

**P&T Committee Meeting Minutes**  
**Medicaid**  
**November 19, 2019**

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

Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, November 19, 2019.

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**Review and Approval of Minutes:**

Dr. Bret Yarczower asked for a motion or approval to accept the September 17, 2019 minutes as written. Keith Hunsicker accepted the motion and Tricia Heitzman seconded the motion. None were opposed.

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**DRUG REVIEWS**

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The following quantity limits were presented and approved:

<b>Drug</b>	<b>Dosage Form</b>	<b>Formulary Therapeutic Recommendation</b>	<b>Outcome</b>
Sunosi	Tablets	Add QL of 1 per day	No comments or questions. Todd Sponenberg made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.
Rozlytrek	Capsules	Add QL of: 100 mg: 1 per day; 200 mg: 3 per day. 30 day supply	No comments or questions. Tricia Heitzman made a motion to accept the recommendations as presented. Keith Hunsicker seconded the motion. None were opposed.
Inrebic	Capsules	Add QL: 4 per day, 30 day supply	No comments or questions. Todd Sponenberg made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.
Nayzilam	Nasal spray	Add QL: 10 nasal spray units per 30 days	No comments or questions. Keith Hunsicker made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.
Nuzyra	Tablets	Add QL of 30 tablets per 14 days	No comments or questions. Kevin Szczecina made a motion to accept the recommendations as amended. Tricia Heitzman seconded the motion. None were opposed

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**ASPARLAS (calaspargase pegol- mknl)**

**Review:** Asparlas is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) in pediatric and young adult patients age 1 month to 21 years. Asparlas is available as 3,750 units/ 5 mL (750 units/mL) clear, colorless solution in a single-dose vial. The recommended dose of Asparlas is 2,500 units/m<sup>2</sup> given intravenously no more frequently than every 21 days.

Asparlas is the 2<sup>nd</sup> pegylated asparaginase product, joining Oncaspar, specifically designed to offer an extended interval between doses. Oncaspar can be administered IV or IM every 2 weeks while Asparlas is administered IV every 3 weeks. Oncaspar has dosing recommendations for patients older than 21 and less than 21

years of age. Asparlas has dosing recommendations for patients  $\geq 1$  month to  $\leq 21$  year of age. Erwinaze is a short-acting asparaginase product specifically indicated for the treatment (in combination with other chemotherapy) of ALL in patients with hypersensitivity to *E. coli*-derived asparaginase. Erwinaze has dosing recommendations for patients 1 year and older.

The efficacy was based on a demonstration of the achievement and maintenance of nadir serum asparaginase activity (NSAA) above the level of 0.1 U/mL using Asparlas 2500 U/m<sup>2</sup> IV every 3 weeks. The pharmacokinetics of Asparlas were studied when used in combination with multiagent chemotherapy in 124 patients with B cell lineage ALL. The results showed that 99% of patients maintained NSAA  $> 0.1$  U/mL at weeks 6, 12, 18, 24, and 30.

Asparlas is contraindicated in patients with history of serious hypersensitivity reactions to pegylated L-asparaginase therapy, history of serious thrombosis, history of serious pancreatitis, and history of serious hemorrhagic events (all during previous L-asparaginase therapy) and severe hepatic impairment. There are warnings and precautions for hypersensitivity reactions, pancreatitis, thrombosis, hemorrhage, and hepatotoxicity. The most common grade  $\geq 3$  adverse reactions were elevated transaminase, bilirubin increased, pancreatitis and abnormal clotting studies. Females should use effective contraceptive methods, including a barrier method, during treatment and for at least 3 months after the last dose of Asparlas. Lactating women should not breastfeed while receiving Asparlas and for 3 months after the last dose. The safety and effectiveness have been established in pediatric patients 1 month to  $< 17$  years.

Several different multi-agent treatment regimens are recommended. L-asparaginase is a key component of first line treatment regimens for all ALL patients. It serves as a backbone therapy in all pediatric and most adult ALL regimens. There are three forms of asparaginase in clinical use: 1) pegaspargase (PEG), 2) Calaspargase pegol-mknl (CALPEG), 3) asparaginase Erwinia chrysanthemi (Erwinia). PEG is a common component of therapy for children, adolescents, and young adults with ALL. Per NCCN, for ALL and pediatric ALL, Asparlas can be substituted for pegaspargase in patients age 1 month to 21 years for more sustained asparaginase activity.

Amy Ellenburg, hematology/oncology clinical pharmacist for Geisinger mentioned that the role of Asparlas is unclear in terms of treating pediatric patients and adults up to 21 years. She mentioned that the FDA approval came from a phase 1 study showing similar PK/PD and has not been incorporated in standard of care treatment for pediatric-inspired ALL. In theory, Asparlas is an alternative. She also mentioned that Asparlas cannot be used if the patient has a history of reaction to pegaspargase and there is no information to say that it is safe to give pegaspargase after reaction to Asparlas. Therefore, she does not feel it would be clinically appropriate to require failure on both agents prior to Erwinaze. The system did not add Asparlas to formulary due to the unclear role in pediatric population.

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:** Bret asked if this would only be used in the inpatient setting. Aubrielle stated this could be used either as inpatient or outpatient setting, but usually in the outpatient setting. No further comments or questions. Todd Spenberg made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

**Financial Discussion:** Tricia Heitzman suggested looking at utilization of Oncaspar, and to consider adding UM if needed. No further comments or questions. Keith Hunsicker made a motion to accept the recommendations as presented. Todd Spenberg seconded the motion. None were opposed.

**Outcome:** Servier Pharma LLC is currently non-participating with CMS. For that reason, Asparlas will be excluded for GHP Family. Asparlas will be covered as a medical benefit when it becomes Medicaid eligible.

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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## NUZYRA (omadacycline)

**Review:** Nuzyra is a semi-synthetic derivative of tetracycline with a broad spectrum of antibacterial activity including against Gram-positive, Gram-negative, aerobes and anaerobes, and atypical pathogens. It is indicated for the treatment of community-acquired bacterial pneumonia (CABP) caused by *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydia pneumoniae* and for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, and *Klebsiella pneumoniae*. Nuzyra has been shown to be effective against bacterial strains with resistance specific to the tetracycline class as well as strains with resistance to other antibiotic classes used in the treatment of ABSSSI. The risk of developing drug-resistant bacteria is increased when Nuzyra is prescribed in the absence of a proven or strongly suspected bacterial infection.

The efficacy of Nuzyra for the treatment of adult patients with CABP was investigated in the OPTIC study, a double-blind, double-dummy, randomized non-inferiority trial comparing 7 to 14 days of treatment with Nuzyra to moxifloxacin. Patients received the IV loading dose of Nuzyra, following by the IV maintenance dose with the option to transition to the oral maintenance dose after 3 days of treatment. The primary efficacy endpoint evaluating early clinical response (improvement in two or more symptoms at 72 to 120 hours after initiation of treatment) showed Nuzyra was non-inferior to moxifloxacin with response rates of 81.1% and 82.7%, respectively. The clinical responses were sustained as shown by secondary endpoints assessing clinical response at the end of treatment and at a post-treatment evaluation (5-10 days after last dose of treatment). Response rates were comparable between treatment groups for all subgroups, with the exception of patients who had a Pneumonia Outcomes Research Team (PORT) risk class IV and in patients  $\geq 65$  years indicating that patients with a higher severity of illness may have a lower clinical response rate to Nuzyra treatment. There was also a morbidity imbalance observed in the OPTIC trial with 8 deaths occurring in the Nuzyra treatment group compared to only 4 deaths in the moxifloxacin group. All deaths occurred in patients over age 65 with various causes of death, including worsening or complications of infection and underlying conditions, but the cause of the mortality imbalance could not be determined.

The efficacy of Nuzyra in the treatment of adult patients with acute bacterial skin and skin structure infections was shown in two randomized, double-blind, double dummy trials, OASIS-1 and OASIS-2, which compared 7-14 days of Nuzyra treatment to linezolid. In OASIS-1, patients received the IV loading dose, followed by the IV maintenance dose, with the option to transition to the oral maintenance dose after 3 days of treatment. In the OASIS-2 trial, patients received the oral loading dose followed by the oral maintenance dose for the duration of treatment. The primary efficacy endpoint evaluating early clinical response (20% or greater decrease in lesion size 48 to 72 hours after the first dose) showed that Nuzyra was non-inferior to linezolid in patients who had at least one gram-positive bacterial pathogen identified at baseline (modified intention to treat population). Nuzyra had sustained efficacy as seen in secondary endpoints evaluation clinical response at a post-treatment evaluation (7 to 14 days after the last treatment dose).

The safety profile appears to be consistent with the known safety profile of the tetracycline class. The most frequently reported adverse reactions reported during clinical trials were gastrointestinal events (nausea, vomiting, and diarrhea), infusion site reactions, headache, insomnia, and increased alanine aminotransferase (ALT).

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, and Other Considerations and a Financial Review Based on Cost Analysis were presented. For Geriatric members, no significant difference in Nuzyra exposure was observed between healthy elderly subjects and younger patients following a single 100 mg IV dose of Nuzyra. In the OPTIC trial, patients  $\geq 65$  years of age had numerically lower clinical success rates at the early clinical response timepoint compared to patients  $< 65$  years of age. Additionally, all deaths that occurred during the OPTIC trial occurred in patients  $> 65$  years of age.

**Clinical Discussion:** Tricia Heitzman recommended modifying the medical quantity limit to 1500 units. No further comments or questions. Kevin Szczecina made a motion to accept the recommendations as amended. Tricia Heitzman seconded the motion. None were opposed.

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

**Outcome:** Nuzyra vials will be a medical benefit. Nuzyra tablets will be included in DHS's Statewide Preferred Drug List and will not be managed by GHP Family.

**QUANTITY LIMIT:** Vials: 15 vials per 14 days

**AUTHORIZATION DURATION:** 14 days

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

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### **TRIPTODUR (triptorelin)**

**Review:** Triptodur is indicated for the treatment of pediatric patients 2 years and older with central precocious puberty (CPP). Triptorelin is a gonadotropin-releasing hormone (GnRH) agonist. It is also available as Trelstar, which is indicated for the palliative treatment of advanced prostate cancer.

Triptodur is available as 22.5 mg single-use kit. Triptodur must be administered under the supervision of a physician. The recommended dose is 22.5 mg administered as a single intramuscular injection once every 24 weeks. Triptodur should be discontinued at the appropriate age of onset of puberty at the discretion of the physician. The response to Triptodur should be monitored with LH levels after a GnRH or GnRH agonist stimulation test, basal LH, or serum concentration of sex steroid levels 1 to 2 months following initiation of therapy, during therapy, and with each subsequent dose. Height should be measured every 3-6 months and bone age should be monitored periodically. If the dose of Triptodur is not adequate switching to an alternative GnRH agonist for the treatment of CPP with the ability for dose adjustment may be necessary.

Triptodur was studied in a single-arm, open-label trial of 44 patients with CPP. All the patients were naïve to GnRH agonist treatment. Patients were administered Triptodur 22.5 mg every 24 weeks and evaluated over 2 dosing intervals for a total of 12 months. At all time points,  $\geq 93\%$  of children achieved LH suppression to prepubertal levels,  $\geq 79\%$  of girls achieved prepubertal levels of estradiol, and  $\geq 80\%$  of boys achieved prepubertal levels of testosterone. Triptodur stopped or reversed progression of clinical signs of puberty with 95% of children showing no increase in bone age/chronological age ratio, and 89% showing stabilization of sexual maturation at Month 12. 1 out of 22 girls experienced an acute-on chronic phenomenon (increase in basal LH or estradiol levels after the second triptorelin injection).

Triptodur is contraindicated in individuals with a known hypersensitivity to triptorelin, any component of the product, or other GnRH agonists or GnRH. Triptodur is also contraindicated in pregnancy because it may cause fetal harm. Triptodur may cause an initial rise of gonadotropins and sex steroid levels. Psychiatric events have been

reported. Postmarketing reports of convulsions have been observed in patients receiving GnRH agonists. The most common adverse reactions ( $\geq 4.5\%$ ) are injection site reactions, menstrual bleeding, hot flush, headache, cough, and infections. The safety and effectiveness has not been established in pediatric patients less than 2 years old.

There have been no direct studies to compare the different sustained-release formulations of GnRH agonists. The choice of GnRH agonist depends on preference. Supprelin LA (histrelin implant) is administered once every 12 months. Lupron (leuprolide acetate) can be given monthly or every 12 weeks, depending on the strength and dosage form. Goserelin acetate 3.6 mg is given once every 28 days. Goserelin acetate 10.8 mg is given once every 12 weeks. Goserelin is not FDA approved for CPP. Triptodur is administered once every 24-weeks. Nafarelin (Synarel ©) is available as a daily intranasal spray. Typically, depot preparations are preferred because of increased compliance, however for certain situations (e.g. such as the development of sterile abscesses), daily preparations can be used as an alternative.

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:** Bret asked if prescriber should be limited to endocrinologist. Nobody was opposed. No further comments or questions. Keith Hunsicker made a motion to accept the recommendations as amended. Tricia Heitzman seconded the motion. None were opposed.

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

**Outcome:** Triptodur will be covered as a medical benefit for GHP Family members. Triptodur will require a prior authorization with the following criteria.

- Medical record documentation that medication is prescribed by or in consultation with an endocrinologist.
- Medical record documentation of a diagnosis of central precocious puberty AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Lupron Depot-Ped

Quantity Limit: 1 vial per 168 days

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

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## FAST FACTS

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**The following quantity limits were presented and approved:**

Drug	Dosage Form	Formulary Therapeutic Recommendation	Outcome
Doptelet	Tablets	Add QL for cITP: 2 per day	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

Fasenra	Pen	Add QL: initially 1 mL per 28 days for 3 months, 1 mL per 56 days thereafter	Kevin Szczecina made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed. Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.
Nucala	Pens, vials, Autoinjector	Add QL: 3 per 28 days	Tricia Heitzman made a motion to accept the recommendations as presented. Todd Sponenberg seconded the motion. None were opposed.

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### ZERBAXA (ceftolozan/tazobactam)

**Updated Indication:** Zerbaxa is now indicated for the treatment of patients 18 years of age or older with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by designated susceptible gram-negative microorganisms (*Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, and *Serratia marcescens*).

Previously the use of Zerbaxa was limited to the treatment of adult patients with complicated intra-abdominal infections and complicated urinary tract infections (including pyelonephritis).

**Current Medicare formulary placement:** Pharmacy benefit on the specialty tier without PA or medical benefit without PA

**Recommendations:** In clinical trials, Zerbaxa was proven non-inferior to alternative antibiotics for the treatment of HABP/VABP as well as complicated intra-abdominal infections. In clinical trials, Zerbaxa was proven superior to levofloxacin for the treatment of complicated urinary tract infection; however, this was likely attributable due to 26.5% of levofloxacin treated patients having baseline organisms resistant to levofloxacin. The Johns Hopkins Antibiotics Guide does not list Zerbaxa as a first- or second-line treatment option for HABP/VABP or cIAI. Zerbaxa is listed as a second line option for cUTI by the guide. In terms of cost, there are more cost-effective regimens available compared to Zerbaxa (pending cultures and susceptibilities).

Based on the discussion above, it is recommended that a prior authorization be added to Zerbaxa for all lines of business. Zerbaxa will remain a pharmacy or medical benefit for Geisinger Gold. It is recommended that the following prior authorization criteria apply.

#### Prior Authorization Criteria:

- Prescription is written by or in consultation with Infectious Disease **AND**
- Medical record documentation that the member is greater than or equal to 18 years of age **AND**
- Medical record documentation of one of the following:
  - Diagnosis of Complicated Intra-abdominal Infection (cIAI) caused by: *Enterobacter cloacae*, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Bacteroides fragilis*, *Streptococcus anginosus*, *Streptococcus constellatus*, or *Streptococcus salivarius* **OR**

- Diagnosis of Complicated Urinary Tract Infection (including Pyelonephritis) (cUTI) caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, or *Pseudomonas aeruginosa* **OR**
- Diagnosis of Hospital-acquired Bacterial Pneumonia or Ventilator-associated Bacterial Pneumonia (HABP/VABP) caused by *Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, or *Serratia marcescens*.
- Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to preferred alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to two (2) preferred alternative antibiotics shown to be susceptible on the culture and sensitivity

**Authorization Duration:**

For cUTI: 7 days

For cIAI or HABP/VABP: up to 14 days

**Discussion:** Aubrielle suggested adding a quantity limit to the criteria (based on max dose; 6 vials/day). No comments or questions

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as amended. 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

**SOLIRIS (eculizumab)**

**Updated Indication:** Soliris is now indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

**Current Formulary Status/Prior Authorization Criteria:** Medical Benefit requiring prior authorization or a non-formulary pharmacy benefit

**Recommendations:** No changes are recommended to the current formulary placement of Soliris. It is recommended to add the following prior authorization criteria to Medical Benefit Policy 54.0 to include the new indication:

**4. Neuromyelitis Optica Spectrum Disorder (NMOSD)**

- Prescribed by or in consultation with a neurologist
- Medical record documentation that member is 18 years or older **AND**
- Medical record documentation of diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) **AND**
- Medical record documentation that member is anti-Aquaporin-4 (AQP4) antibody positive **AND**
- Medical record documentation of failure on intolerance to, or contraindication to Rituxan.

**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 patient experiences toxicity or worsening of disease.



It is recommended to make the following change to the existing policy to include the new indication.

1. Medical record documentation of a diagnosis of:

- paroxysmal nocturnal hemoglobinuria (PNH) OR
- atypical hemolytic uremic syndrome (aHUS) OR
- myasthenia gravis in members 18 years and older who are anti-acetylcholine (AchR) antibody positive
- Neuromyelitis Optica Spectrum Disorder (NMOSD) in members 18 years and older who are anti-aquaporin-4 (AQP4) antibody positive.

**Discussion:** No comments or questions.

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

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

**SYMDEKO (tezacaftor/ivacaftor)**

**Updated Indication:** Symdeko is indicated for the treatment of patients with cystic fibrosis (CF) age 6 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence, see Table 1.

Note: Previously, Symdeko was only indicated for patients 12 years and older.

**Table 1. List of CFTR Gene Mutations that Produce CFTR Protein and are Responsive to Symdeko– (from Symdeko Prescribing Information)<sup>1</sup>**

<i>P67L</i>	<i>E193K</i>	<i>F508del*</i>	<i>S977F</i>	<i>F1074L</i>	<i>3849+10kbC→T</i>
<i>R74W</i>	<i>L206W</i>	<i>D579G</i>	<i>F1052V</i>	<i>D1152H</i>	
<i>D110E</i>	<i>R347H</i>	<i>711+3A→G</i>	<i>K1060T</i>	<i>D1270N</i>	
<i>D110H</i>	<i>R352Q</i>	<i>E831X</i>	<i>A1067T</i>	<i>2789+5G→A</i>	

\*A patient must have two copies of the F508del mutation or at least one copy of a responsive mutation presented in Table 1 to be indicated.

This list is based on a clinical FEV<sub>1</sub> response and/or *in vitro* data.

Note: *CFTR* gene mutations that are not responsive to ivacaftor alone are not expected to respond to Symdeko except for F508del homozygotes.

**How Supplied:** Symdeko is now available as tezacaftor 50 mg/ ivacaftor 75 mg fixed-dose combinations and ivacaftor 75 mg tablets. Previously, it was only available as tezacaftor 100 mg/ivacaftor 150 mg fix-dosed combination tablets and ivacaftor 150 mg tablets.

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

**Recommendation:** There is no change recommended to formulary status at this time. The current age restriction reflects the updated indication, so there is no update to the policy.

**Discussion:** No comments or questions.

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

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

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**KEYTRUDA (pembrolizumab) AND LENVIMA (lenvatinib)**

**Updated Indication:** Keytruda and Lenvima, used in combination, are indicated, under accelerated approval, for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation.

Previously, neither product was indicated for the treatment of endometrial carcinoma. Both products maintain their previously approved indications.

**Current Formulary Status:** Keytruda is a medical benefit requiring prior authorization. Lenvima is covered under the Statewide PDL and not managed by GHP Family.

**Recommendation:** No changes are recommended to the formulary placement of Keytruda at this time. It is recommended that the current Keytruda policy be updated to account for the updated indication.

For Keytruda:

**Endometrial Carcinoma**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of advanced endometrial carcinoma **AND**
- Medical record documentation of disease progression following at least one prior systemic therapy **AND**
- Medical record documentation that patient is not a candidate for curative surgery or radiation **AND**
- Medical record documentation that tumors are **not** microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) **AND**
- Medical record documentation that Keytruda will be given in combination with lenvatinib (Lenvima)

**Discussion:** No comments or questions.

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

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

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**DARZALEX (daratumumab)**

**Updated Indication:** Darzalex is now indicated for the treatment of adult patients with multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone (DVTd) in newly diagnosed patients who are eligible for autologous stem cell transplant (ASCT).

Previously, the use of Darzalex in newly diagnosed multiple myeloma patients was limited to patients not eligible for stem cell transplant

**Current Formulary Status:** medical benefit requiring PA

**Recommendation:** No changes are recommended to the formulary placement of Darzalex at this time. It is recommended that the prior authorization criteria are changed as outlined below to account for the updated indication.

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation a diagnosis of multiple myeloma **AND**

If newly diagnosed multiple myeloma (transplant **ineligible**):

- Medical record documentation that the member is not eligible for stem-cell transplantation (e.g. coexisting conditions, age greater than 65, etc.) **AND**
- Medical record documentation that Darzalex will be given in combination with one of the following options:
  - Bortezomib (Velcade), melphalan, AND prednisone [VMP] **OR**
  - Lenalidomide (Revlimid) AND dexamethasone

**OR**

If newly diagnosed multiple myeloma (transplant **eligible**):

- Medical record documentation that the member is eligible for stem-cell transplantation AND
- Medical record documentation that Darzalex will be given in combination with bortezomib (Velcade), thalidomide, and dexamethasone (DVTd)

**OR**

If relapsed/refractory multiple myeloma:

- One of the following:
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three prior lines of therapy including a proteasome inhibitor (including but not limited to Velcade\*, Kyprolis\*, or Ninlaro\*) and an immunomodulatory agent (including but not limited to Pomalyst\*, Revlimid\*, Thalomid\*) **OR**
  - Medical record documentation that the patient is double-refractory to a proteasome inhibitor (including but not limited to Velcade\*, Kyprolis\*, or Ninlaro\*) and an immunomodulatory agent (including but not limited to Pomalyst\*, Revlimid\*, Thalomid\*) **OR**
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 1 prior therapy including a proteasome inhibitor (including but not limited to Velcade\*, Kyprolis\*, or Ninlaro\*) or an immunomodulatory agent (including but not limited to Pomalyst\*, Revlimid\*, Thalomid\*) **AND** one of the following:
    - Medical record documentation that Darzalex will be prescribed in combination with lenalidomide and dexamethasone **OR**
    - Medical record documentation that Darzalex will be prescribed in combination with bortezomib and dexamethasone

**Discussion:** No comments or questions.

**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.

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## **RITUXAN (rituximab)**

**Updated Indication:** Rituxan is now indicated in adult and pediatric patients 2 years of age and older in combination with glucocorticoids for the treatment of Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA).

Previously, this indication was restricted to the adult population.

**Current Formulary Status:** medical benefit requiring PA

**Recommendation:** No changes are recommended to the formulary placement of Rituxan at this time. The diagnosis of Wegner's Granulomatosis is already addressed by the applicable Rituxan policies. Age is not restricted by those policies. It is recommended that MBP 48.0 be updated as follows to further clarify covered diagnoses.

5. **For Granulomatosis with Polyangiitis (GPA) (Wegner's Granulomatosis) and Microscopic Polyangiitis (MPA)**

- Medical record documentation of a diagnosis of Granulomatosis with Polyangiitis (GPA) (Wegner's granulomatosis) or Microscopic Polyangiitis (MPA) used in combination with glucocorticoids

**Discussion:** No comments or questions.

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

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

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## **UPDATES**

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### **GATTEX – policy update**

**Current Policy Criteria:**

- Patient must be 1 year of age or older **AND**
- Must be prescribed by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of short bowel syndrome **AND**
- Medical record documentation that the member has been dependent on parenteral nutrition/intravenous support for a minimum of 12 consecutive months continuously **AND**
- Medical record documentation that the member requires parenteral nutrition at least 3 times per week.

**Recommendation:** The study inclusion criteria for adults was to be an adult with SBS who was dependent on parenteral nutrition/intravenous (PN/I.V.) support for at least 12 months and required parenteral nutrition at least 3 times per week. However, the study inclusion criteria for pediatrics included those aged 1 year through 17 years with SBS who were dependent on parenteral support. It is recommended to update the criteria to the following for all LOB:

- Prescription is written by a gastroenterologist **AND**
- Member is  $\geq 1$  year of age **AND**
- Medical record documentation of a diagnosis of short bowel syndrome **AND**

If age 1 to 17 years of age:

- Medical record documentation that the member is dependent on parenteral nutrition/intravenous support

If age  $> 18$  years of age:

- Medical record documentation that the member has been dependent on parenteral nutrition/intravenous support for a minimum of 12 consecutive months continuously **AND**
- Medical record documentation that the member requires concurrent parenteral nutrition at least three days per week

It is also recommended that the authorization/reauthorization criteria for **GHP Family** be updated to:

If approved, authorization will be for an initial duration of six (6) months. For continuation, medical record documentation of a decrease of at least 20% volume of parenteral nutrition/intravenous support from baseline, enteral autonomy, or reduction in parenteral support infusion of  $\geq 1$  day per week is required.

After the initial six (6) month approval, subsequent approvals will be for the duration of one (1) year. Reevaluation will be every (1) year requiring medical record documentation of sustained improvements in the volume of parenteral nutrition/intravenous support that the member requires while on Gattex therapy, enteral autonomy, or continued reduction in parenteral support infusion of  $\geq 1$  day per week.

**Discussion:** No comments or questions.

**Outcome:** Tricia Heitzman 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.

### **Freestyle Libre**

FreeStyle Libre is a continuous glucose monitoring (CGM) device indicated for replacing blood glucose testing and detecting trends and tracking patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments in persons (age 18 and older) with diabetes. The systems are intended for single patient use and require a prescription.

In order to improve access to members and to provide an alternative to the traditional fingerstick glucose monitoring system, it is recommended that Freestyle Libre be added to the GHP Family formulary on the Brand Tier requiring a prior authorization. The following prior authorization, and quantity limit criteria are recommended:

Prior Authorization Criteria:

- Medical record documentation of type 1 or 2 diabetes mellitus **AND**
- Medical record documentation of member age greater than or equal to 18 years **AND**
- One of the following:
  - Medical record documentation of current insulin therapy use **OR**
  - Medical record documentation of functional barriers to finger stick blood glucose monitoring **OR**
  - Medical record documentation of history of recurrent hypoglycemia episodes **OR**
  - Medical record documentation of HgA1c greater than 9

Quantity Limit:

- Freestyle Libre 10 or 14 day reader: 1 reader every 2 years
- Freestyle Libre 10 day sensors: 3 sensors per 30 days (quantity limit by ratio)
- Freestyle Libre 14 day sensors: 2 sensors per 28 days (quantity limit by ratio)

**Discussion:** No comments or questions.

**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.

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Meeting adjourned at 4:25 pm.

**Future Scheduled Meetings**

An electronic P&T meeting will be held sometime in December.

The next bi-monthly scheduled meeting will be held on Tuesday, January 21, 2019 at 1:00 HCN3A & 3B Conference room

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