# ALASKA MEDICAID
# PHARMACY AND THERAPEUTICS COMMITTEE

**Location of Meeting**
**Frontier Building, 3601 C Street, Room 890/896**

## MINUTES OF MEETING
**January 18, 2019**
**8:00 a.m.**

**Committee Members Present:**
Jenna Hiestand, MD, Chair
Sarah Doran Atchison, PharmD (telephonic)
Vincent Greear, MD (telephonic)
Claudia Phillips, MD (telephonic)
John Riley, PA (telephonic)
Ryan Ruggles, PharmD
Charles Ryan, MD
Trish White, R.Ph. (telephonic)

**Committee Members Absent:**
Robert Carlson, MD (excused)

**Others Present:**
Erin Narus, PharmD, State of Alaska
Charles Semling, PharmD, R.Ph.
Umang Patel, PharmD, R.Ph., Magellan Medicaid Administration
Marti Padilla, R.Ph., Magellan Medical Administration
Colette Grower, Kron Associates

Dr. Umang Patel announced that the new committee chair was Dr. Jenna Hiestand.

### 1. Call to Order – Chair

Dr. Hiestand called the meeting to order at 8:00 a.m.

### 2. Roll Call

The roll call was taken, and a quorum was present.

### 3. Public Comments - Local Public/Health Practitioners

There were no local public/health practitioner comments.

## 4. Class Review, Discussion & Vote

**4-A. Respiratory:** COPD Agents (Red Class); Glucocorticoids, Inhaled, Single Entity (Blue Class); Glucocorticoids, Inhaled, Combination (Red Class); Beta Agonists Bronchodilators, Long (Green Class); Beta Agonists Bronchodilators, Short (Green Class)

***Public Comments for Respiratory: COPD Agents (Red Class)***

**NICOLAS NGUYEN**, a representative of Sunovion, discussed Lonhala Magnair. It is the first and only nebulized LAMA indicated for the long-term, twice-daily, maintenance treatment of COPD. It is not a rescue medication. It is available as a 1 mL, single-use vial containing a solution of 25 micrograms of Glycopyrrolate for use by nebulization with a Magnair device, which is a closed system designed for use with Lonhala pre-filled vials only. It is virtually silent, portable, and designed to deliver Lonhala in two to three minutes with normal breathing. It may be an acceptable option for patients with PIFR, lower inspiratory flow rate and other issues. Several trials/studies and their outcomes were reviewed. The most common adverse events were dyspnea and urinary tract infections. We request that Lonhala Magnair be added to the PDL because the health outcomes and clinical data for provides a treatment option with high potential value.

**JULIE MCDAVITT**, a representative of Boehringer Ingelheim, discussed Spiriva Respimat, which is Tiotropium a long-acting, antimuscarinic antagonist, as well as Stiolto Respimat, which is a combination of Tiotropium and Olodaterol, a long-acting beta agonist. Please see the package insert for the safety and efficacy data. Last October, the FDA approved new labeling for Stiolto Respimat that includes data showing a reduction in COPD exacerbations. The FDA also broadened the indication for the treatment of COPD, rather than the previous indication for airflow limitation in patients with COPD. The revised language illustrates that the medication does more than just improve airflow. From a safety perspective, the safety data remains consistent. There is no clear evidence that one mode of delivery for COPD patients is superior. Each inhaler has different attributes and patients have various characteristics that impact direct delivery. Patients with COPD have damaged lungs, and many cannot forcefully inhale. As patients age, the severity of COPD progresses, and lung function is impacted. Many inhalers require patients to forcefully inhale to optimally activate. Dry powder inhalers are breath-actuated and optimal flow is required to properly deliver the medication. There must be enough turbulent airflow, or peak inspiratory flow, to separate the drug molecule from the carrier or the medication cannot get to where it needs to go. The Respimat inhaler is a hand-held, pocket-sized device that actively delivers a slow-moving mist. Unlike dry powder inhalers, Respimat works independent of inspiratory effort or peak inspiratory flow rate. Therefore, it works in lungs that may not work. Based on the robust safety and efficacy data of Spiriva and Stiolto Respimat, we request that they be included on the PDL.

**CRAIG SEXTON**, a representative of GlaxoSmithKline, discussed GSK's portfolio of COPD products. Please refer to the full prescribing information for safety and efficacy information. According to the 2017 Gold Guidelines on COPD on average more than two-thirds of patients make at least one error in using an inhalation device. The key differentiator of the Ellipta portfolio is that all of the medications are delivered in one inhalation and once daily via an easy-to-use Ellipta device. The Ellipta portfolio is the only products in the COPD/asthma space that offer this continuity of dosing and device across all COPD and asthma indications. Trelegy Ellipta was initially proved in September 2017. It is a combination of Fluticasone, Furoate, Umeclidinium and Vilanterol. Trelegy Ellipta is

indicated for the long-term, once-daily, maintenance treatment of COPD including bronchitis and emphysema for airflow obstruction and for patients with a history is exacerbations. Several trials and their outcomes were reviewed. We request that Trelegy Ellipta be included on the PDL as a preferred agent.

Dr. Umang Patel read a letter from Beth Baker advocating for the inclusion of Spiriva Respimat and Stiolto Respimat on the PDL.

In response to Dr. Hiestand, Dr. Umang Patel said both Spiriva Respimat and Stiolto Respimat were currently on the PDL. *These drugs are covered outpatient drugs on the proposed PDL.*

Dr. Umang Patel reminded the committee that the drugs in the classes were divided into three categories. The red class means there are new medication and it is open to provider testimony. The blue class means there is new significant information and it is open to provider testimony. The green class means there is no new significant information and it is not open to provider testimony.

Dr. Umang Patel gave the Magellan presentation on Respiratory: COPD Agents. Chronic obstructive pulmonary disease (COPD) is a disease state characterized by the presence of airflow obstruction due to chronic bronchitis or emphysema. The airflow obstruction is generally progressive, it may be accompanied by airway hyperreactivity, and it may be partially reversible. This progressive persistent obstruction or limitation of airflow is associated with an enhanced chronic inflammatory response in both the airways and the lung to noxious particles or gases. Exacerbations and comorbidities contribute to the overall severity in individual patients. COPD continues to be a leading cause of chronic morbidity and mortality worldwide carrying with it significant economic and social burdens. COPD is projected by the World Health Organization to become the third leading cause by 2030. In the 2015 National Health Interview Survey, the CDC reported that the percentage of adults who were diagnosed with chronic bronchitis in the past year was 3.8% and those that have ever been diagnosed with emphysema was 1.5%.

The guidelines from the Global Initiative for Chronic Obstructive Lung Disease (GOLD) and the European Respiratory Society/American Thoracic Social Joint Guidelines were reviewed.

The new drugs in the class were reviewed. Glycopyrrolate (Lonhala Magnair) is indicted for the long-term, maintenance treatment of airflow obstruction in patients with COPD. The most common adverse effects include dyspnea and urinary tract infections. Dosing guidelines were reviewed. It is available as a 25 mcg per 1 mL starter kit containing 60-unit-dose vials and one Magnair nebulizer or refill kit containing 60 unit-dose vials and a Magnair handset refill. Revefenacin (Yulperi) is indicated for the maintenance treatment of airflow obstruction in patients with COPD. Do not initiate in acutely deteriorating COPD or to treat acute symptoms. If paradoxical bronchospasm occurs, discontinue Yupelri and institute an alternative therapy. Worsening of narrow-angle glaucoma may occur. Use with caution in patients with narrow-angle glaucoma and instruct patients to contact a healthcare provider immediately. Dosage recommendations were reviewed. It is available in an inhalation solution in a unit-dose vial for nebulization.

Roflumilast (Daliresp) is indicated as a treatment to reduce the risk o COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. Warnings and precautions include moderate to severe liver impairment. Do not use for the relief of acute

bronchospasm. Advise patients to be alert for the emergency or worsening of insomnia, anxiety, depression, suicidal throughs or other mood changes, and if such changes occur to contact their healthcare provider. Carefully weigh the risks and benefits of treatment with Daliresp in patients with a history of depression and/or suicidal thoughts or behavior. Dosing recommendations were reviewed. It is available as a tablet and is to be taken with or without food.

The utilization report was reviewed and 99.7% of the prescriptions were for preferred agents. At the last review, a motion for therapeutic alternatives to include at least one product from each subclass, as well as a grandfather clause for patients already using Spiriva, passed unanimously.

Dr. Ryan asked the committee if they felt Lonhala Magnair should be added to the PDL. Dr. Ruggles said he read an article that said the mist-type delivery systems, especially nebulizers, penetrate a little bit better. Dr. Greear said Lonhala Magnair had a unique delivery system with its own nebulizer solution and device, but it might be too new to make it a preferred agent.

**DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE PRODUCT FROM EACH SUBCLASS AND INCLUDE A GRANDFATHERING CLAUSE FOR PATIENTS ALREADY USING SPIRIVA. SECONDED BY DR. RYAN.**

The committee discussed the fact that Spiriva was currently on the PDL.

**DR. RUGGLES AMENDED THE MOTION TO THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE PRODUCT FROM EACH SUBCLASS. THE MAKER OF THE MOTION AND THE SECOND CONCURRED. THE MOTION PASSED UNANIMOUSLY.**

***Public Comments for Respiratory: Glucocorticoids, Inhaled, Single Entity (Blue Class)***

There were no public comments.

Dr. Umang Patel noted that he would review both Glucocorticoids, Inhaled, Single Entity and Combinations together, but the utilization and the motion would be done separately.

Dr. Umang Patel gave the Magellan presentation on Respiratory: Glucocorticoids, Inhaled, Single Entity and Combinations. In 2010, total asthma prevalence was estimated to be 8.4% of the population, or about 25.7 million Americans. The National Health Statistics Report shows that asthma appears to disproportionately affect minority groups, females, children, and individuals of low socioeconomic status which can place significant pressure on public health systems. The National Asthma Education and Prevention Program has defined asthma as a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role. In susceptible individuals, inflammation may cause recurrent episodes of wheezing, breathlessness, chest tightness, and coughing. These episodes are usually associated with airflow obstruction that is often reversible, either spontaneously or with treatment. The inflammation also causes an increase in bronchial hyper-responsiveness to a variety of stimuli. Studies have demonstrated the efficacy of inhaled corticosteroids in improving lung function, reducing symptoms, reducing frequency and severity of exacerbations, and improving the quality of life of patients with asthma.

The guidelines from the Global Initiative for Asthma were reviewed.

The new drugs in the class were reviewed. In May 2018, Fluticasone Furoate inhalation powder (Arnuity Ellipta) received approval for the use of a 50-mcg strength for the maintenance treatment of asthma in pediatric patients ages 5 to 11 years of age. It was previously approved for patients 12 years of age and older for the maintenance treatment of asthma at a dose of 100-200 mcg by inhalation once daily. For the newly approved use in patients 5-11 years of age, it is dosed as 50 mcg once daily and a 50 mcg/actuation inhalation power was approved. It is indicated for the maintenance treatment of asthma as prophylactic therapy. It can be used in patients 5 years of age and older. Dosage recommendations were reviewed. It is available as a blister strip of powder for inhalation and with a breath activated device.

Fluticasone Furoate/Umeclidinium/Vilanterol (Trelegy Ellipta) is triple therapy for the treatment of COPD. It is dosed once daily. It is not approved for asthma. The FDA approved an expanded indication for the maintenance treatment of airflow obstruction in patients with COPD and to reduce exacerbations of COPD in patients with a history of exacerbations; the indication no longer specifies current use of Fluticasone Furoate/Vilanterol (Breo Ellipta) in patients who require additional bronchodilation or the current use of Umeclidinium plus Breo Ellipta. The expanded indication is based on the IMPACT trial that showed superiority of Trelegy compared to Breo Ellipta and Anoro Ellipta in reducing moderate and severe exacerbations. Warnings and precautions were reviewed. It is contraindicated in patients who have a severe hypersensitivity to milk proteins. While no longer a boxed warning, the label still retains a warning related to the increased risk of asthma-related death when LABAs are used without an ICS to treat asthma. Trelegy Ellipta should not be used in patients with rapidly deteriorating, potentially life-threatening episodes or for the relief of acute symptoms of COPD. As an anticholinergic agent, it should be used with caution in patients with urinary retention. Dosage recommendations were reviewed. It is available as a 100/62.5/25 mcg per actuation DPI with dose counter. It is supplied as an inhalation powder with two foil blister strips per actuation.

Effective April 2018, Mylan Specialty will discontinue any future shipments of Aerospan Inhalation Aerosol, 80 mcg per actuation (NDC Number: 0037-7590-12) 120 metered actuations. All open order for this product will be cancelled.

The utilization report was reviewed. For glucocorticoids, inhaled, single entity, 79.8% of the prescriptions were for preferred agents. For glucocorticoids, inhaled, combinations, 99.8% of the prescriptions were for preferred agents.

The motion at the last review for glucocorticoids, inhaled, single entity, was class effect to include one high-potency product, one low- to medium-potency product, and a Budesonide product, which passed unanimously.

In response to Dr. Ruggles, Dr. Riley said Budesonide was included in the last motion because it was the only nebulized steroid. Dr. Semling said another reason for including Budesonide on the PDL was that it could be used orally for pediatrics.

**DR. RUGGLES MOVED A CLASS EFFECT TO INCLUDE ONE HIGH-POTENCY PRODUCT, ONE LOW- TO MEDIUM-POTENCY PRODUCT, AND A BUDESONIDE PRODUCT. SECONDED BY DR. RILEY. THE MOTION PASSED UNANIMOUSLY.**

***Public Comments for Respiratory: Glucocorticoids, Inhaled, Combination (Red)***

There were no public comments.

The motion at the last review for glucocorticoids, inhaled, combination, was class effect to include one high-potency product and one low- to medium-potency product passed unanimously.

**DR. RYAN MOVED A CLASS EFFECT TO INCLUDE ONE HIGH-POTENCY PRODUCT AND ONE LOW- TO MEDIUM-POTENCY PRODUCT. SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.**

***Respiratory: Beta Agonists, Bronchodilators, Long-Acting (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Respiratory: Beta Agonists, Bronchodilators, Long-Acting. The utilization report was reviewed and 52.4% of the prescriptions were for preferred products. At the last review, a motion for class effect to include both an inhaler and a nebulized product passed unanimously.

**DR. RYAN MOVED A CLASS EFFECT TO INCLUDE BOTH AN INHALER AND A NEBULIZED PRODUCT. SECONDED BY DR. RILEY. THE MOTION PASSED UNANIMOUSLY.**

Dr. Phillips (telephonic) was excused from the remainder of the meeting due to a fire drill at her location.

***Respiratory: Beta Agonists, Bronchodilators, Short (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Respiratory: Beta Agonists, Bronchodilators, Short-Acting. The utilization report was reviewed and 98.9% of the prescriptions were for preferred products. At the last review, a motion for class effect to include at least one Albuterol inhaled product and a nebulized solution passed unanimously.

**DR. GREEAR MOVED A CLASS EFFECT TO INCLUDE AT LEAST ONE ALBUTEROL INHALED PRODUCT AND A NEBULIZED SOLUTION. SECONDED BY DR. WHITE. THE MOTION PASSED UNANIMOUSLY.**

**4-B. Allergy:** Epinephrine, Self-Injected (Blue Class); Intranasal Rhinitis Agents (Green Class); Leukotriene Modifiers (Green Class); Antihistamines, Minimally-Sedating (Green Class)

***Public Comments for Allergy: Epinephrine, Self-Injected (Blue Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Allergy: Epinephrine, Self-Injected. Anaphylaxis is an acute, life-threatening medical emergency with many potential triggers. It may occur as a result of exposure to specific agents such as food, medication, insect bites or stings. According to the 2015 anaphylaxis practice parameter, it is defined as one of three scenarios based on the National Institute of Allergy an Infectious Disease and Food Allergy and Anaphylaxis Network criteria: the acute onset of a reaction, which is minutes to several hours, with involvement of the skin, mucosal tissue, respiratory tract, and/or reduced blood pressure; rapid onset of reactions after exposure to a likely allergen that involves two organ systems, including the skin/mucosal tissue, respiratory tract, reduced blood pressure, and/or persistent gastrointestinal symptoms; and reduced blood pressure after exposure to a known allergen. Anaphylaxis may be fatal and requires prompt recognition and immediate management. It has a rapid onset with multiple organ-system involvement and is primarily seen in sensitized individuals after exposure to specific antigens. Reactions typically follow a uniphasic pattern; however, about 20% of reactions are biphasic in nature. The second phase usually occurs after an asymptomatic period of one to eight hours with as much as a 24-hour delay.

The guidelines from the NIAID-Sponsored Food Allergy Guidelines and the American Academy of Pediatrics were reviewed.

New drugs in the class were reviewed. Epinephrine auto-injector is indicated for the emergency treatment of Type I allergic reactions including anaphylaxis to stringing insects, biting insects, allergen immunotherapy, foods, drugs, diagnostic testing substances, and other allergens; the emergency treatment of idiopathic anaphylaxis; and the emergency treatment of exercise-induced anaphylaxis. The FDA approved Teva's generic version of Epipen (0.3 mg) and Epipen Jr. (0.15 mg) under the ANDA. The launch date has not been published. Teva announced the release of a limited amount of supply of their FDA-approved generic version of the Epipen (0.3 mg). Additional supplies of generic Epipen Jr. (0.15 mg) is not anticipated until 2019.

Epinephrine auto-injector (Symjepi) has a new formulation approval. The FDA approved a new formulation of Symjepi 0.15 mg (Epinephrine auto-syringe) for emergency treatment to allergic reactions (Type I) including anaphylaxis. It is intended for patients weighing 33 to 65 pounds. It is indicated for the emergency treatment of Type I allergic reactions including anaphylaxis to stinging insects, biting insects, allergen immunotherapy, foods, drugs, diagnostic testing substances, and other allergens; the emergency treatment of idiopathic anaphylaxis; and the emergency treatment of exercise-induced anaphylaxis.

There is a nationwide shortage with both Impax and Mylan reporting intermittent availability. Teva announced the release of a limited amount of supply of their FDA-approved generic version of the Epipen (0.3 mg). Release of additional supply in their .15 mg strength is expected in 2019.

The utilization report was reviewed and 80.6% of the prescriptions were for approved products. At the last review, a motion for class effect to include a grandfathering clause for patients already trained on specific devices, and to table the review of Symjepi until it is available on the market passed unanimously.

In response to Dr. Hiestand, Dr. Ryan said there were differences between the devices that require specific training. The mechanics of using various devices are different enough that you cannot just assume that a patient will be able to use one device if they were trained on another device. Dr. Ruggles

noted that in an emergency situation, you cannot assume a patient will be able to use a different device than the one they were trained on. Pharmacies generally have sample devices that you use for patient demonstrations.

In response to Dr. Ruggles, Dr. Ryan said it was an improvement to have smaller doses available through Auvi-Q, but there were very few patients who required the smaller dosage due to their weight.

**DR. RYAN MOVED A CLASS EFFECT TO INCLUDE A GRANDFATHERING CLAUSE FOR PATIENTS ALREADY TRAINED ON SPECIFIC DEVICES. SECONDED BY DR. RILEY. THE MOTION PASSED UNANIMOUSLY.**

***Allergy: Intranasal Rhinitis Agents (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Allergy: Intranasal Rhinitis Agents. Allergic rhinitis is a constellation of symptoms affecting approximately 8% of adults and 10% of children in the United States. It is characterized by sneezing, itching of the eyes, nose, and palate, rhinorrhea, and nasal obstruction. It is often associated with post-nasal drip, cough, irritability, and fatigue. Symptoms develop when patients inhale airborne antigens to which they have previously been exposed and have made antibodies. These antibodies bind to receptors on mast cells in respiratory mucosa and to basophils in peripheral blood. These cells release pre-formed and granule-associated chemical mediators. They also generate other inflammatory mediators and cytokines, which lead to nasal inflammation and, with continued allergen exposure, chronic symptoms. There two types of allergic rhinitis. Perennial allergic rhinitis is an IgE-mediated reaction to allergens with little or no seasonal variation. It is characterized as persistent, chronic, and generally less severe than seasonal allergic rhinitis. Vasomotor rhinitis, or irritant rhinitis, is a condition of unknown origin. It is aggravated by fumes, odors, temperature, atmospheric changes, smoke, and other irritants. This form of rhinitis, generally a condition diagnosed in adults, causes year-round symptoms that include congestion and headache.

The utilization report was reviewed, and 97.4 percent of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include one anticholinergic, one antihistamine, and one corticosteroid passed unanimously.

**DR. RUGGLES MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE ANTICHOLINERGIC, ONE ANTIHISTAMINE, AND ONE CORTICOSTEROID. SECONDED BY DR. GREEAR. THE MOTION PASSED UNANIMOUSLY.**

***Allergy: Leukotriene Modifiers (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Allergy: Leukotriene Modifiers. In the United States, asthma affects approximately 25.7 million people. It is one of the most common chronic childhood diseases, affecting approximately 7 million children. Asthma is a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role. The inflammation also causes an increase in bronchial hyper-responsiveness to a variety of stimuli. In susceptible individuals, inflammation may cause recurrent episodes of wheezing, breathlessness, chest tightness, and coughing.

These episodes are usually associated with airflow obstruction that is often reversible, either spontaneously or with treatment.

The utilization report was reviewed, and 99.9% of the prescriptions were for preferred products. At the last review, a motion for class effect to exclude Zileuton passed unanimously.

In response to Dr. Hiestand, Dr. Umang Patel said the reason for Zileuton being excluded from the motions in 2017 and 2018 was due to risks related to liver disease.

**DR. RYAN MOVED A CLASS EFFECT TO EXCLUDE ZILEUTON. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

***Allergy: Antihistamines, Minimally-Sedating (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Allergy: Antihistamines, Minimally-Sedating. The utilization report was reviewed, and 98.1% of the prescriptions were for preferred products. At the last review, a motion of class effect to include an oral syrup for pediatric dosing or a suspension passed unanimously.

**DR. GREEAR MOVED A CLASS EFFECT TO INCLUDE AN ORAL SYRUP FOR PEDIATRIC DOSING OR A SUSPENSION. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.**

**4-C. Immunological:** Cytokine & CAM Antagonists, Non-GI Indications (Red Class); Immunosuppressants, Oral (Blue Class)

***Public Comments for Immunological: Cytokine &CAM Antagonists, None-GI Indication (Red Class)***

**KATE KREITZER,** a representative of Novartis, discussed Cosentyx (Secukinumab) for the treatment of moderate to severe plaque psoriasis, active ankylosing spondylitis, and active psoriatic arthritis. Cosentyx works by a novel mechanism action by binding directly to IL-17A and inhibiting its interaction with the IL-17 receptor. IL-17A is produced by various cells from both the innate and adaptive immune systems. Cosentyx inhibits IL-17A mediated diseases regardless of the source of IL-17A. It provides comprehensive patient management with demonstrated efficacy in all of the domains of psoriatic disease. Up to 40% of patients with psoriasis also develops psoriatic arthritis. The Cosentyx label was recently updated to include both scalp psoriasis and inhibition of radiographic progression in psoriatic arthritis. Several studies and their outcomes were reviewed. Cosentyx is the only non-anti-TNF therapy approved to treat active ankylosing spondylitis. It has also demonstrated efficacy out to five years in clinical trials. It has a consistent safety profile across three indications. The most common adverse reactions were nasopharyngitis, diarrhea, and upper respiratory tract infections. Cosentyx has been prescribed for more than 150,000 patients with psoriasis, psoriatic arthritis, and ankylosing spondylitis worldwide. Cosentyx has demonstrated consistent efficacy in treating the whole disease, giving patients relief in their joints, as well as including those most difficult areas to treat. We request that Cosentyx be included on the PDL.

**DAVE GROSS,** a representative of Pfizer, discussed Xeljanz (Tofacitinib). It is indicated for the treatment of adult patients with rheumatoid arthritis or active psoriatic arthritis who have had an inadequate response or intolerance to Methotrexate or other disease modifying drugs, and for the treatment of adult patients with moderately to severely active ulcerative colitis. The dosing recommendations were reviewed. There is a boxed warning for serious infections and malignancy. There are increased risks of developing serious infections that may lead to hospitalization or death. The most common serious adverse events were serious infections. The safety profile observed in patients in the long-term safety extension trials were consistent with those in the initial clinical trials. The studies have proven efficacy and long-term safety across all three approved indications. To manage these diseases effectively, there needs to be alternative disease modifying agents available in the formulary continuum. Having access to a medication with a novel mechanism of action and available for oral administration, such as Xeljanz, offers an additional treatment option for patients with these disease states in the Alaska State Medicaid population. Based on the efficacy and safety of Xeljanz, we urge you to continue to retain Xeljanz on the PDL.

**DAVID CROSBY,** a representative of Bristol-Myers Squibb, discussed Orencia (Abatcept). Since 2018, Orencia's labeled indications and safety profile for rheumatoid arthritis, psoriatic arthritis, and juvenile idiopathic arthritis have not changed. Bristol-Myers Squibb, in collaboration with the rheumatology community, has uncovered evidence of a clinically meaningful serologic biomarker predicting treatment response to Orencia in adult patients with rheumatoid arthritis. This biomarker, anti-CCP, an autoantibody commonly utilized for its diagnostic value, has recently been shown to correlate with enhanced treatment response to Orencia versus other biologic agents indicated for rheumatoid arthritis. Several studies and their outcomes were reviewed. We request that you allow for a differentiated, non-TNF inhibitor, biologic treatment option to the PDL by adding Orencia as a preferred agent.

**MARGARET OLMON**, a representative of AbbVie, discussed Humira. Humira has 10 FDA approved indications. Reviewed the currently approved indication for Humira other than GI diseases. Humira is FDA approved in rheumatoid arthritis for reducing signs and symptoms inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately- to severely-active RA. In juvenile idiopathic arthritis, it is indicated for reducing the signs and symptoms of moderately- to severely-active polyarticular JIA in patients 2 years of age and older. In psoriatic arthritis, it is indicated for reducing the signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active disease. It is indicated to reduce the signs and symptoms in adult patients with active ankylosing spondylitis. It is indicated for plaque psoriasis in the treatment of adult patients with moderate to severe psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are moderately less appropriate. It is indicated for hidradenitis suppurativa (HS) in the treatment of moderate to severe HS. The indication has been expanded to treat patients 12 years of age and older. It is indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in adults patients. And now it has been expanded to also treat pediatric patients who are 2 years of age and older. The majority of Humira utilization is in rheumatoid arthritis, Crohn's disease, and psoriasis. With longstanding safety data, 71 global clinical trials, 14 years of market experience, and over one million patients exposed, Humira has a well-defined, published benefit-to-risk database. All TNF antagonists carry similar boxed warnings regarding serious infections, tuberculosis, and malignancies. Patients starting any anti-TNF, including Humira, should be screened for TB and carefully monitored for serious events. Please see the full prescribing information online at www.rxabbvie.com for any

comprehensive safety and efficacy data. We request that Humira be maintained on the PDL as a preferred agent.

**JAYNE FORTSON**, a dermatologist at Fortson Dermatology and Skin Care Center, discussed medications for psoriasis. Some patients with psoriasis respond to one drug whereas other patients respond to other drugs, which is why I urge you to maintain the drugs currently on the PDL and add additional medications, such as Cosentyx and others, because physicians have tailor the treatment to each patient. There is not a good way to figure out which patient will benefit from which drugs in advance. You have to try them until you find one that works for that patient. Patients with psoriasis suffer tremendously, and they benefit tremendously from these drugs. Cosentyx works well and has a good safety record. I would urge you to include Cosentyx on the PDL, as well as some of the other agents, so that patients can have a choice. Eucrisa is a non-steroidal alternative for patients with atopic dermatitis. It is a good drug when used correctly. For people who have chronic eczema, you do not want to be using steroids all the time, so Eucrisa is a good alternative. This is the golden age of dermatology and medicine, and I have seen lives change with these newer drugs. I urge you to broaden the PDL and include more of these life-changing medication on the PDL.

Dr. Phillips returned to the meeting after the fire drill ended.

In response to Dr. Phillips, Dr. Fortson said patients had to go through step-therapy process before Cosentyx could be prescribed, even though it was currently on the PDL with a prior authorization requirement.

**ALVIN ONG**, a representative of Sanofi-Aventis, discussed Kevzara. Please refer to the full prescribing information for additional points on safe and effective use of Kevzara. It is an IL-6 receptor antagonist indicated for the treatment of adult patients with moderately- to severely-active RA who have had an inadequate response to one or more DMARDs. It is approved for use as monotherapy or in combination with NTF or other conventional DMARDs. The recommended dosage is a 200-milligram subcutaneous injection once every two weeks, which can be reduced to 150 milligrams every two weeks for the management of neutropenia, thrombocytopenia, and elevated liver enzymes. Several trials and their outcomes were reviewed. Kevzara has long-term efficacy and safety data through two years with no dose escalation. We request that Kevzara be added to the PDL.

Dr. Umang Patel read a letter from Richard Blake, PA-C, from Cottonwood Creek Clinic, advocating for the inclusion of Xeljanz on the PDL for rheumatoid arthritis and psoriatic arthritis.

Dr. Umang Patel gave the Magellan presentation on Immunological: Cytokine & CAM Antagonists, Non-GI Indications. Cytokines and cell-adhesion molecules (CAMs) are chemical mediators involved in inflammatory processes throughout the body. Cytokines are small proteins secreted in response to an immune stimulus for the purpose of mediating and regulating immunity, inflammation, and hematopoiesis. It is derived from monocytes and macrophages and induce gene expression of a number of proteins that contribute to the inflammatory response. The actions of the individual cytokines are widely varied and contribute to fibrosis and tissue degeneration associated with chronic inflammatory, primarily by inducing the proliferation of fibroblasts and collagenase. The pro-inflammatory cytokines, tumor necrosis factor (TNF), and interleukin (IL)-1, are involved in tissue destruction in many chronic inflammatory diseases affecting various organs. TNF-alpha also has a role in Crohn's disease in stimulation of inflammation. CAMs are cell surface proteins involved in the binding of cells, usually

leukocytes, to each other, endothelial cells, or the extracellular matrix. Specific signals produced in response to wounds and infection control the expression and activation of these molecules. Most of the CAMs characterized fall into three general families of proteins. The immunoglobulin superfamily in which the adhesion molecules that bind to integrins on leukocytes and mediate their flattening onto the blood vessel wall. The integrin family which consists of an alpha and beta chain that mediate cell-to-cell interactions, such as leukocyte adherence to the vascular endothelium. The selectin family is involved in the adhesion of leukocytes to activate endothelium followed by extravasation through the blood vessel walls into lymphoid tissues and sites of inflammation. Other proteins that are functionally classified as CAMs are involved in strengthening the association of T cells with antigen-presenting cells or target cells, in T cell activation, and in recirculating lymphocytes back to the circulation via the lymphatic system. Different CAMs have been implicated in inflammatory, fibrotic, and autoimmune diseases.

The guidelines from the American College of Rheumatology for Rheumatoid Arthritis were reviewed. The background and treatment guidelines for rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, plaque psoriasis and psoriasis arthritis, periodic fever syndrome, giant cell arteritis were reviewed.

New drugs in the class were reviewed. Ilumya (Tildrakizumb-asmn) was approved by the FDA in March 2018. It is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. It is contraindicated in patients with a known serious hypersensitivity reaction to it or any of the excipients. Cases of angioedema and urticaria have occurred. It should be discontinued immediately should serious hypersensitivity occurs. Live vaccines should be avoided in patients treated with Ilumya. Treatment with Ilumya should not be initiated in patients with any significant active infection until the injection resolves or is adequately treated. Dosing recommendations were reviewed. It is available as a single-dose prefilled syringe.

Olumiant (Baricitinib) was approved by the FDA in June 2018. It is indicated for the treatment of adult patients with moderate to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies. It should be avoided in select anemic or lymphogenic patients, as well as select patients with renal or hepatic impairment. It carried a boxed warning regarding serious infections, malignancy, and thrombosis. Use is not recommended in patients with an absolute lymphocyte count of more than 500 cells/$mm^3$, absolute neutrophil count of more than 1,000 cells/$mm^3$, hemoglobin more than 8 g/dL, or those with serious, active injections. There is insufficient data for pregnant patients and pediatric patients. Dosage recommendations were reviewed. It is available as a tablet.

Cimzia (Certolizumab) received an expanded FDA indication in June 2018 for use in adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. It is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Cimzia was already approved for moderately- to severely-active rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis, and Crohn's disease. Do not start Cimzia during an active infection. If an infection develops, monitor carefully and stop Cimzia if infection becomes serious. Dosage recommendations were reviewed. It is available in a syringe kit, a vial kit, and a starter kit. Cimzia contains latex derivatives so use with caution in latex-sensitive patients.

Actemra (Tocillzumab) received an expanded FDA indication in May 2018 for Actemra SC for the treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older as monotherapy or in combination with Methotrexate (Actemra IV is already approved for this population). It is indicated for polyarticular juvenile idiopathic arthritis in patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis. There may be serious infections leading to hospitalization or death including tuberculosis, bacterial, invasive fungal, viral, and other opportunistic infections. If a serious infection develops, interrupt Actemra until the infection is controlled. Testing should be performed for latent TB. If positive, start treatment for TB prior to starting Actemra. Dosing recommendations were reviewed. It is available as a single-use vial or a prefilled syringe.

Humira (Adalimumab) received an expanded FDA indication in October 2018 for the treatment of hidradenitis suppurative, to include adolescents 12 years of age and older; and Humira's indication for the treatment of noninfectious intermediate, posterior, and panuveitis, to include use in patients as young as 2 years of age. Previously, it was approved in adults only for this indication. Humira also carries indications for use in patients with RA, JIA, PsA, AS, CD, UC, Ps, and hidradenitis suppurative. There is increased risk of serious injections leading to hospitalization or death, including tuberculosis, bacterial sepsis, invasive fungal infections, and injections due to other opportunist pathogens. Discontinue use if patient develops a serious injection or sepsis during treatment. Perform tests for latent tuberculosis and, if positive, start treatment. Monitor all patients for active tuberculosis during treatment, even if initial latent TB test is negative. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treatment with TNF blockers including Humira. Post-marketing cases of hepatosplenic T-cell lymphoma, a rate type of T-cell lymphoma, have occurred in adolescent and young adults with inflammatory bowel disease treatment with TNF blockers, including Humira. Dosing recommendations were reviewed. It is available as an SC solution and a kit.

Hyrimoz (Adalimumab-adz) was approved by the FDA in October 2018 as a biosimilar to Humira for all eligible indications of the reference product, including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis, and plaque psoriasis. Hyrimoz will likely not be available in the United States until September 30, 2023. It also carries indications for use in patients with RA, JIA, PsA, AS, CD, UC, and Ps. There limitations are the same as for Humira. Dosing recommendations were reviewed. It is available as a single-dose prefilled syringe or a pen.

Kevzara (Sarilumab) received FDA approval in April 2018. It is indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response or intolerance to one or more DMARDs. Serious infection leading to hospitalization or death including bacterial, viral, invasive fungal, and other opportunistic infections have occurred in patients. If a serious infection develops, interrupt Kevzara until the infection is controlled. Cases of tuberculosis have been reported. Prior to starting Kevzara, tests for latent tuberculosis. If positive, start treatment for tuberculosis. Closely monitor patients for signs and symptoms of infection during treatment. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Kevzara, and physicians and women are encouraged to register. The dosing recommendations were reviewed. It is available as an injection.

The utilization report was reviewed, and 96.1% of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include at least one formulation for pediatrics, one for arthritis, one for psoriasis, and an oral agent for rheumatoid arthritis passed unanimously.

In response to Dr. Greear, Dr. Semling said some of the drugs in this class to require a prior authorization. Some of them may also be on the interim prior authorization list, which would require a step-therapy. In most cases, these drugs exceed $7,500 a month, so a prior authorization is required for a second-level review.

**DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE FORMULATION FOR PEDIATRICS, ONE FOR ARTHRITIS, ONE FOR PSORIASIS, AND AN ORAL AGENT FOR RHEUMATOID ARTHRITIS. SECONDED BY DR. RILEY. THE MOTION PASSED UNANIMOUSLY.**

***Public Comments for Immunological: Immunosuppressants, Oral (Blue Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Immunological: Immunosuppressants, Oral. The ultimate goal of immunosuppressive therapy after organ transplantation is to prevent organ rejection, prolong graft and patient survival by providing an environment of permanent acceptance or tolerance where the new organ is recognized as "self" by the host's immune system. Rejection can be classified as hyperacute, acute cellular, or chronic. Hyperacute rejection may occur when donor-specific antibodies are present in the recipient at the time of transplant. It often occurs within minutes of transplant but may occur anytime within the first two weeks following surgery. Alloreactive T lymphocytes that appear in circulation can infiltrate the allograft through the vascular endothelium and mediate acute cellular rejection. This type of rejection may occur as early as a few days postoperatively; however, it can occur anytime after transportation. The process of chronic rejection is poorly understood, although it may simply be a slow form of cellular rejection. The clinical presentation of chronic rejection is dependent on the organ grafted and generally presents as normal organ aging. The onset of chronic rejection is very slow, and changes in organ function are not usually reversible. The sequence of events in graft rejection was reviewed. The immunosuppressive drugs and dosing used in the maintenance of a transplanted organ varies, but the regimens generally follow the sample principles. Following induction therapy at the time of surgery, transplant recipients are started on drug regimens that consist of several categories. Using multiple agents capitalizes on the different immune-mediated mechanism of action and may also allow for the use of lower doses of individual agents in order to minimize toxicity.

The new drugs in the class were reviewed. Prograf (Tacrolimus) received an FDA approval for Prograf Granules (oral suspension) for the prevention of rejection in heart, kidney, or liver transplant in pediatric patients. The warnings and precautions were reviewed. Dosing recommendations were reviewed. It is available as capsules and unit-dose packets containing granules.

Astagraf XL (Tacrolimus ER) received an expanded FDA indication to include pediatric patients less than 16 years of age. It is indicated as adjunctive prophylaxis against kidney organ rejections. Dosing recommendations were reviewed. It is available as an extended-release capsule.

The utilization report was reviewed, and 66.9 percent of the prescriptions were for preferred products. At the last review, a motion for class effect passed unanimously.

The committee discussed why the percentage of prescriptions for non-preferred products was so high. Dr. Phillips said physicians seemed to be shifting to Myfortic instead of Imuran due to less cell depression, which is something that could be consider in the motion. Dr. Narus said that seemed like a reasonable interpretation of the utilization. The state will look at the utilization trends and review the committee's motions when creating the next PDL.

In response to Dr. Riley, Dr. Semling said the prescriptions for Mycophenolate acid used the medically necessary clause and there was no prior authorization requirement. Dr. Narus said there were many independent and individual variables in this class. There are no specific prior authorizations or clinical criteria for use established by the DUR Committee. When patients need drugs not on the PDL, they are available through the medically necessary clause and would not require a prior authorization process.

Dr. Phillips said her motion was contingent upon staff looking at why there was a provider shift among these drugs.

**DR. PHILLIPS MOVED A CLASS EFFECT. SECONDED BY DR. RILEY. THE MOTION PASSED UNANIMOUSLY.**

After a short break, the roll call was taken, and Dr. Riley was no longer present but returned sometime during the presentation on dermatological agents.

**4-D. Dermatological:** Antipsoriatics, Topical (Green Class); Immunomodulators, Atopic Dermatitis (Blue Class); Topical Steroids, Low Potency (Green Class); Topical Steroids, Medium Potency (Green Class); Topical Steroids, High Potency (Green Class); Topical Steroids, Very High Potency (Blue Class); Acne, Topical (Blue Class)

***Dermatological: Antipsoriatics, Topical (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Dermatological: Antipsoriatics, Topical. Psoriasis is a chronic, auto-immune disease that appears on the skin. It is estimated that psoriasis affects approximately 7.5 million people in the United States. The prevalence of psoriasis is 1.9% in African Americans versus 3.6% in Caucasians. It usually presents between the ages of 15 to 35 years, but psoriasis can develop at any age. There are five types of psoriasis: plaque, guttate, inverse, pustular, and erythrodermic. The most common type is plaque psoriasis, psoriasis vulgaris, in which patches or lesions of skin become inflamed and is covered by a silvery white scale. The plaques frequently occur on the skin of the elbows and knees but can affect any area, including the scalp. Psoriasis can range from mild, to moderate, to severe. It may be associated with comorbidities including cardiovascular disease, type 2 diabetes mellitus, metabolic syndrome, cancer, and depression.

The utilization report was reviewed, and 75% of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

**DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.**

***Public Comments for Dermatological: Immunomodulators, Atopic Dermatitis (Blue Class)***

**DAVE GROSS**, a representative of Pfizer, discussed Eucrisa. Eucrisa is a topical, non-steroidal ointment for the treatment of mild to moderate atopic dermatitis. Nearly 18 million people in the United States suffer from atopic dermatitis. The prevalence rate in children is between 11% and 13%. Approximately 90% of the people with atopic dermatitis have the mild to moderate form of the condition. Treatment can be a lifelong commitment with approximately 50% of the pediatric patients having recurrent symptoms on into adulthood. Eucrisa is non-steroid containing topical treatment that inhibits the PD-4 enzyme within the skin. It can be applied twice daily to the skin, anywhere on the face and body. It is indicated for the topical treatment of mild to moderate atopic dermatitis in patients 2 years of age and older. Several trials and their outcomes were reviewed. Eucrisa is the first and only non-steroid containing topical PD-4 inhibitor for mild to moderate atopic dermatitis in patients 2 years of age and older. We request that Eucrisa be retained on the PDL as a preferred agent.

**DAN ALLEN**, a representative of Sanofi, discussed Dupixent and reviewed the clinical highlights of a new indication. Please refer to the full prescribing information for additional details. The new indication for Dupixent, which is an IL-4 receptor antagonist, is as an add-on maintenance treatment in patients with moderate to severe asthma, ages 12 years and older, with an eosinophilic phenotype or with oral corticosteroid dependent asthma. It is not indicated for the relief of acute bronchospasm or status asthmaticus. Dupixent is available as a 200-milligram or 300-milligram single-dose prefilled syringe for subcutaneous self-administered injection. The recommended dosages were reviewed. Several trials and their outcomes were reviewed. The most common adverse reaction was injection site reaction. We request that Dupixent be available on the PDL.

In response to Dr. Narus, Mr. Allen reviewed Dupixent's FDA-labeled indications for atopic dermatitis. It is indicated for the treatment of patients with mild to severe atopic dermatitis whose disease is not controlled with topical prescription therapies, or when those therapies are not advisable. It is also indicated as an add-on maintenance treatment of patients with mild to severe asthma, ages 12 years and older, with an eosinophilic phenotype of with oral corticosteroid dependent asthma.

Dr. Semling read an email from Dr. Jeffrey Demain advocating for the inclusion of Eucrisa on the PDL as it is beneficial to have a non-steroid alternative available for patients with mild to moderate eczema that are not controlled with appropriate skin care alone.

Dr. Umang Patel gave the Magellan presentation on Dermatological: Immunomodulators, Atopic Dermatitis. Atopic dermatitis (AD) is a chronic, non-contagious, inflammatory disease of the skin resulting from a combination of genetic and environmental factors. Approximately 70% of patients diagnosed with AD have a positive family history of atopic diseases. The odds of developing AD are two to three times higher in children with one atopic parent and increases to three to five times higher if both parents are atopic. Often referred to as eczema, AD affects about 17.8 million Americans and accounts for 10% to 20% of all visits to a dermatologist. Although symptoms can develop at any age, it has been estimated that 60% of patients develop symptoms in the first year of life, while 90% develop symptoms before the age of 5.5 years. AD is characterized by extremely dry, itchy skin on the insides

of the elbows, behind the knees, and on the fact, hands, and feet. In response to intense itching, patients may scratch or rub the affected area, which leads to further irritation and inflammation. As the skin loses moisture from the epidermal layer, it becomes increasingly dry and may begin to crack, weep, crust, and scale. This damage to the integrity of the skin renders it less protective and more prone to infection. Despite the chronic nature of this dermatological condition, there may be period of the disease when the skin improves the periods when the skin worsens. Irritants, such as detergents, fumes, tobacco smoke, and alcohol-containing skin products, and allergens like dust mites, pollen, and animal dander can exacerbate AD or cause flare ups.

The new drug in the class was reviewed. Dupixent (Dupilumab) received an new FDA indication for add-on maintenance treatment of moderate to severe asthma in patients 12 years of age and older. With an eosinophilic phenotype or with oral corticosteroid dependent asthma. It is indicated for the treatment of adult patients with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. It may be used with or without topical corticosteroids. Dosage recommendations were reviewed. It is available as an subcutaneous injection and a single-dose solution in a prefilled syringe with a needle shield.

The utilization report was review, and 89% of the prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives passed unanimously.

**DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RILEY. THE MOTION PASSED UNANIMOUSLY.**

***Dermatological: Topical Steroids, Low Potency (Green Class)***
***Dermatological: Topical Steroids, Medium Potency (Green Class)***
***Dermatological: Topical Steroids, High Potency (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Dermatological: Topical Steroids, Low Potency, Medium Potency and High Potency. The utilization reports were reviewed. For topical steroids, low potency, 89.5% of the prescriptions were for preferred products. For topical steroids, medium potency, 80.5% of the prescriptions were for preferred products. For topical steroids, high potency, 96.7% of the prescriptions were for preferred products.

***Public Comments for Dermatological: Topical Steroids, Very High Potency (Blue Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Dermatological: Topical Steroids, Very High Potency. The new drugs in the class were reviewed. Bryhali (Halobetasol Propionate) received FDA approval in December 2018 for a new formulation of Bryhali, a corticosteroid lotion indicated for the topical treatment of plaque psoriasis in adults. It was approved as a 0.1% lotion. It is dosed as a thin layer applied to the affected areas once daily. Treatment beyond eight weeks is not recommended. An immediate launch is planned. In June 2018, the FDA approved an additional formulation of a 0.05% foam. It is a corticosteroid in 50-gram and two 50-gram aluminum cans for the topical treatment of plaque psoriasis in patients 18 years of age and older. After shaking, it should be applied as a thin, uniform film to the affected area, rubbing in gentle, twice daily for up to two weeks. Avoid use on the face, groin, or axillae. It is not for ophthalmic, oral, or intravaginal use.

Merck has discontinued Elocon (Mometasone Furoate) 0.1% ointment in 15-gram and 45-gram tubes. The final selling date was July 2, 2018. Mometasone 0.1% ointment is available from generic manufacturers.

The utilization report was reviewed. For topical steroids, very high potency, 92.8% of the prescriptions were for preferred products. All four of the topical steroid classes were handled with one motion last year. The motion for class effect within each potency group, and to include at least one ointment and one cream from each potency group, passed unanimously.

In response to Dr. Hiestand, Dr. White said Cordan Tape, which accounts for 7% of the utilization, comes in a roll and forms an occlusive dressing, which patients find to be convenient. Dr. Narus read the package insert. The tape serves as both a vehicle for the steroids and an occlusive dressing. Retention of insensible perspiration by the tape results in hydration of the stratum corneum and improved diffusion of the medication. The skin is also protected from scratching, rubbing, desiccation, and chemical irritation by the tape. And it acts as a mechanical splint to fissured skin. She suggested looking at the cost of the tape as compared to the other agents, as well as whether the product was being used appropriately, which the DUR Committee may want to consider.

**DR. RILEY MOVED A CLASS EFFECT WITHIN EACH POTENCY GROUP, AND TO INCLUDE AT LEAST ONE OINTMENT AND ONE CREAM FROM EACH POTENCY GROUP. SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.**

***Public Comments for Dermatological: Acne, Topical (Blue Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Dermatological: Acne, Topical. Acne vulgaris is the most common cutaneous condition in the United States. It is a disorder that affects primarily teenagers and young adults, but it can sometimes persist beyond young adulthood. In adolescence, sebaceous glands increase sebum release after puberty. Small cysts called comedones form in hair follicles due to blockage of the pore from accumulated sebum and keratinous material. Bacteria, most often Propionibacterium acnes, release free fatty acids from sebum within the comedones, which causes inflammation to form a cyst. This results in a rupture of the cyst wall and subsequent inflammatory reaction due to extrusion of oily and keratinous debris from the cyst. There are three categories of the severity of acne and includes either acne occurring on the face or the trunk of the body. These categories are graded as mild, moderate, or severe depending on the presence and number of lesions, which consist of comedones, papules, pustules, and/or cysts. Mild acne is defined by the presence of fewer than 20 comedones, fewer than 15 inflamed papules, or fewer than 30 lesions consisting of the combination comedones and papules. Moderate acne is defined by the presence of 15 to 50 papules and pustules, in addition to comedones and rare cysts, and the total number of lesions on the face can range from 30 to 125. Severe acne is defined by the presence of mostly inflamed nodules and cysts and includes more than 125 lesions consisting of comedones, papules, and pustules.

The new drug in the class was reviewed. Altreno (Tretinoin) received a new FDA-approval for its lotion formulation in August 2018. It is Tretinoin 0.05% lotion and is used to treat acne vulgaris in

patients 9 years of age and greater. It is applied topically to affected skin once daily. It is approved as 45-gram tubes. Dosage recommendations were reviewed. It is available as a lotion.

The utilization report was reviewed, and 55% of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include at least one drug from each subclass and at least one combination Benzoyl Peroxide and antibiotic passed unanimously.

In response to Dr. Ruggles, Dr. Semling said the reason so many of the prescriptions were not in line with the PDL was Benzaclin was the preferred agent and then a generic became available in the marketplace after the PDL was approved.

**DR. RUGGLES MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE DRUG FROM EACH SUBCLASS AND AT LEAST ONE COMBINATION BENZOYL PEROXIDE AND ANTIBIOTIC. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.**

**4-E. Ophthalmic:** Ophthalmic, Allergic Conjunctivitis (Green Class); Ophthalmic, Antibiotics (Green Class); Ophthalmic, Antibiotics-Steroid Combination (Green Class); Ophthalmic, Anti-inflammatory (Red Class); Ophthalmic, Glaucoma Agents (Red Class); Ophthalmic, Immunomodulators (Blue Class)

***Ophthalmic: Ophthalmic, Allergic Conjunctivitis (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Ophthalmic: Ophthalmic, Allergic Conjunctivitis. The utilization report was reviewed, and 89.6% of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

**DR. RUGGLES MOVED THE DRUGS INT EH CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.**

***Ophthalmic: Ophthalmic, Antibiotics (Green Class)***
***Ophthalmic: Ophthalmic, Antibiotics-Steroid Combinations (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Ophthalmic: Ophthalmic, Antibiotics, combined with that of Ophthalmic, Antibiotics-Steroid Combinations. Historically, Ophthalmic, Antibiotics and Antibiotics-Steroid Combination has been grouped under one motion. The utilization report was reviewed for ophthalmic, antibiotics, and 97.4% of the prescriptions were for preferred products. The utilization report was reviewed for ophthalmic, antibiotics-steroid combinations, and 67.5% of the prescriptions were for preferred products. At the last review, a motion for class effect was made for each subclass for the ophthalmic, antibiotics; and therapeutic alternatives for ophthalmic, antibiotics-steroid combinations passed unanimously.

Dr. White noted that the high percentage of prescriptions that were not in line with the PDL was probably due to availability of the preferred drugs due to shortages.

**DR. PHILLIPS MOVED A CLASS EFFECT FOR EACH SUBCLASS OF THE OPHTHALMIC, ANTIBIOTICS; AND THAT THE DRUGS IN THE OPHTHALMIC, ANTIBIOTIC-STEROID COMBINATIONS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.**

***Public Comments for Ophthalmic: Ophthalmic, Anti-inflammatory (Red Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Ophthalmic: Ophthalmic, Anti-inflammatory. Uveitis is an inflammation of the middle layer of the eye or uvea, consisting of the iris, ciliary body, and choroid. It can be caused by eye trauma, secondary to autoimmune diseases or infection, or may be idiopathic in nature. It may present as acute, chronic, or recurrent attacks with unilateral pain or photophobia. Aqueous cells and flare, due to cellular infiltration and protein exudation in the anterior chamber, are seen as spots and haze on slit-beam examination; both are signs of ocular inflammation. If left untreated, uveitis can lead to glaucoma, cataracts, or retinal edema and ultimately loss of vision. Initial treatment for uveitis typically includes ophthalmic corticosteroids (topical drops or intravitreal implants) to reduce pain and inflammation. Temporal arteritis, affecting the superficial temporal arteries, is a systemic inflammatory vasculitis of unknown etiology that occurs in older individuals and can result in systemic, neurologic, and ophthalmologic complications. Permanent visual impairment is estimated in up to 20% of patients with the condition. Timely initiation of therapy may prevent irreversible damage, including blindness. The mainstay of therapy includes corticosteroids, which are typically prescribed for up to two years.

The new drugs in the class were reviewed. Yutiq (Fluocinolone Acetonide) was approved by the FDA in October 2018. It is a corticosteroid intravitreal implant approved for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. Dosage recommendations were reviewed. It is available as a non-bioerodible intravitreal implant.

Dextenza (Dexamethasone ophthalmic insert) was approved by the FDA in December 2018 for the treatment of ocular pain following ophthalmic surgery. It is preservative-free resorbable insert that releases a 0.4 mg dose of Dexamethasone for up to 30 days following insertion; removal is not required, but it can be removed if needed with saline irrigation or manual expression. Ocular Therapeutix is working with the FDA toward a commercial launch. Dosing recommendations were reviewed. It is contraindicated in patients with active or suspected ocular or periocular infections. It is available as a fluorescent yellow, cylindrical-shaped insert. There are no adequate or well-controlled studies for patients who are pregnant or for pediatrics.

Dexycu (Dexamethasone) was approved by the FDA in February 2018. It is a long-acting, injectable Dexamethasone insert for the treatment of post-operative inflammation associated with cataract surgery. Launch plans have not been announced. Dosing recommendations were reviewed. It is available as a kit with an intraocular suspension in a single-dose vial.

The utilization report was reviewed, and 88.2% of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include one drug from each subgroup passed unanimously.

**DR. RUGGLES MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE DRUG FROM EACH SUBGROUP. SECONDED BY DR. RILEY. THE MOTION PASSED UNANIMOUSLY.**

Dr. Narus noted that a couple of these products were intraocularly administered. She wanted to ensure that the committee was comfortable with the interpretation that these products were for medical benefits only and should be administered by a physician in a surgical setting. From a safety perspective, we would prefer that these prescriptions were billed along with the surgical procedure for which it was being utilized. The committee concurred with Dr. Narus.

***Public Comments for Ophthalmic: Ophthalmic, Glaucoma Agents (Red Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Ophthalmic: Ophthalmic, Glaucoma Agents. Approximately 2.7 million people in the United States suffer from glaucoma. It is the second most common cause of permanent blindness in the U.S. and most common cause of blindness among African Americans and Hispanics. Risk factors for the development of glaucoma include elevated intraocular pressure (IOP), advancing age (defined as over 40 years of age), a family history of glaucoma, and African American or Hispanic descent. Increased IOP is common in glaucoma and is believed to contribute to the damage to the optic nerve, which can lead to loss of visual sensitivity and field. However, some patients with glaucoma have normal IOP, and many patients with elevated IOP do not have glaucoma. IOP alone is no longer considered a diagnostic criterion for glaucoma. Two major types of glaucoma have been identified: open-angle and closed-angle. In open-angle glaucoma, there is reduced flow through the trabecular meshwork. Open-angle glaucoma accounts for the majority of the cases. In closed-angle glaucoma, the iris is pushed forward against the trabecular meshwork, blocking fluid from escaping. Reduction of IOP may be achieve either by decreasing the rate of production of aqueous humor or increasing the rate of outflow of aqueous humor from the anterior chamber of the eye. Topical ocular hypotensive agents can delay or prevent the development of primary open-angle glaucoma in some patients.

The new drugs in the class were reviewed. Rhopressa (Netarsudil) is a Rho Kinase inhibitor indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. There is no available data for pregnant patients or patients below the age of 18 years of age. The most common adverse reaction is conjunctival hyperemia at 53%. Other common adverse reactions include corneal verticillate, instillation site pain, and conjunctival hemorrhage. Dosing recommendations were reviewed. It is available as a solution.

Vyzulta (Latanoprostene Bunod) received an expanded FDA approval in June 2018 for a 2.5 mL fill size of the 0.024% ophthalmic solution. It was already approved as a 5 mL fill size. It is a prostaglandin analog indicated for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Dosing recommendations were reviewed. Increased pigmentation of the iris and periorbital tissue can occur. Iris pigmentation is likely to be permanent. There can be gradual changes to eyelashes, including increased length, increased thickness, and number of eyelashes, which is usually reversible upon discontinuation of treatment. It is available as a solution.

Timoptic-XE (Timolol Maleate) received an expanded FDA approval in July 2018 for pediatrics, 2 to 17 years of age. Dosing in pediatrics is the same as in adults. It is indicated for the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma. Dosing recommendations were reviewed. It is available as a solution.

Iopidine (Apraclonidine HCI) was discontinued in September 2018. Novartis made a business decision to permanently discontinue Iopidine solution 0.5%, 5 mL and 10 mL.

Xelpros (Latanoprost) is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Dosing recommendations were reviewed. Safety and efficacy have not been established in pediatric patients. It is pregnancy category C. It is available as an ophthalmic emulsion containing Latanoprost. It does not include the preservative Benzalkonium Chloride.

The utilization report was reviewed, and 76.9% of the prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives to include at least one drug from each subclass passed unanimously.

**DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE DRUG FROM EACH SUBCLASS. SECONDED BY DR. GREEAR.**

In response to Dr. Narus, Dr. Umang Patel said he did not know of any specific benefits of the new Latanoprostene products over the generic formulation, but he would look into it.

**THE MOTION PASSED UNANIMOUSLY.**

***Public Comments for Ophthalmic: Ophthalmic, Immunomodulators (Blue Class)***

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Ophthalmic: Ophthalmic, Immunomodulators. The new drug in the class was reviewed. Cequa (Cyclosporine ophthalmic solution) was approved by the FDA in August 2018. It is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye). Dosing recommendations were reviewed. To avoid the potential for eye injury and contamination, patients should be advised not to touch the vial tip to the eye or other surfaces. It should not be administered while wearing contact lenses. It is available as a solution.

The utilization report was reviewed, and 89.9% of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

**DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE BOTH DRUGS. SECONDED BY DR. DORAN-ATCHISON.**

After discussion, the committee determined that there were three or four drugs in the class although the information only contained two drugs.

**DR. PHILLIPS AMENDED THE MOTION AND MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. THE SECOND CONCURRED. THE MOTION PASSED UNANIMOUSLY.**

The next meeting is scheduled for April 19, 2019. The committee moved into a closed session.

**5. Review Minutes from November 2018 Meeting**

**6. Comments from Committee Members or Chair**

**7. Adjourn**

The public portion of the meeting adjourned at 11:33 a.m.