P&T Committee Meeting Minutes
GHP Family
November 21, 2017

Present:	**Absent:**
Bret Yarczower, MD, MBA – Chair	Dean Christian, MD
Jamie Miller, RPh	Perry Meadows, MD
Kristen Bender, Pharm.D – via phone	Beverly Blaisure, MD
Rajneel Chohan Pharm.D.	Keith Boell, DO
Kimberly Clark, Pharm.D.	Jonas Pearson, MS, RPh
Kristi Clarke, Pharm. D. – via phone	Holly Bones, Pharm.D
Patrick Ferguson, RPh, MBA – via phone	Sandra Garrett, RPh, MBA
Tricia Heitzman, Pharm.D.	Steven Moscello, RPh
Jason Howay, Pharm.D. – via phone	
Keith Hunsicker, Pharm.D.	
Phillip Krebs, R.EEG T. – via phone	
Anastasia Mauger Pharm.D.	
Thomas Morland, MD – via phone	
Aubrielle Prater Pharm.D.	
Kristen Scheib, Pharm. D. – via phone	
William Seavey, Pharm.D. – via phone	
Richard Silbert, MD – via phone	
Todd Sponenberg, Pharm.D., RPh	
Kevin Szczecina, RPh	
Michael Spishock RPh – via phone	
Elaine Tino, CRNP – via phone	
Lori Zaleski, RPh – via phone	
Steven Kheloussi, Pharm.D – via phone	
Michael Evans, Pharm.D. B.S. – via phone	
Kenneth Bertka, MD – via phone	
Elizabeth Ray, Pharmacy Student	
Sangjae Jang, Pharmacy Student	

Call To Order:
Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, November 21, 2017.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the September 19, 2017 minutes as written. Keith Hunsicker accepted the motion and Aubrielle Prater seconded the motion. None were opposed.

DRUG REVIEWS

XADAGO (Safinamide)

Review: Xadago is a selective MAO-B inhibitor with dual mechanism of action to also reduce glutamate, indicated to increase the "on" time for Parkinson disease patients taking levodopa. Xadago has a similar mechanism of action to Azilect (rasagiline), except it is reversible with a higher specificity for MAO-B and the added reduction of glutamate. Xadago was designed as an adjunct to levodopa in order to increase the "on" time with less incidence of dyskinesia. Xadago is available as both a 50mg and 100mg tablet. The recommended starting dosage of Xadago is 50 mg administered orally once daily (at the same time of day), without regard to meals. After two weeks, the dosage may be increased to 100 mg once daily, based on individual need and tolerability. Patients with moderate hepatic impairment (Child-Pugh B: 7-9) should not exceed 50mg daily, while Xadago should not be given to patients with severe hepatic impairment (Child-Pugh C: 10-15). Two double-blind, placebo-controlled, multi-national, 24-week studies were conducted in PD patients experiencing "off" time during treatment with carbidopa/levodopa and other PD medications (e.g., dopamine agonists, COMT inhibitors, anticholinergics, and/or amantadine). Both studies had a similar statistically significant end point of increased "on" time experienced while taking Xadago vs placebo. There are no current head to head trials between Xadago and other agents with the same indication. Adverse reactions during the studies included dyskinesia (17-21%), fall, nausea, insomnia, hypertension, orthostatic hypotension, anxiety. Xadago has not been compared head-to-head with any other medications with a similar indication and as current guidelines stand, there is no one agent better than another. Xadago states that it's dual mechanism of action was designed to reduce incidence of dyskinesia in patients, but number incidence of falls in clinical trials, 17-21%, falls in line with the most comparable drug, rasagiline, at 18%. Xadago is contraindicated in patients with severe hepatic impairment (Child-Pugh C), hypersensitivity to safinamide, and those with concomitant use of dextromethorphan or drugs that increase concentrations of serotonin or other catecholamines, such as those with MAOI pharmacologic properties, opioid drugs, serotonin-norepinephrine reuptake inhibitors, tricyclic, tetracyclic, or triazolopyridine antidepressants (trazodone), cyclobenzaprine, stimulants, or St. John's wort. Xadago is pregnancy category C and not approved in children, both due to lack of testing. Of the 1516 subjects exposed to Xadago in clinical studies, 38% were 65 and over, while 4% were 75 and over. A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: Kim Clark recommended revising the indication criteria to include those experiencing "off" episode, and to remove the criteria of a Child-Pugh score less than 10, as this information may not be readily available with the submitted required for coverage. Dr. Yarczower recommended changing to documentation that member does not have severe hepatic impairment. Jamie Miller made a motion to accept the amended recommendations. Aubrielle Prater seconded the motion. None were opposed

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

Outcome: For GHP Family, Xadago will be a pharmacy benefit and will be non-formulary. The following criteria will apply:

- Medical record documentation of a diagnosis of Parkinson's disease **AND**
- Medical record documentation that Xadago is prescribed by or in consultation with a neurologist **AND**

- Medical record documentation that member is concomitantly receiving carbidopa/levodopa and experiencing "off" episodes **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that the member does not have severe hepatic impairment **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary alternatives, one of which must be rasagiline or selegiline

QUANTITY LIMIT: 1 tablet per day

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

HAEGARDA (C1 esterase inhibitor (human))

Review: Haegarda is a C1 esterase inhibitor (C1-INH) indicated for routine prophylaxis to prevent hereditary angioedema (HAE) attacks in adolescent and adult patients. Dosing for Haegarda is 60 IU/kg subcutaneously (SC) twice weekly. Haegarda is supplied as 2000 IU or 3000 IU vials and is only available through specialty pharmacies. Patients with HAE have low levels of endogenous or functional C1-INH, and Haegarda replaces the absent or defective C1-INH protein to suppress contact system activation and prevent HAE attacks. In the Phase III COMPACT trial, Haegarda reduced the number of HAE attacks per month as well as the number of times a rescue medication was used for an acute attack. There are no black box warnings for Haegarda, and the most common adverse events are injection site reactions, nasopharyngitis, hypersensitivity and dizziness. Although several other C1-INH products are available, Haegarda is unique in that it can be self-administered. The World Allergy Organization (WAO) and the Hereditary Angioedema Association Medical Advisory Board (HAEA MAB) both recommend considering long-term prophylaxis in all severely symptomatic patients with HAE type I or II. The HAEA MAB states that patients should not be required to fail androgen therapy prior to receiving a C1-INH product as prophylaxis but does not specify a preference between Haegarda and Cinryze. A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

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

Financial Discussion: Tricia Heitzman recommended adding a note to the policy for the reviewer to specify, per the manufacturer, that although dose may be administered every 3 days, it is limited to twice weekly administration. No additional comments or questions. Tricia Heitzman made a motion to accept the recommendations as presented (with additional note). Keith Hunsicker seconded the motion. None were opposed

Outcome: For GHP Family, Haegarda will be considered a pharmacy benefit and will be added to the Brand Tier requiring prior authorization. The following criteria will apply:

- Member is ≥ 12 years of age **AND**
- Prescription written by an allergist, immunologist, hematologist, or dermatologist **AND**
- Medication is being used as prophylactic therapy for HAE attacks **AND**
- Medical record documentation of a hereditary angioedema diagnosis established and supported by documentation of:
    - Recurrent, self-limiting non-inflammatory subcutaneous angioedema without urticaria, last more than 12 hours **OR**

    - Laryngeal edema **OR**
    - Recurrent, self-remitting abdominal pain lasting more than 6 hours, without clear organic etiology

AND

- For HAE type I and type II, medical record documentation of 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

- Medical record documentation of history of more than one (1) severe event per month **OR** a history of laryngeal attacks
- Medical record documentation of failure on, intolerance to, or contraindication to danazol

Quantity Limit: 8 doses per 28 days

**Note: Haegarda is dosed once every 3 to 4 days with a maximum of 2 doses per week.*

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 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

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

KEVZARA (sarilumab)

Kevzara is the second interleukin-6 (IL-6) receptor antagonist indicated for the treatment of moderate to severe active RA, after Actemra (tocilizumab). By binding to IL-6 (a pro-inflammatory cytokine), Kevzara inhibits IL-6-medicated signaling and reduces the cytokine and inflammatory response. The IL-6 inhibitors are just one of several biological agents indicated for RA, including TNF blockers (e.g., Humira, Enbrel), IL-1 inhibitors (Kineret), T-cell modulators (Orencia), and CD-20 directed antibodies (Rituxan). Kevzara may be used as monotherapy or in combination with methotrexate(MTX) or other conventional DMARDs. The recommended dosage of KEVZARA is 200 mg once every 2 weeks, administered as a subcutaneous injection. The ACR guidelines have not been updated since 2015 and thus do not have recommendations explicitly for drugs like Kevzara. Kevzara has a similar safety profile to Actemra, both in the labeling and in reported treatment-emergent adverse events in RA-ASCERTAIN. Both agents have a boxed warning for risk of serious infections, including bacterial, viral, invasive fungal, or other opportunistic infections. Both agents also share warnings and precautions for neutropenia, thrombocytopenia, elevated liver enzymes, lipid abnormalities, gastrointestinal perforation, hypersensitivity reactions, and the avoidance of live vaccines due to the risk of infection. In contrast to the TNF blockers, there is no warning for malignancies, heart failure, or demyelinating disease. A

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

Clinical Discussion: Keith Hunsicker addressed concerns for the number of drug interactions with a quite a few commonly administered medications. It was agreed to review the clinical significance, and to potentially revise the crtieria for nivolumab pending the severity. No additional comments or questions. Kevin Szczecina made a motion to accept the recommendations as presented. Aubriell Prater seconded the motion. None were opposed

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

Outcome: Kevzara will be added to the GHP Family Formulary on the brand tier and will require prior authorization. Requests for coverage will require the following:

- Patient must be at least 18-years-of-age **AND**
- Prescribed by a Rheumatologist **AND**
- Have a diagnosis of moderate to severe rheumatoid arthritis made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of RA
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira* and Enbrel*
- Documentation that medication is not being used concurrently with a TNF Blocker or other biologic agent

Quantity Limits: 2 syringes (2.28 ml) per 28 days

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

After the initial six (6) month approval, subsequent approvals will be for a duration of 12 months. Reevaluation will be every one (1) year required medical record documentation of continued or sustained improvement in the signs and symptoms of rheumatoid arthritis while on Kevzara therapy.

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

KYMRIAH (tisagenlecleucel)

Kymriah is the first gene therapy to be approved by the FDA. Kymriah is a genetically-modified autologous T-cell immunotherapy, also known as a chimeric antigen receptor T (CAR-T) cell therapy, which targets CD19, a protein expressed on the surface of B-cell leukemia and lymphoma cells. Each dose of Kymriah is a customized treatment created using an individual patient's own T-cells. The patient's T-cells are collected and sent to a manufacturing center where they are genetically modified to include a new gene that contains the CAR protein; the CAR protein directs the T-cells to target and kill leukemia cells with CD19 on the surface. Once the cells are modified, they are infused back into the patient to kill the cancer cells. Kymriah is an alternative treatment for pediatric patients with refractory ALL or ALL that has relapsed after trial of at least two standard therapies. It is also an option for

Philadelphia chromosome negative patients for whom targeted tyrosine kinase inhibitors are not treatment options. Among children with ALL, about 95% are Philadelphia chromosome negative. Data from the Kymriah pivotal trial demonstrated that the overall remission rate within 3 months of treatment was 83%, with a 12% stem cell transplantation rate among patients who achieved complete remission. Thus, Kymriah may allow more patients to proceed to potentially curative stem cell transplantation in comparison to standard chemotherapy; however, long-term follow-up is necessary to determine whether treatment with Kymriah is considered curative. Kymriah maintains a black box warning for cytokine release syndrome (CRS) and neurological toxicities. There is an associated REMS program, called the Kymriah REMS associated with the black box warning. In addition to the black box warning, the package insert describes warnings and precautions including hypersensitivities reactions, serious infections, prolonged cytopenias, hypogammaglobulinemia, secondary malignancies, and effects on the ability to drive and use machines. A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: Keith Hunsicker recommended modifying the age criteria to less than 26 years of age. Tricia Heitzman recommended adding a note to the reviewer addressing the concerns that the manufacturer will not make the product for anyone who does not meet the approved indication. No additional comments or questions. Kevin Szczecina made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed

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

Outcome: Kymriah is a medical benefit for GHP Family. Requests will require the following criteria:

Acute Lymphoblastic Leukemia (ALL)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is <u>less than</u> 26 years of age **AND**
- Medical record documentation of a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second (or later) relapse

Note: The indication of Kymriah is intended to treat patients up to the age of 25 years 364 days. Upon reaching 26 years of age the patient is no longer a candidate for Kymriah treatment. Per Novartis, Kymiah will <u>not</u> be manufactured for any patient who does not meet the specific FDA approved indication.

Authorization Duration/Quantity Limit: One-time authorization for one administration of Kymriah.

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

<u>BESPONSA (inotuzumab ozogamicin)</u>

Review: Besponsa is a single-agent immunotherapy approved for the treatment of relapsed or refractory B-cell precursor ALL, a rare and rapidly progressing cancer of the blood and bone marrow. It is intended

for patients whose cancer returned after treatment (relapsed) or did not respond to previous treatment (refractory). Besponsa joins Blincyto (blinatumomab), which was the first immunotherapy approved for relapsed or refractory B-cell precursor ALL. Although Besponsa and Blincyto are approved for use in treating relapsed/refractory ALL, Besponsa is only approved for use in adult patients, while Blincyto is approved in adult and pediatric patients 2 years of age and older. In contrast to Blincyto's fixed dose, continuous infusion schedule, Besponsa can be delivered in an outpatient infusion center (on days 1, 8 and 15 of a 28-day cycle), allowing for ease of administration for patients requiring therapy. Data from the pivotal trial demonstrated significantly improved rates and duration of remission, as well as rates of patients able to proceed to stem cell transplantation, however, the trial did not produce statistically significant improvements in its primary endpoint of median overall survival per predefined study parameters. Notably, in a subgroup analysis of patients with Ph-positive or t(4;11)-positive ALL abnormalities (which traditionally have poorer prognoses and higher associated treatment resistance), had complete remission rates that did not significantly differ between Besponsa and standard chemotherapy. Given the results of its pivotal trial, Besponsa provides an alternative treatment for patients with relapsed/refractory ALL with improved rates of complete remission and rates of proceeding to stem cell transplantation. Besponsa maintains a black box warning for hepatotoxicity and increased risk of post-hematopoietic stem cell transplant non-relapse mortality. In addition to the listed black box warnings, the package insert indicates other warnings and precautions including: myelosuppression, infusion related reactions, QT interval prolongation, and embryo-fetal toxicity. Besponsa should be used in combination with other QT interval prolongating agents only under close medical supervision. A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented**.**

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

Financial Discussion: Bret Yarczower asked if the initial approval for 3 cycles was in line with what will clinically be done. Reviewer in agreement that it is, because if there is no complete remission following three cycles, the medication should be discontinued. No additional comments or questions. Tricia Heitzman made a motion to accept the recommendations as presented. Todd Sponenberg seconded the motion. None were opposed

Outcome: Besponsa will considered a medical requiring prior authorization. The following criteria will 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 relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

Authorization Duration: An initial authorization duration of 3 cycles (3 months) should be approved.

Reauthorization: One subsequent authorization will be for an additional 3 cycles (3 months) and will require medical record documentation of the following:

- Medical record documentation that patient is <u>not</u> receiving hematopoietic stem cell transplant (HSCT) **AND**
- Medical record documentation that patient has achieved complete remission or complete remission with incomplete hematologic recovery and minimal residual disease (MRD) **AND**

- Medical record documentation that the patient is not experiencing 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.

ALIQOPA (copanlisib)

Review: Aliqopa is an IV formulation PI3K inhibitor approved for the treatment of relapsed follicular lymphoma in patients who have previously failed 2 alternative therapies. Aliqopa works through inhibitory activity predominantly against PI3K-α and PI3K-δ isoforms expressed in malignant B cells. Aliqopa has been shown to induce tumor cell death by apoptosis and inhibition of proliferation of primary malignant B cell lines. Aliqopa inhibits several key cell-signaling pathways, including B-cell receptor (BCR) signaling, CXCR12 mediated chemotaxis of malignant B cells, and NFκB signaling in lymphoma cell lines. Aliqopa is an IV infusion given over 1 hour on day 1, 8, and 15 of a 28 day cycle. In its phase 2 clinical trial, Aliqopa showed positive results for overall response rate of 59% and 14% complete response. These results got Aliqopa's approval fast tracked to the market. There were also many adverse reactions experienced in the trial including; infection, hyperglycemia, hypertension, non-infectious pneumonitis, neutropenia, severe cutaneous reactions. Of these adverse reactions, hyperglycemia and pneumonitis were the main reasons patients discontinued the therapy. Aliqopa has drug interactions with both CYP3A inducers and inhibitors, doses should be monitored and adjusted accordingly. Aliqopa is not the first PI3K inhibitor, but it is the first IV formulation. Zydelig is another PI3K inhibitor with the same FDA approved indication, but Zydelig is available as an oral medication. In comparison Aliqopa had a higher response rate, 59% vs 54%, and a lower adverse reaction rate, 26% vs 50%. Both medications are indicated to be continued until disease progression or intolerable toxicity. A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

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

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

Outcome: Aliqopa will be considered a medical benefit requiring quantity limit and authorization duration for GHP Family**.** The following criteria will apply:

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed follicular lymphoma (FL) **AND**
- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to at least two prior systemic therapies

Quantity Limit: 180 mg (3 vials) per 28 days

Authorization Duration: Each treatment period will be defined as 12 months. Re-review will occur every 12 months. Aliqopa will no longer be considered medically necessary if there is medical record documentation of disease progression.

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

VERZENIO (abemaciclib)

Review: Verzenio is one of the three currently available CDK4/6 inhibitors FDA-approved in combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and as monotherapy for the HR +/HER2 - advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting. In clinical trials, Verzenio has shown superior efficacy primarily in terms of progression-free survival (PFS) when compared to placebo. Verzenio is available as oral tablets in four different strengths (50mg, 100mg, 150mg, and 200mg) and is dosed twice daily by mouth without regard to food until disease progression or unacceptable toxicity. Diarrhea, neutropenia, hepatotoxicity, venous thromboembolism, and embryo-fetal toxicity are listed as warnings and precautions. The most common adverse reactions (incidence ≥20%) were diarrhea, neutropenia, nausea, abdominal pain, infections, fatigue, anemia, leukopenia, decreased appetite, vomiting, headache, and thrombocytopenia. Verzenio, as a CYP3A4 substrate, should be used cautiously when administered with strong CYP3A4 inhibitors/inducers. Lastly, Verzenio shouldn't be used in pregnant women, nursing mothers, and pediatrics since there is no established data in these populations. A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

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

Financial Discussion: Steve Kheloussi recommended limiting fills to one month at a time. No additional comments or questions. Kevin Szczecina made a motion to accept the recommendations as presented. Aubrielle Prater seconded the motion. None were opposed.

Outcome: Verzenio will be added to the GHP Family formulary on the brand tier requiring prior authorization, quantity limit and authorization duration. The following criteria will apply:

- Patient is at least 18 years old or older **AND**
- Prescribed by an oncologist **AND**
- Medical record documentation of postmenopausal status **OR** if the patient is pre/perimenopausal, that they have received a gonadotropin-releasing hormone agonist (e.g. LHRH agonist; goserelin) for at least 4 weeks prior to and will continue for the duration of Verzenio therapy **AND**
- Medical record documentation of a diagnosis of advanced or metastatic breast cancer that is hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+/HER2-) **AND**
- One of the following:
    - Medical record documentation that the patient experienced disease progression following prior endocrine therapy* AND prior chemotherapy^ in the metastatic setting **AND**
    - Medical record documentation that Verzenio is being used as monotherapy

OR

- Medical record documentation that the patient experienced disease progression following prior endocrine therapy* **AND**
- Medical record documentation that fulvestrant (Faslodex) will be administered along with Verzenio

QL: A quantity limit of 56 tablets for a 28-day supply should apply.

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

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

^Examples of preferred chemotherapy include[2]: Anthracyclines (doxorubicin/pegylated liposomal doxorubicin), taxanes (paclitaxel), anti-metabolites (capecitabine/gemcitabine), other microtubule inhibitors (vinorelbine/eribulin). Other chemotherapy agents that can be used include: cyclophosphamide, carboplatin, docetaxel, albumin-bound paclitaxel, cisplatin, epirubicin, and ixabepilone.

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

CLASS REVIEW

Basal insulin Class Review

Available basal insulins

Brand Name	Lantus/Lantus SoloStar[1]	Basaglar KwikPen[2]	Toujeo SoloStar[3]	Levemir/Levemir FlexTouch[4]	Tresiba FlexTouch[5]
Generic Name	Insulin glargine	Insulin glargine	Insulin glargine	Insulin detemir	Insulin degludec
Generic Availability	No	No	No	No	No
Manufacturer	Sanofi-aventis	Eli Lilly and Company	Sanofi-aventis	Novo Nordisk, Inc	Novo Nordisk, Inc

How Supplied	10 mL vials (100 Units/mL): Pack of 1 3 mL SoloStar prefilled pen (100 Units/mL): Pack of 5	3 mL KwikPen prefilled pen (100 Units/mL): Pack of 5	1.5 mL SoloStar prefilled pen (300 Units/mL): Pack of 3 1.5 mL SoloStar prefilled pen (300 Units/mL): Pack of 5	10 mL vials (100 Units/mL): Pack of 1 3 mL FlexTouch prefilled pen (100 Units/mL): Pack of 5	3 mL FlexTouch prefilled pen (100 Units/mL): Pack of 5 3 mL FlexTouch prefilled pen (200 Units/mL): Pack of 3
FDA Approval Date	04/20/2000	12/16/2015	02/25/2015	06/16/2005	09/25/2015

Review: There are currently five basal insulin products commercially available: Lantus (insulin glargine 100 units/mL), Basaglar (insulin glargine 100 units/mL), Toujeo (insulin glargine 300 units/mL), Levemir (insulin detemir 100 units/mL), and Tresiba (insulin degludec 100 units/ml and 200 units/mL). All products are available as a prefilled insulin pen, with Lantus and Levemir available additionally in a 10 mL vial. All five products are injected subcutaneously once daily at the same time, with Levemir being the only basal insulin that can be divided into twice daily dosing. Basal insulins, compared to bolus insulins, are often preferred when initiating insulin therapy in insulin-naïve patients with type 2 diabetes due to the simplicity of use and need for only one daily injection. Basal insulins provide a consistent availability of insulin that results in a favorable pharmacokinetic profile to prevent large fluctuations in blood glucose levels leading to hypoglycemia and hyperglycemia. The use of insulin is associated with the highest potential lowering in HbA1c compared to oral antidiabetic therapies or other injectable therapies. However, their superior HbA1c reduction capacity is confounded by a high risk of hypoglycemia, higher risk of weight gain, and increased cost compared to other antidiabetic agents. In addition, the use of basal insulin requires patient education on injection technique, symptoms and management of hypoglycemia, the purchase of additional supplies for injection (pen needles, alcohol swabs, sharps container, etc.), and consistent follow-up with the prescriber to assess safety and efficacy and recommend dose adjustments. Unused insulin pens and vials must be refrigerated and expire within a short time frame after initial use, adding to the complexity of administration and handling. Insulin glargine is available as three different basal insulin formulations: Lantus (100 units/mL), Basaglar (100 units/mL), and Toujeo (300 units/mL). Despite differences in manufacturer and drug strength, all three products were shown to be non-inferior in clinical trials. Tresiba (insulin degludec 100 units/mL and 200 units/mL) was found to be non-inferior to both Levemir and insulin glargine in clinical trials. Additionally, clinical trials of Levemir found similar results in safety and efficacy when compared to insulin glargine. A Cochrane review comparing insulin detemir and insulin glargine in patients with type 2 diabetes reported no clinical difference in safety or efficacy between the 2 products. However, insulin detemir resulted in less weight gain in comparison to insulin glargine. Insulin glargine resulted lower risk of injection site reaction and overall lower total daily dose of basal insulin. In the SWITCH 1 trial, the rate of overall symptomatic hypoglycemia, nocturnal hypoglycemia, and severe hypoglycemia was significantly lower in patients with type 1 diabetes who were treated with degludec compared to glargine. In SWITCH 2 trial, the rate of overall symptomatic hypoglycemia and nocturnal hypoglycemia was

significantly lower in those with type 2 diabetes treated with insulin degludec compared to glargine, but there was no difference in the rates of severe hypoglycemia. The DEVOTE trial, showed that there was no difference in major CV events when comparing degludec to glargine, however there was lower rates of severe hypoglycemia and nocturnal hypoglycemia with degludec. In the Lantus package insert trials, there was no difference in cardiovascular outcomes for patients receiving Lantus compared to those receiving standard care.

All five basal insulin products have very similar warnings and precautions, including the following: hypoglycemia, hyperglycemia/hypoglycemia with changes in insulin regimen, medication errors, hypersensitivity/allergic reactions, hypokalemia, and fluid retention when used in combination with PPAR-gamma agonists. Common side effects are similar between all products, with hypoglycemia being the most significant adverse effect to monitor. Drug interactions for all products include drugs that increase the risk for hypoglycemia, drugs that decrease the blood glucose lowering effects of basal insulin, drugs that increase or decrease the blood glucose lowering effects of basal insulin, and drugs that may blunt signs and symptoms of hypoglycemia. Dosing remains consistent among all 5 products for type 1 and type 2 diabetes, with specific information provided for each product for switching between basal insulin therapies. All basal insulin therapies have indications for use in pediatric populations, except Toujeo. Lantus and Basaglar can be used in pediatrics ≥ 6 years of age with type 1 diabetes. Levemir can be used in pediatrics ≥ 2 years of age with type 1 diabetes. Tresiba can be used in both type 1 and/or type 2 diabetes in patients ≥ 1 year of age. Caution should be taken when adjusting therapy in patients with renal and hepatic impairment for all basal insulins, and frequent blood glucose monitoring should be encouraged. The use of all five insulin products should be used with caution in both pregnancy and nursing mothers and only be used when the benefits of therapy outweigh the potential risks of fetal harm.A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented.

Formulary recommendations based on clinical review

Medication	Current Policy	Recommendations
Lantus	No current criteria.	Lantus is a pharmacy benefit and should remain on the formulary. Lantus will require a prior authorization for new starts only: • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Basaglar or Toujeo
Basaglar	No current criteria	Basaglar is a pharmacy benefit. Basaglar should be added to the formulary. Basaglar will not require a prior authorization.
Toujeo	Age Minimum of 18 Years **Policy:** Medical record documentation of peer reviewed literature citing well-designed clinical trials to indicate that use of Toujeo has been shown to be safe and effective in patients under the age of 18 years.	Toujeo is a pharmacy benefit and should remain on the formulary. No changes recommended at this time.
Levemir	No current criteria.	Levemir is a pharmacy benefit and should remain on the formulary. No changes recommended at this time.

Tresiba FlexTouch	**Formulary Exception Policy**: Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to: Lantus **OR** Toujeo **AND** Levemir	Tresiba is a pharmacy benefit, and should be added to the formulary. Tresiba will not require a prior authorization.

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

Formulary Recommendations Based on Cost Review

Medication	Current Formulary Status	Recommendations
Lantus	Formulary, Tier 2	Lantus should remain on the GHP Family formulary at the Brand Tier. No additional criteria should apply.
Basaglar	Non-formulary	Basaglar should be added to the GHP Family formulary at the Brand Tier. No additional criteria should apply.
Toujeo	Formulary, Tier 2	Toujeo should remain on the GHP Family formulary at the Brand Tier. No additional criteria should apply.
Levemir	Formulary, Tier 2	Levemir should remain on the GHP Family formulary at the Brand Tier. No additional criteria should apply.
Tresiba	Non-formulary	Tresiba should be added to the GHP Family formulary at the Brand Tier. No additional criteria should apply.

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

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

FAST FACTS

MIRENA (levonorgesterol-releasing Intrauterine Device)

Updated Indication[1]:

- Contraception: Prevention of pregnancy (up to 5 years)
- Heavy Menstrual bleeding: Treatment of heavy menstrual bleeding in women who choose to use intrauterine contraception as their method of contraception.

Recommendation: No changes to formulary recommended at this time. .

Discussion: No questions or comments.

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

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

DYSPORT (abobotulinumtoxinA)

Updated Indication[1]: Dysport is now indicated for the treatment of spasticity in adult patients. This indication was previously limited to "upper limb spasticity" in adults.

Previously, Dysport was indicated for the treatment of Cervical Dystonia, Glabellar Lines (cosmetic use), Upper limb spasticity in adults, and pediatric lower limb spasticity.

Recommendation: It is recommended that the prior authorization criteria be updated to account for the new indication as outlined below.

MBP 11.0 – Subsection Botulinum Toxin Type A (Dysport)

Geisinger Health Plan approved FDA labeled indications for Botulinum Toxin Type A (**Dysport**) are:

1. **Cervical dystonia**

OR

2. **Upper Limb Spasticity**
   - Medical record documentation that Dysport is being used for the treatment of upper limb **AND**
   - Documentation that the patient is ≥ 18 years of age

OR

3. ~~**Pediatric**~~ **Lower Limb Spasticity**
   - Medical record documentation that Dysport is being used for the treatment of the lower limb(s) **AND**
   - Documentation that the member is ≥ 2 years of age

~~***Note: Adult lower limb spasticity is indicated under Botox Only, NOT Dysport.*~~

Other Recommendations

For all botulinum toxin products:

Quantity Limit: One (1) visit per 12 weeks (3 months)*

**Note: Patients utilizing botulinum toxin products for more than one indication may require additional visits. The following cumulative doses should not be exceeded if being used for 1 (or more) indication(s):*

- *Botox – 400 units per 12 weeks (3 months)*
- *Dysport – 1500 units per 12 weeks (3 months)*
- *Myobloc – 5000 units per 12 weeks (3 months)*
- *Xeomin – 400 units per 12 weeks (3 months)*

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 **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Medical record documentation of continued disease improvement or lack of disease progression** **AND**
- Medical record documentation of one of the following:
    - Repeated administrations are not being given more frequently than once every 12 weeks **OR**
    - Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing more frequently than every 12 weeks.

***Note: The requested medication will no longer be covered if the patient fails to present clinical benefit after two sequential therapies using maximum doses.*

Discussion: No questions or comments.

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

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

BENLYSTA (belimumab)

Indication: Benlysta is indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.

Limitations of use: Benlysta has not been evaluated in patients with severe active lupus nephritis or severe active CNS lupus. Benlysta has not been studied in combination with other biologics or IV cyclophosphamide. It is not recommended for use in these situations.

Updated How supplied: Benlysta is now available as a subcutaneous injection. Benlysta is supplied as 200 mg/mL single-dose prefilled autoinjector or single-dose prefilled syringe.

Note: Benlysta was previously only available as 120 mg or 400 mg lyophilized powder in single-dose vials for reconstitution and dilution for IV infusion.

Recommendation: Benlysta subcutaneous injection will be a pharmacy benefit. It is recommended that Benlysta should be added to the GHP Family formulary at the Brand Tier. Benlysta will require a prior authorization.

Prior authorization of Benlysta subcutaenous injection will be made for members who meet the following criteria:

- Medical record documentation of active systemic lupus erythematosus AND
- Positive ANA/anti-dsDNA antibody AND
- Stable treatment regimen with prednisone, NSAID, anti-malarial or immunosuppressant AND
- No active severe nephritis or CNS involvement
- Prescribed by a rheumatologist

Note: Benlysta has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of Benlysta is not recommended in these situations

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

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

Quantity Limit: 4 mL per 28 days

Discussion: No questions or comments.

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

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

VIMOVO (naproxen and esomeprazole)

Updated Indication: Vimovo is indicated for management of Juvenile idiopathic arthritis (JIA) of patient 12 years of age and older who weigh 38kg or greater.

Recommendation: No changes are recommended for the formulary placement of Vimovo at this time. It is recommended that the criteria for use be updated to include:

- Diagnosis of Juvenile Idiopathic Arthritis (JIA) **AND**
- Medical record documentation the patient is 12 years of age or over **AND**
- Medical record documentation the patient weighs 38kg or greater **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to naproxen and 2 formulary PPI (proton pump inhibitor) agents used in combination.

- Diagnosis of osteoarthritis, rheumatoid arthritis, or ankylosing spondylitis **AND**
- Medical record documentation patient is 18 years of age or older **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to naproxen and 2 formulary PPI (proton pump inhibitor) agents used in combination.

  A quantity limit of 60 tablets per 30 days should also be applied.

Discussion: No questions or comments.

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

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

BRIVIACT (brivaracetam)

Updated Indication: Briviact is indicated for the treatment of partial-onset seizures (POS) as monotherapy or adjunctive therapy in patients 16 years of age and older with epilepsy.

Previously, Briviact was indicated as *adjunctive therapy only* in the treatment of POS in patients 16 years of age and older with epilepsy.

Recommendation: It is recommended that the following prior authorization criterion be removed to reflect the new indication:

- Medical record documentation that Briviact is being used as an adjunctive therapy

No changes to QL or formulary placement are recommended.

Discussion: No questions or comments.

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

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

DESCOVY (emtricitabine/tenofovir alafenamide)

Updated Indication: Descovy is indicated:

- In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg.
- In combination with other antiretroviral agents other than protease inhibitors that require a CYP3A4 inhibitor, for the treatment of HIV-1 infection in pediatric patients weighing at least 25 kg and less than 35 kg.

Limitations of Use: Descovy is not indicated for use as pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 in adults at high risk.

Note: The safety and effectiveness of Descovy coadministered with a protease inhibitor that is administered with ritonavir or cobicistat has not been established in pediatric patients weighing < 35 kg. Also, the safety and effectiveness of Descovy in pediatric patients weighing <25 kg has not been established.

Previous indication: Descovy was previously indicated in combination with other retroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older.

Recommendation: Descovy is available at the Brand Tierwithout prior authorization. No changes are recommended to the formulary placement of Descovy at this time.

Discussion: No questions or comments.

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

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

GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide fumarate)

Updated Indication: Genvoya is indicated:

- As a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 25 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Genvoya.

Previous Indication: Genvoya was previously indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older.

Recommendation: Genvoya is a pharmacy benefit at the Brand Tier. Genvoya does not require a prior authorization. No changes to formulary placement are recommended at this time.

Discussion: No questions or comments.

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

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

FYCOMPA (perampanel)

Updated Indication: Fycompa is indicated for:

- Treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 12 years of age and older
- Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older

Note: Previously Fycompa was indicated as adjunctive therapy for the treatment of:

- Partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 12 years of age and older
- Primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older

Recommendation: There are no changes to formulary status recommended at this time for all lines of business. It is recommended that the Fycompa policy be updated to reflect the new indication:

• Medical record documentation of a diagnosis of partial onset seizures
• Patient is at least 12 years of age AND
• Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

OR

• Medical record documentation of a diagnosis of primary generalized tonic-clonic seizures AND
• Fycompa is being used concomitantly with at least one (1) other formulary antiepileptic drug AND
• Patient is at least 12 years of age AND
• Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

There are no changes to the quantity limit at this time.

Discussion: No questions or comments.

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

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

OPDIVO (nivolumab)

Updated Indication: Opdivo is now indicated under accelerated approval for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

Other previously approved indications include: Unresectable or metastatic melanoma, metastatic non-small cell lung cancer, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, and MSI-H or dMMR metastatic colorectal cancer.

Recommendation: No changes are recommended to the formulary placement of Opdivo at this time. It is recommended that the Opdivo prior authorization criteria of applicable policies are changed to account for the new indication.

Hepatocellular Carcinoma (HCC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of hepatocellular carcinoma **AND**
- Medical record documentation of a therapeutic failure on or intolerance to sorafenib (Nexavar)

No changes are recommended to the existing prior authorization criteria or the authorization duration at this time.

Discussion: No questions or comments.

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

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

LYNPARZA (olaparib)

Updated Indication: Lynparza (tablet) is indicated for:

- The maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy.
- The treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Patients selected for therapy should be based on an FDA-approved companion diagnostic for Lynparza.

Note: Lynparza capsules are indicated for the treatment of patients with deleterious or suspected deleterious germline *BRCA*-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Patients selected for therapy should be based on an FDA-approved companion diagnostic for Lynparza.

Recommendation: Lynparza tablets will be a pharmacy benefit. It will be added to the GHP Family formulary at the Brand tier.

It is recommended that all Lynparza formulations be included for the Lynparza policies. The following updates will apply to the current Lynparza policies:

If the request is for Lynparza tablets:

- Prescription written by an oncologist/hematologist AND
- Age greater than or equal to 18 years AND
- Medical record documentation of deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer as verified by a Food and Drug Administration (FDA) approved test AND medical record documentation of therapeutic failure on, intolerance to, or contraindication to three or more prior lines of chemotherapy OR
- Medical record documentation of a diagnosis of recurrent epithelial ovarian, primary peritoneal, or fallopian tube cancer AND medical record documentation of Lynparza being used as maintenance therapy after a complete or partial response to platinum-based chemotherapy

If the request is for Lynparza capsules:

- Prescription written by an oncologist/hematologist AND
- Age greater than or equal to 18 years AND
- Medical record documentation of deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer as verified by a Food and Drug Administration (FDA) approved test AND medical record documentation of therapeutic failure on, intolerance to, or contraindication to three or more prior lines of chemotherapy

Note: The FDA approved test is the BRACAnalysis Cdx™

Quantity Limit:

- 50 mg capsules: 16 capsules per day, 28-day supply per fill
- 100 mg tablets: 4 tablets per day, 30-day supply per fill
- 150 mg tablets: 4 tablets per day, 30-day supply per fill

Authorization Duration: Initial approval will be for 12 months or less if the reviewing provider feels it is medical appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing

provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression.

Discussion: No questions or comments.

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

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

APTIOM (eslicarbazepine)

Updated Indication: Aptiom is indicated for the treatment of partial-onset seizures (POS) as monotherapy or adjunctive therapy in patients 4 years of age and older.

Previously, Aptiom was indicated for adult patients 18 years of age and older.

Recommendation: It is recommended that the prior authorization criteria be updated in the Aptiom policies as follows to reflect the new age indication:

- Prescription is written by a neurologist **AND**
- Patient is at least 4 years of age **AND**
- Medical record documentation of a diagnosis of partial-onset seizures **AND**
- Medical record documentation of contraindication to, therapeutic failure on, or intolerance to 3 formulary alternatives, one of which must be oxcarbazepine

Discussion: No questions or comments.

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

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

KEYTRUDA (pembrolizumab)

Updated Indication: Keytruda is now approved under the accelerated approval process for the treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by an FDA-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing therapy and if appropriate, HER2/neu-targeted therapy.

Recommendation: No changes are recommended to the formulary placement of Keytruda at this time. It is recommended that the Keytruda prior authorization criteria of applicable policies are changed to account for the new indication.

Gastric Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma **AND**
- Medical record documentation that tumors express PD-L1 (combined positive score [CPS] greater than or equal to 1) as determined by an FDA-approved test **AND**
- Medical record documentation of disease progression on or after two or more prior lines of therapy (including fluoropyrimidine- and platinum-containing chemotherapy)* **AND**
- If patient has HER2-positive disease, medical record documentation of disease progression on or after HER2/neu-targeted therapy (including but not limited to trastuzumab (Herceptin)*

*Note to reviewer: Current recommendations intend Keytruda to be used as third-line treatment (i.e. patient is to have 2 prior lines of therapy, one of which must include HER2/neu-targeted therapy if the patient has HER-2 positive disease)

No changes are recommended to the existing prior authorization criteria or the authorization duration at this time.

Discussion: No questions or comments.

Outcome: Kevin Szczecina made a motion to accept the recommendations as presented. Anastasia Mauger 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.

FASLODEX (fulvestrant)

Updated Indication: Faslodex is indicated as monotherapy for the:
- Treatment of hormone receptor (HR)-positive, human epidermal growth receptor 2 (HER2)- negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy.
- Treatment of HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy.

Faslodex is indicated as combination therapy for the:
- Treatment of HR-positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib in women with disease progression after endocrine therapy.

Faslodex was *previously* indicated as:
Monotherapy:
- For the treatment of HR-positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy.

Combination Therapy:
- For the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib in women with disease progression after endocrine therapy.

Recommendation: Faslodex is available without restrictions for GHP Family. No changes recommended.

Discussion: No questions or comments.

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

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

UPDATES

INGREZZA (valbenazine)

Initial approval of Ingrezza included only the 40mg dosage form. Based on this, the initial Ingrezza drug review recommended a quantity limit of 2 capsules per day. Since initial review, an 80mg capsule has been made commercially available. For a patient requiring the 80mg dose, utilizing (1) 80mg capsule daily as opposed to (2) 40mg capsules daily can result in a cost savings of $5,190.00 per patient per month ($62,280.00 annually per patient).

Recommendations: It is recommended that the existing quantity limits are changed to the following for all lines of business:
All Strengths: 1 capsule per day, maximum 30-day supply per fill

Discussion: No comments or questions.

Outcome: Todd Sponenberg made a motion to accept the amended recommendations. Kim Clark seconded the motion. None were opposed

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

Non-Preferred Ophthalmic AntihistaminesRecommendation:

Current Formulary Status:

	GHP Family
Alomide	NF
Azelastine	Generic
Bepreve	NF
Emadine	NF
Epinastine	Generic
Lastacaft	NF
Olopatadine (generic Pataday/Patanol)	Generic
Pazeo	NF

Existing Prior Authorization Criteria:
GHP Family Policy 1101.0F Alomide, Emadine, Pataday, and Lastacaft

- Medical record documentation of allergic conjunctivitis **AND**

- Medical record documentation of failure on, intolerance to or contraindication to, azelastine eye drops, and epinastine

Recommendations

GHP Family Policy: In order to ensure consistency amongst reviewers, it is recommended that Bepreve and Pazeo are added to the existing policy. Pataday should be removed at this time. The following updates are recommended:

- Medical record documentation of allergic conjunctivitis **AND**
- Medical record documentation of failure on, intolerance to or contraindication to azelastine eye drops, epinastine eye drops, **AND** olopatadine (generic Pataday or Patanol)

Discussion: No questions or comments.

Outcome: Kevin Szczecina made a motion to accept the recommendation as presented. Jamie Miller seconded the motion. None were opposed

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

COPD Formulary Updates

Current Formulary Status:

	GHP Family
Combivent Respimat	Brand
Stiolto Respimat	NF
Striverdi Respimat	NF

Stiolto Respimat & Striverdi Respimat

Anoro Ellipta (anticholinergic/long-acting beta$_2$-adrenergic agonist) and Serevent (long-acting beta$_2$-adrenergic agonist) are currently in a preferred formulary position on all Geisinger drug formularies. Both of these medications deliver their active ingredient via a dry powder formulation. Dry powder inhalers require a deep, fast inhalation as well as dexterity to ensure the dose is delivered appropriately which may be difficult for some members. In order to allow physicians an aerosolized option for those members who may not be good candidates for a dry powder inhaler, it is recommended that Stiolto Respimat (anticholinergic/long-acting beta$_2$-adrenergic agonist) and Striverdi Respimat (long-acting beta$_2$-adrenergic agonist) are added to the prescription drug formulary on the brand tier.

Discussion: No questions or comments.

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

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

TOBACCO CESSATION QUANTITY LIMITS

Recommendation: a quantity limit of two starter packs per year should be added to the Chantix policy

Discussion: No questions or comments

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

NORPACE CR (disopyramide CR)

Norpace CR is a class I antiarrhythmic drug indicated for the treatment of ventricular arrhythmias, such as sustained ventricular tachycardia, that are considered life-threatening. It is used off label (medically acceptable) for the treatment of symptomatic hypertrophic obstructive cardiomyopathy (HOCM)

Recommendation: It is recommended that Norpace CR not be added to the GHP Family formulary at this time. The following prior authorization criteria and quantity limits should apply.

- Medical record documentation that Norpace CR is being used for an FDA-approved indication (ventricular arrhythmia considered life-threatening) **AND**
- Medical record documentation of therapeutic failure on or intolerance to disopyramide IR

OR

- Medical record documentation that Norpace CR is being used to treat hypertrophic obstructive cardiomyopathy **AND**
- Medical record documentation of therapeutic failure on a beta-blocker AND verapamil

Quantity Limits:

- 100 mg capsules: 8 capsules/day
- 150 mg capsules: 5 capsules/day

Discussion: No comments or questions

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

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

DPP-4 Inhibitor Policy Updates

Recommendation:

Medication	Recommendations to Policies
Januvia (brought to Sept P&T)	Januvia is a pharmacy benefit and should be removed from formulary. The following prior authorization criteria should apply: • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta* *Step therapy required
Janumet (brought to Sept P&T)	Janumet is a pharmacy benefit and should be removed from formulary. The following prior authorization criteria should apply: • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta* + metformin, Jentadueto*, OR Jentadueto XR* *Step therapy required

Janumet XR (brought to Sept P&T)	Janumet XR is a pharmacy benefit and should be removed from formulary. The following prior authorization criteria should apply: • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta* + metformin, Jentadueto*, OR Jentadueto XR* *Step therapy required
Onglyza	Onglyza is a pharmacy benefit and should remain non-formulary. Onglyza should require prior authorization on the pharmacy benefit with the following criteria: • Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Tradjenta* *Step therapy required
Kombiglyze XR	Kombiglyze XR is a pharmacy benefit and should remain non-formulary. Kombiglyze should require prior authorization on the pharmacy benefit with the following criteria: • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta* + metformin, Jentadueto*, OR Jentadueto XR* *Step therapy required
Tradjenta	Tradjenta is a pharmacy benefit and should be added to formulary. Tradjenta will require step therapy. Medical record documentation of current utilization of metformin or intolerance to or contraindication to metformin
Jentadueto	Jentadueto is a pharmacy benefit and should be added to formulary. Jentadueto will require step therapy. Medical record documentation of current utilization of metformin or intolerance to or contraindication to metformin
Jentadueto XR	Jentadueto XR is a pharmacy benefit and should be added to formulary. Jentadueto XR will require step therapy. Medical record documentation of current utilization of metformin or intolerance to or contraindication to metformin
Glyxambi	Glyxambi is a pharmacy benefit and should be added to formulary. Glyxambi will require step therapy. Medical record documentation of current utilization of metformin or intolerance to or contraindication to metformin
Nesina	Nesina is a pharmacy benefit available generically and should remain non-formulary.
Alogliptin	Alogliptin is a pharmacy benefit and should remain non-formulary. Alogliptin should require a prior authorization on the pharmacy benefit with the following criteria: • Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Tradjenta* *Step therapy required
Oseni	Oseni is a pharmacy benefit available generically and should remain non-formulary.
Alogliptin/pioglitazone	Alogliptin/pioglitazone is a pharmacy benefit and should remain non-formulary. Alogliptin/pioglitazone should require a prior authorization on the pharmacy benefit with the following criteria: • Therapeutic failure on, intolerance to, or contraindication to Tradjenta* + pioglitazone *Step therapy required

Kazano	Kazano is a pharmacy benefit available generically and should remain non-formulary.
Alogliptin/metformin	Alogliptin/metformin is a pharmacy benefit and should remain non-formulary. Alogliptin/metformin should require a prior authorization on the pharmacy benefit with the following criteria: • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Tradjenta* + metformin, Jentadueto*, OR Jentadueto XR* *Step therapy required

Discussion: No comments or questions

Outcome: Jamie Miller made a motion to accept the amended recommendations. 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

POLICY CHANGES:

Recommendation: The following changes existing policies are recommended:

Policy 1382.0F Opioid Use

To eliminate non-formulary opioids or formulary opioids requiring prior authorization from having to be reviewed twice (using policy 1382.0F and also using their respective drug specific policy or policy 4.0F) and to clarify the existing policy it is recommended the following additions be approved (the additions are underlined):

PROCEDURE:
Prior authorization of opioids will be made for members who meet the following criteria:

- Diagnosis of active cancer or palliative care **OR**
- Diagnosis of sickle cell disease **OR**
- Member is receiving hospice care

Note: Authorizations will be entered for an opioid class override for members who meet these criteria

For members who do not meet the above criteria, the following documentation will be required:

- Medical record documentation of why a non-opioid alternative is not advised **AND**
  - Medical record documentation that the member is: ▪ being treated for chronic non-cancer pain **AND** • the prescription is written by a Pain Management Specialist **OR** the member has been referred to a Pain Management Specialist for the same condition within the previous 24 months **OR**
  - the member has a signed pain contract in place

OR

- the member requires more than a 7 day supply if under the age of 18 or more than a 14 day supply if an adult to stabilize an acute medical condition or the member is being tapered off opioids AND the duration of treatment is stated

AND

- The prescriber will conduct urine drug screening (UDS) per the American Society of Addiction Medicine (ASAM) guidelines **AND**
- Provider has evaluated member for risk of opioid use disorder using CAGE-AID, Opioid Risk Tool, or a similar screening tool upon initiation of opioids and every 3 months or as needed **AND**
- There is a plan for the tapering of benzodiazepines or rationale for continued use (if applicable) **AND**
- The prescriber has queried the State's Prescription Drug Monitoring System with every controlled substance written to ensure controlled substance history is consistent with prescribing record **AND**
- The prescriber has discussed the risks of addiction and overdose with the minor and parent, guardian or authorized adult if under the age of 18 **AND**
- If under the age of 18, the prescriber has obtained written consent for the prescription from the minor's parent/guardian/authorized adult on a standardized consent form **AND**
- There is medical record documentation that that the member or parent/guardian has been educated on the potential adverse effects of opioid analgesics, including the risk for misuse, abuse and addiction **AND** the member will receive a prescription for naloxone if dose of opioid is 120 MEDs (50 MEDs for minors) or greater and member is not being treated for end of life **OR** if the prescriber determines the member is at risk for an overdose at any MED.

OR if the above criteria is not met:

- The Plan will work with the prescriber and provide authorization for the requested medication during a period of tapering in accordance with accepted standards of care. During this tapering process, referral will be made to case management to offer assistance to the member during the transition process.

AND for non-preferred opioids:

- Medical record documentation of therapeutic failure on, intolerance to or contraindication to three formulary alternatives, one of which must be morphine (short acting non-preferred opioid) OR morphine ER (long acting non-preferred opioid) **OR**
- If the requested non-preferred opioid is abuse deterrent: ▪ Medical record documentation that the member is at risk to abuse opioids by crushing

Note: Authorizations will be entered by GPID for each drug meeting the above criteria
QUANTITY LIMITS: please see chart below

AUTHORIZATION DURATION:

- For chronic non-cancer pain, active cancer or palliative care, and hospice care: 1 year
- For sickle cell disease: lifetime

- For stabilization of an acute medical condition: stated duration of treatment
- For tapering the member off opioids: 1 year or the time requested by the prescriber for tapering, whichever is less

The following changes were made for the policy to be approved by DHS. It is recommended they be approved by the Plan's P&T Committee (addition/change is underlined):

Policy 1252.0F Controlled Substances Used Concurrently with Buprenorphine:

- The prescription for the oral buprenorphine agent and the other controlled substance(s) are written by the same prescriber and the other controlled substance(s) are medically necessary **OR**
- There is medical record documentation that, if the oral buprenorphine agent and other controlled substance(s) are written by different prescribers, that all prescribers are aware of the other prescription(s) and the other controlled substance(s) are medically necessary.

Policy 1262.0F Orenitram (New labeling allows for the conversion from injection to oral dosing):

- Prescription is written by a cardiologist or pulmonologist **AND**
- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation of WHO Group 1 pulmonary arterial hypertension **AND**
- Medical record documentation of WHO functional class II or III symptoms **AND**
- Medical record documentation of a baseline 6-minute walking distance **AND**
- Medical record documentation that Orenitram is NOT being used in combination with endothelin receptor antagonists (ambrisentan [Letairis], bosentan [Tracleer], or macitentan [Opsumit]) or PDE5 inhibitors (sildenafil [Revatio] or tadalafil [Adcirca]) unless transitioning to Orenitram and the other medication will be discontinued after transition is complete OR the provider can provide clinical justification for remaining on both therapies **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, contraindication to Uptravi (requires prior authorization)

AUTHORIZATION DURATION: Orenitram will require reauthorization every 6 months. For reauthorization, the following criteria should apply:

- Medical record documentation of a 6-minute walking distance improved from baseline or of improved or stable diagnosis of WHO functional class **AND**
- Medical record documentation that Orenitram is NOT being used in combination with endothelin receptor antagonists (ambrisentan [Letairis], bosentan [Tracleer], or macitentan [Opsumit]) or PDE5 inhibitors (sildenafil [Revatio] or tadalafil [Adcirca]) unless transitioning to Orenitram is complete and the provider can provide clinical justification for remaining on both therapies

Policy 1267.0F Grastek:

• Prescription is written by an allergist or a prescriber qualified to prescribe immunotherapy **AND**

• Medical record documentation of age greater than or equal to 5 years and less than or equal to 65 years **AND**

• Medical record documentation of Timothy grass pollen or cross-reactive grass pollen induced allergic rhinitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies **AND**

• Medical record documentation of therapeutic failure on, intolerance to, or contraindication to loratadine, cetirizine, fexofenadine **AND** Levocetirizine***AND**

• Medical record documentation that member will no longer be receiving injectable allergy shots **AND**

• Medical record documentation that Grastek will not be used in combination with

Ragwitek or Oralair.

Quantity Limit: 1 tablet per day for 34 days and 180 tablets per 365 days

Note: Grastek may be taken daily for 3 consecutive years (including intervals between grass pollen seasons).

Policy 1302.0F Lenvima (NCCN now recommends Lenvima for use in predominant clear cell histology [Category 1] and non-clear cell histology [Category 2A]):

Renal Cell Carcinoma

- 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 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)

Discussion: No comments or questions

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

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

Non-Schedule II Opioid Alternatives

In order to increase access and utilization of non-schedule II opioid medications, the following changes are recommended:

Buprenorphine Patch

	Current Formulary Status
GHP Family	Non-Formulary, QL 4 patches per 28 days

Buprenorphine Patch is the only schedule III transdermal extended-release opioid. While there is still potential for abuse, physical dependence, or psychological dependence, the risk is less than that of schedule II products. It is recommended that buprenorphine patch be added to the GHP Family formulary on the generic tier and prior authorization requirements are removed for all other lines of business. Existing quantity limits should continue to apply.

Diclofenac 1% Gel

	Diclofenac 1% Gel
GHP Family	Generic, PA

A quantity limit of 300 grams per 30 days should apply.

Discussion: **The above recommendations were approved electronically by the P&T Committee on October 19, 2017 with 25 votes of approval.**

Meeting adjourned at 4:26 pm.

Future Scheduled Meetings
Tuesday, January 16, 2018 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.