ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

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

MINUTES OF MEETING
January 17, 2020
8:00 a.m.

Committee Members Present:
Jenna Hiestand, Chair, MD
Robert Carlson, MD (telephonic)
Sarah Doran-Atchison, Pharm D (telephonic)
Diane Liljegren, MD (telephonic)
Vincent Greear, R.Ph. (telephonic)
Charles Ryan, MD
John Riley, PA (telephonic)
Ryan Ruggles, PharmD
Trish White, R.Ph. (telephonic)

Committee Members Absent:
Claudia Phillips, MD (excused)

Others Present:
Erin Narus, PharmD, R.Ph., State of Alaska
Charles Semling, PharmD, R.Ph., State of Alaska
Marti Padilla, R.Ph., Magellan Medical Administration
Umang Patel, Pharm D, R.Ph., Magellan Medical Administration
Betty Caudle, Kron Associates

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

Dr. Erin Narus said individuals who testify before the committee must fill out conflict of interest form. Committee members also fill out conflict of interest forms annually to ensure that any financial conflicts of interest or other related conflicts of interest are disclosed to the committee. The Federal Open Payments website is also used to identify any potential conflicts of interest. Written guidelines

for providing testimony will be posted to our website. When presenting to the committee, you are bound by federal law under the Food, Drug and Cosmetic Act as well as any relevant federal regulations on drug promotions. Anything you say here is subject to scrutiny by the FDA and is considered part of the labeling under the Food, Drug and Cosmetic Act. It is important that comments are consistent with those laws and regulations. If there are minor errors made during testimony, we will try to clarify. If there are egregious errors during testimony, we will ask the industry representative to stop their testimony and something will be filed with the Office of Prescription Drug Promotion with the FDA.

JANE FORTSON said she was a board-certified dermatologist who has worked in Alaska for 29 years. She spoke in favor of including Taltz on the PDL. It is FDA approved and has proven efficacy, safety and a quick response time. Even though there is another IL17 blocker on the PDL, patients need an alternative, because they may respond to one medication and not another one for unknown reasons. She felt Taltz was more efficacious than the medication currently on the PDL.

Dr. Hiestand noted they were having audio technical difficulties.

In response to Dr. Narus, Jane Fortson said she had no conflict of interest disclosures.

4. Class Review, Discussion & Vote

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

Public Comments for Respiratory: COPD Agents (Red Class)

There were no public testimonies.

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. Airflow obstruction is generally progressive and may be accompanied by airway hyperreactivity. 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 burden. COPD is projected by the World Health Organization to become the third leading cause by 2030. In their 2017 National Health Interview Survey, the CDC reported that the percentage of adults who were diagnosed with chronic bronchitis in the past year was 3.5%, and those that have ever been diagnosed with emphysema was 1.4%. However, the United States Preventive Services Task Force recommends against routine screen in asymptomatic adults.

Although the precise distinctions between chronic bronchitis and emphysema are a subject of debate, common belief holds that chronic bronchitis is responsible for 85% of COPD. Patients with chronic bronchitis experience intermittent airway inflammation and excessive mucus production that leads to frequent, prolonged episodes of productive cough. In contrast, 15% of patients with COPD suffer

primarily from emphysema, in which destruction of the infrastructure of alveoli and distal airspaces that provide gas exchange and elastic recoil occur. Both chronic bronchitis and emphysema predispose patients to a common collection of symptoms and impairments in respiratory function, such as reduction in forced expiratory volume (FEV_1) in one second, forced vital capacity (FEC), FEV_1/FEC ratio, and forced expiratory flow.

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

Aclidinium Bromide/Formoterol (Duaklir Pressiar) was approved by the FDA in March 2019. It is a combination of aclidinium bromide (an anticholinergic) and formoterol fumarate (a LABA) indicated for the maintenance treatment of COPD. It is indicated for the maintenance treatment of patients with COPD. It is not indicted for the initial treatment of acute episodes of bronchospasm or acute deterioration of COPD. Avoid using these agents to relieve sudden breathing problems and avoid taking extra doses. Other common adverse reactions include respiratory tract infection and back pain at 8.9% and 3.8%, respectively. Dosage recommendations were reviewed. There are no formal studies in pregnant patients or those with renal impairment.

The utilization report was reviewed, and 99.6% of the prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives to include at least one product from each subclass passed unanimously.

DR. RUGGLES MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE PRODUCT FROM EACH SUBCLASS. SECONDED BY MR. RILEY. THE MOTION PASSED UNANIMOUSLY.

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

There were no public testimonies.

Dr. Umang Patel gave the Magellan presentation on Respiratory: Glucocorticoids, Inhaled, Single Entity and Glucocorticoids, Inhaled, Combination. In 2017, total asthma prevalence was estimated to be 8.4% of the population or approximately 29 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 NAEPP 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 in patients with asthma. The 2007 National Heart, Lung, and Blood Institute states that inhaled glucocorticoids are currently the most effective anti-inflammatory medication for the treatment of

persistent asthma. The 2019 GINA full report advises that all patients with asthma should receive ICS-containing controller treatments to reduce risk of serious exacerbations and to control symptoms.

The guidelines from the Global Initiative for Asthma (GINA) and the Global Initiative for Chronic Obstructive Lung Disease (GOLD) were reviewed.

The new single entity medication was reviewed.

Mometasone Furoate (Asmanex HFA) received an expanded indication for the maintenance treatment of asthma as prophylactic therapy in patients 5 to 11 years of age by the FDA in August 2019. Previously, it was approved in patients 12 years of age and older. It is indicated for the maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older. It is not indicated for the relief of acute bronchospasm. It is contraindicated in patients with hypersensitivity to any of the ingredients.

New combination medications were reviewed.

Mometasone Furoate/Formoterol Fumarate (Dulera) receive an expanded indication for the maintenance treatment of asthma in patients 5 to 12 years of age by the FDA in October 2019. Previously, it had been approved in patients 12 years of age and older. It is indicated as a combination product containing a corticosteroid and a long-acting beta 2-adrenergic agonist (LABA) indicated for the treatment of asthma in patients 5 years of age and older. LABA monotherapy increases the risk of serious asthma-related events. Do not initiate in in acutely deteriorating asthma or to treat acute symptoms.

Fluticasone Propionate/Salmeterol (AirDuo Digihaler) was approved by the FDA in July 2019. It is a new combination of fluticasone propionate (an ICS) and salmeterol (a LABA). It is indicated for the treatment of asthma in patients 12 years of age and older. It should be used for patients not adequately controlled on a long-term asthma control medication such as an ICS or whose disease warrant initiation of treatment with both an ICS and LABA. It is not indicated for the relief of acute bronchospasm. The dosage recommendations were reviewed.

Fluticasone Propionate/Salmeterol Xinafoate (Xixela Inhub) was approved by the FDA in February 2019. It is a combination dry powder inhaler containing a corticosteroid and a LABA. It is indicated for the twice-daily treatment of asthma in patients 4 years of age and older. It is also indicated for the maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD).

The utilization report was reviewed. For glucocorticoids, inhaled, single entity, 92.9% of the prescription were for preferred products. For glucocorticoids, inhaled, combination, 74.8% of the prescriptions were for preferred products.

At the last review there were two motions. Single-entity: A motion of class effect to include one high-potency product, one low-to-medium potency product, and a budesonide product passed unanimously. Combination: A motion of class effect to include one high-potency product and one low-to-medium potency product passed unanimously.

The committee discussed which medication was best to use during an acute attack and how to convince the patients to change to the newer medication when they were used to using an albuterol inhaler. Dr. Umang Patel said treatment for acute attacks was moving towards ICS or fumarate rather than short-acting beta agonists. He did not know how to convince patients to use the newer medications other than telling them it was the preferred practice according to the guidelines. Mr. Riley noted that LABAs were still being used for acute symptom control, but ICS should be introduced earlier. Mr. Greear said physicians should ensure that patients are not using the short-acting medication all the time just because it is convenient.

The committee discussed the utilization report. Dr. Semling said the 74.8% utilization for the combination products were partially due to the fact that Advair went generic and many pharmacies shifted to the generic rather than the brand-name medication on the PDL.

The committee discussed the price differences between generic and brand-name medications, other issues that affect the overall cost, and whether pharmacies are educated as to which drugs are on the PDL. Dr. Narus said part of the issue was the timing of when Advair went generic relative to the PDL change. Generally, we move toward generics. The committee discussed possible mechanisms for getting the information out to the pharmacies when a brand-name drug was preferred over a generic.

SINGLE ENTITY: DR. RYAN MOVED A CLASS EFFECT TO INCLUDE ONE HIGH-POTENCY PRODUCT, ONE LOW-TO-MEDIUM POTENCY PRODUCT, AND A BUDESONIDE PRODUCT. SECONDED BY MR. GREEAR. THE MOTION PASSED UNANIMOUSLY.

COMBINATION: MR. RILEY MOVED A CLASS EFFECT TO INCLUDE ONE HIGH-POTENCY PRODUCT AND ONE LOW-TO-MEDIUM POTENCY PRODUCT. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

Respiratory: Beta Agonists Bronchodilators, Long-Acting (Green Class)
Public Comments for Respiratory: Bega Agonists Bronchodilators, Short-Acting (Blue Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Respiratory: Beta Agonists Bronchodilators, Long-Acting and Respiratory: Beta Agonists Bronchodilators, Short-Acting. A new product for beta agonists bronchodilators, short-acting, is Albuterol Sulfate (ProAir Digihaler). The FDA approved this medication as a breath-actuated albuterol digital inhaler with built-in sensors which connects to a companion mobile application and provides inhaler use information. Its launch is anticipated in 2019 through a small number of "Early Experience" programs, and a national launch planned in 2020. It is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease and the prevention of exercise-induced bronchospasm in patients 4 years of age and older. Life-threatening paradoxical bronchospasm may occur. Discontinue immediately and treat with alternative therapy. ProAir Digihaler is not a substitute for corticosteroids. Cardiovascular effects may occur. Use with caution in patients sensitive to sympathomimetic drugs and patients with cardiovascular or convulsive disorders. Dosage recommendations were reviewed. Safety and efficacy have not been evaluated for patients with hepatic impairment.

The utilization report for beta agonists long-acting was reviewed, and 50% 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.

MR. RILEY MOVED A CLASS EFFECT TO INCLUDE BOTH AN INHALER AND A NEBULIZED PRODUCT. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

The utilization report for beta agonists short-acting was reviewed, and 48.2% of the prescriptions were for preferred products. At the last review, a motion for class effect to include at least one Albuterol inhaled produce and a nebulized solution passed unanimously.

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

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

Public Comments for Allergy: Epinephrine, Self-Injected (Red 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, and insect bite/stings. According to the 2015 anaphylaxis practice parameter, anaphylaxis is currently defined as one of three scenarios based on the National Institute of Allergy and Infectious Disease (NIAID) and Food Allergy and Anaphylaxis Network (FAAN) criteria: The acute onset of a reaction (minutes to several hours) with involvement of the skin, mucosal tissue, respiratory tract, and/or reduced blood pressure; the rapid onset of a reaction 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 1 to 8 hours with as much as a 24-hour delay.

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

Symjepi, an epinephrine auto-injector, 0.3 mg and 0.15 mg availability were extended to the retail level; initially only the 0.3 mg strength was available and only in institutional settings. It is available as a single-dose prefilled syringe and device combination (not an auto-injector). 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.

An epinephrine auto-injector was approved as a generic in August 2018. Teva Pharmaceutical Industries launched its AB-rated generic for Mylan's Epipen Jr. (0.15 mg). The 0.3 mg strength had already been launched. It is indicated for the emergency treatment of Type I allergic reactions including anaphylaxis to stinging insets, biting insets, 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 utilization report was reviewed, and 86% of the prescriptions were for preferred products. At the last review, a motion for class effect to include a grandfathering clause for patients already trained on specific devices passed unanimously.

Mr. Greear said Symjepi was not an auto-injector. It was a prefilled syringe, and patients has to be conscious enough to inject themselves or have someone else do it for them. If the recommendation is for an auto-injector, Symjepi should be excluded. Most of the products come with a training device and work in a similar fashion. Although they are slightly different, children are able to do it after being given directions. These types of products are often short-dated on the shelves, although data suggests some companies have extended the expiration dates.

Dr. Ruggles said he did not believe that the Adrenaclick generic came with a training device.

The committee discussed how expensive the epinephrine auto-injectors were.

MR. GREEAR MOVED A CLASS EFFECT, TO INCLUDE AT LEAST ONE 0.15 MG AND ONE 0.3 MG AUTO-INJECTING PRODUCT.

In response to Dr. Hiestand, Mr. Greear said he was not including the grandfathering clause in his motion.

SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.

Allergy: Intranasal Rhinitis Agents (Green Class)

Dr. Umang Patel gave the Magellan presentation on Allergy: Intranasal Rhinitis Agents. The utilization report was reviewed, and 98% 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.

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

Allergy: Leukotriene Modifiers (Green Class)

Dr. Umang Patel gave the Magellan presentation on Allergy: Leukotriene Modifiers. The utilization report was reviewed, and 100% of the prescriptions were for preferred products. At the last review, a motion for class effect to exclude Zileuton passed unanimously.

MR. RILEY MOVED A CLASS EFFECT TO EXCLUDE ZILEUTON. SECONDED BY MR. GREEAR. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Allergy: Antihistamines, Minimally-Sedating (Red Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Allergy: Antihistamines, Minimally-Sedating. Rhinitis is defined as inflammation of the membranes lining the nose and is characterized by nasal congestion, rhinorrhea, sneezing, itching of the nose, and/or postnasal drainage. Although rhinitis may be caused by non-allergic (infectious, hormonal or occupational) factors, allergic rhinitis (AR) is the most common form. It is characterized by inflammation of the nasal mucous membranes due to an allergic response. There are two common forms of AR. Seasonal allergic rhinitis (SAR) occurs when plant pollens are at their highest levels in spring, summer and early fall. Perennial allergic rhinitis (PAR) occurs year-round and is usually caused by home or workplace pollutants. Individuals may have one or both forms of AR. Estimates from 2008 suggest that 10% to 30% of adults and up to 40% of children experience AR. It is the number one cause of work absenteeism. In children, approximately two million school days per year are lost due to AR.

Intranasal corticosteroids and oral antihistamines are the primary treatment options for AR. They are most effective in controlling symptoms of AR, particularly in relieving nasal allergy symptoms such as congestion, sneezing and runny nose. Alternative agents such as leukotriene modifiers, cromolyn sodium, and antihistamine nasal sprays may be appropriate in some patients. Oral antihistamines are particularly effective for severe rhinorrhea, sneezing, pruritus, and conjunctivitis associated with AR, although less effective for nasal congestion. The usefulness of first-generation antihistamines is reduced because the agents may produce significant sedation, impair performance, and/or result in anticholinergic effects. Consequently, the second-generation (minimally sedating) antihistamines, associated with a lower incidence of side effects, are generally considered before first-generation (sedating) antihistamines, especially in older adults and school-age children. For patients with more significant nasal congestion, several minimally-sedating antihistamines are available as combination dosage forms with the decongestant pseudoephedrine.

Chronic Idiopathic Urticaria (CIU) is defined as a transient appearance of elevated, erythematous pruritic wheals, or hives. The condition commonly affects the trunk and extremities, sparing the palms and soles, but urticaria may affect any epidermal or mucosal surface. Urticaria is predominantly due to release of mast cell mediators, mainly histamine, as a result of an ongoing immediate hypersensitivity reaction. CIU is when disease actively continues for more than six weeks, comprises 70% of all cases. In most patients, lesions clear spontaneously or respond rapidly to treatment with antihistamines; however, some patients continue to have lesions for prolonged periods. Of patients with CIU and angioedema, 75% have symptoms for longer than one year, 50% have symptoms for longer than five years, and 20% have symptoms for decades.

When attempts at identifying the cause of urticaria have failed, thus eliminating the possibility of reducing exposure, the patient requires treatment. Minimally-sedating histamine-1 (H_1)-receptor antagonists represent the basic therapy for all CIU patients. Older sedating antihistamines, such as hydroxyzine and diphenhydramine, may be indicated if symptoms are severe and if the patient is anxious and/or disturbed at night. Approximately 50% of CIU cases will result in antihistamine treatment. If clinical response is not adequate, H_2-inhibitory drugs, such as cimetidine and ranitidine, may be added to the antihistamine. Other agents reported to be beneficial in some cases include dioxepine, a tricyclic antidepressant with anti-H_1 and antihistamine-2 (H_2) properties, and the leukotriene receptor antagonist, which is off label. In addition, the anti-immunoglobulin E (lgE) antibody omalizumab (Xolair) is approved by the FDA to treat CIU in patient who are 12 years of age and older and who remain symptomatic despite H1 antihistamine therapy. If all agents fail, a course of glucocorticoids may be required. Third-line therapies involving immunosuppressive agents are only appropriate for patients with CIU refractory to other measures. All minimally-sedating antihistamines are effective treatments for CIU.

Guidelines from the American Academy of Allergy, Asthma and Immunology, and the American Academy of Otolaryngology - Head and Neck Surgery were reviewed.

Cetirizine Hydrochloride Injection (Quzyttir) is indicated for the treatment of acute urticaria in adults and children 6 months of age and older. It is not recommended in pediatric patients less than 6 years of age with impaired renal or hepatic function. There is a somnolence and sedation precaution so caution should be exercised when driving a car or operating potentially dangerous machinery. Dosage recommendations were reviewed.

The utilization report was reviewed, and 95.9% of the prescriptions were for preferred agents. At the last review, a motion for class effect to include an oral syrup for pediatric dosing or a suspension passed unanimously.

MR. 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, Non-GI Indications (Red Class)

ANTHONY HAGER, a representative if Bristol-Meyers Squibb, discussed Orencia. Since January 2018, Orencia's indications for rheumatoid arthritis, psoriatic arthritis, and juvenile idiopathic arthritis have not changed. Commonly reported adverse events include headache, upper respiratory tract infections, and nausea. Several studies and their outcomes were reviewed. (Audio difficulties.) We request that Orencia be included on the PDL as an option to patients not responding to other therapies.

MAE KWONG, a representative of Johnson & Johnson, discussed Stelara and Tremfya. Stelara is the only IL12 and IL23 agonist approved by the FDA for the treatment of adult patients with moderate to severe plaque psoriasis, active psoriatic arthritis (alone or in combination with methotrexate), moderate

to severely active Crohn's disease, and moderate to severely active ulcerative colitis, as well as for adolescent patients 12 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. (Audio difficulties.) Stelara has an established safety profile with low rates of serious infection. Tremfya is a first in class psoriasis therapy comprised of the first IL23 blocker approved by the FDA over two and a half years ago. It is indicated for the treatment of adult patients with moderate and severe plaque psoriasis. Its mechanism of action was reviewed. Several trials and studies were reviewed. Tremfya is the first and only IL23 with a patient-controlled self-injection device. We request that Stelara and Tremfya to the PDL. Both have demonstrated long-term efficacy and safety data and require fewer injections than the current PDL options. Stelara is approved for adolescents over the age of 12 where there are limited treatment options.

MARGARET OLMON, a representative of Abbvie, discussed Skyrizi, Rinvoq, and Humira. Please see the full prescribing information at www.rxabbie.com for comprehensive safety and efficacy data. Skyrizi is an IL23 inhibitor indicated for the treatment of moderate to severe plaque psoriasis in adults. It is given as a subcutaneous injection at week zero, week four, and every 12 weeks, which means that four doses per year are needed for maintenance therapy. Several trials and their outcomes were reviewed. There were no unexpected safety findings and there are no contraindications to treatment. Rinvoq is an oral JAK inhibitor indicated for the treatment of patients with moderate to severe active rheumatoid arthritis. It is given as a 15-milligram tablet once a day. Several trials and their outcomes were reviewed. It is the only approved JAK inhibitor to demonstrate inhibition of joint damage in its approved population of methotrexate IR patients. It is also the only targeted immunomodulator to show clinical superiority, Humira plus methotrexate. The most common adverse reactions were respiratory tract injections, nausea, coughing and fever. The committee is familiar with Humira, so no information will be provided at this time. We urge the committee to maintain the preferred status of Humira on the PDL, and to add Skyrizi and Rinvoq as available treatments for Medicaid patients in Alaska.

ANTHONY WHEELER, a representative of Eli Lilly, discussed Taltz. Taltz is an IL17 inhibitor that was originally approved for the treatment of plaque psoriasis, but it has since been approved for psoriatic arthritis and ankylosing spondylitis. Several studies and their outcomes were reviewed. Please review the package insert for additional information.

Dr. Umang Patel gave the Magellan presentation of Immunological: Cytokine & CAM Antagonists, Non-GI Indications. Cytokines and cell-adhesion molecules (CAMs) are chemical mediators involving inflammatory processes throughout the body.

Cytokines are small proteins secreted in response to an immune stimulus for the purpose of mediating and regulatory immunity, inflammation, and hematopoiesis. It is derived from monocytes and macrophages and induce gene expression with a number of proteins that contribute to the inflammatory response. The actions of the individual cytokines are widely varied, and they contribute to fibrosis and tissue degeneration associated with chronic inflammation, primarily by inducing the proliferation of fibroblasts and collagenase. The pro-inflammatory cytokines, tumor necrosis factors (TNFs) and interleukins (IL)-1s 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.

Cell adhesion molecules (CAMs) are cell surface proteins involved in the binding of cells, usually leukocytes, to each other, and 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 (lg) superfamily, the integrin family, and the selectin family. 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.

Guidelines from the American College of Rheumatology (ACR), the Juvenile Idiopathic Arthritis-ACR/Arthritis Foundation, the Ankylosing Spondylitis-ACR Spondylitis Association of America (SAA) & Spondylarthritis Research and Treatment Network (SPARTAN), the American Academy of Dermatology (AAD), the ACR & National Psoriasis Foundation, the Periodic Fever Syndrome, and the Giant Cell Arteritis (GCA) were reviewed. The guidelines covered rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, plaque psoriasis and psoriatic arthritis, periodic fever syndrome, giant cell arthritis, and other disease states.

Guselkumb (Tremfya) is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Tremfya may increase the risk of injection. Patients should be instructed to seek medical advice if signs or symptoms of clinically important chronic or acute infection occurs. If a serious infection develops, discontinued until it resolves. Patients should be evaluated for tuberculosis prior to initiating treatment. Live vaccines should be avoided in patients treated with Tremfya. Dosing recommendations were reviewed. There is no available data for pregnant women. There are no indications for anyone less than 18 years of age. No specific studies were conducted to determine hepatic or renal impairment for the PK of this medication.

Risankizumab-rzza (Skyrizi) was approved by the FDA in April 2019. It is an IL-23 antagonist indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. It may increase the risk of injection. Patients should be instructed to seek medical advice if signs or symptoms of clinically important chronic or acute injections occur. If a serious infection develops, discontinue until it resolves. Patients should be evaluated for tuberculosis prior to initiating treatment. Live vaccines should be avoided in patients treated with Skyrizi. Dosing recommendations were reviewed. There is no available data in terms of pregnancy, hepatic and renal impairment dose adjustments.

Etanercept-ykro (Eticovo) was approved by the FDA in April 2019. It is a biosimilar to Amgen's Enbrel for the treatment of rheumatoid arthritis, polyarticular JIA, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. There is an increased risk of serious infections leading to hospitalization or death, including tuberculosis, bacterial sepsis, invasive fungal infections, and injections due to other opportunistic pathogens. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including etanercept products. Dosing recommendations were reviewed. There is no available data in terms of pregnancy, hepatic and renal impairment dose adjustments.

Infliximab-abda (Renflexis) is a TNF blocker indicated for the treatment of Crohn's disease, pediatric Crohn's disease, ulcerative colitis, pediatric ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis. There is an increased risk of serious infections leading to hospitalization or death including tuberculosis, bacterial sepsis, invasive fungal injections, and injections due to other opportunistic pathogens. Lymphoma and other malignancies, some fatal,

have been reported in children and adolescent patients treated with TNF blockers, including etanercept products. Dosing recommendations were reviewed.

Apremilast (Otezla) was approved by the FDA in July 2019 with a new indication to treat adults with oral ulcers associated with Bechet's disease. Dosage for this indication is consistent with PSO and PSA indications. Dosing reductions or suspension should be considered if patients develop severe diarrhea, nausea, or vomiting. Patients, caregivers and families should be advised to be alert for the emergency or worsening of depression, suicidal, thoughts or other mood changes. If such changes occur, they should contact their healthcare provider. Physicians should carefully weight risks and benefits of treatment in patients with a history of depression and/or suicidal thoughts and behaviors. Weight should be monitored regularly. If unexplained or clinically significant weight loss occurs, evaluate weight loss and consider discontinuation.

Adalimumab-bwwd (Hadlima) was approved by the FDA in July 2019. It is a biosimilar to Humira for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, and ulcerative colitis. The launch is expected on or after June 30, 2023. There is an increased risk of serious infections leading to hospitalization or death including tuberculosis, bacterial sepsis, invasive fungal injections, and injections due to other opportunistic pathogens. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including etanercept products. 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 treated with TNF blockers including adalimumab products. Do not start treatment during an active injection.

Upadacitinib (Rinvoq) was approved by the FDA in August 2019. It is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. Use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. There is an increased risk of serious infections leading to hospitalization or death including tuberculosis, bacterial sepsis, invasive fungal injections, and injections due to other opportunistic pathogens. Lymphoma and other malignancies have been observed in patients treated with Rinvoq. Thrombosis, including deep vein thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treatment with JAK inhibitors used to treat inflammatory conditions. Prior to starting, perform a test for latent tuberculosis. If positive, start treatment for tuberculosis prior to starting Rinvoq. Dosing recommendations were reviewed.

Ixekizumab (Taltz) received an expanded indication by the FDA in August 2019 for the treatment of adults with active ankylosing spondylitis. It is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, active psoriatic arthritis, and active ankylosing spondylitis. Liver vaccines should not be given with Taltz. Serious infections have occurred. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infections occur. If a serious injection develops, discontinue until the infection resolves. Patients should be evaluated for tuberculosis prior to initiating treatment. Crohn's disease and ulcerative colitis, including exacerbations, have occurred during clinical trials, so patients who are treated with Taltz and have inflammatory bowel disease should be monitored closely.

Certolizumab pegol (Cimzia) received an expanded indication by the FDA in March 2019 for the treatment of non-radiographic axial spondylarthritis with objective signs of inflammation. Live vaccines should not be given with Cimzia. There is an increased risk of serious infections leading to hospitalization or death including tuberculosis, bacterial sepsis, invasive fungal injections, and injections due to other opportunistic pathogens. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including etanercept products. Patients should be evaluated for tuberculosis prior to initiating treatment.

Ustekinumab (Stelara) received FDA approval in October 2019 for a new indication for the treatment of moderately to severely active ulcerative colitis in adults. This is a GI indication. Because it already had other non-GI indications, it was included for informational purposes.

Etanercept-szzs (Erelzi) received FDA approval in October 2019 for a new indication for the treatment of psoriatic arthritis and psoriasis in adults. It was already approved for rheumatoid arthritis, ankylosing spondylitis and polyarticular JIA. Live vaccines should not be given with Erelzi. There is an increased risk of serious infections leading to hospitalization or death including tuberculosis, bacterial sepsis, invasive fungal injections, and injections due to other opportunistic pathogens. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including etanercept products. There are no available studies to indicate any form of adverse effects with pregnant patients or the fetus. There have been reports of hypoglycemia following initiation of this medication in specific patients receiving medications for diabetes, necessitating a reduction in anti-diabetic medications due to a drug-drug interaction.

Adalimumab-afzb (Abrilada) was approved by the FDA in November 2019. It is a new biosimilar to Humira. It is indicated for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn's disease, ulcerative colitis and plaque psoriasis. Live vaccines should not be given with Abrilada. There is an increased risk of serious infections leading to hospitalization or death including tuberculosis, bacterial sepsis, invasive fungal injections, and injections due to other opportunistic pathogens. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including etanercept products. For patients who develop a systemic illness on Abrilada, consider empiric antifungal therapy for those who reside or travel to regions where mycoses are endemic.

Guselkumab (Tremfya) received an FDA approval in November 2019 for a new formulation as a single-dose One-Press patient-controlled injector. Its single-dose prefilled syringe was already approved.

Infliximab-axxq (Avsola) was approved by the FDA in December 2019. It is a new biosimilar to Remicade. It is indicated for the treatment of Crohn's disease in adults and pediatric patients, ulcerative colitis in adults and pediatric patients, rheumatoid arthritis in combination with methotrexate, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis. Live vaccinations should not be given with Abrilada. There is an increased risk of serious infections leading to hospitalization or death including tuberculosis, bacterial sepsis, invasive fungal injections, and injections due to other opportunistic pathogens. Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including etanercept products. For patients who develop a systemic illness on Abrilada, consider empiric antifungal therapy for those who reside or travel to regions where mycoses are endemic. Severe hepatic reactions, some fatal or necessitating

liver transportation has been reported. Stop Avsola in case of jaundice and/or marked liver enzyme elevations. Use with anakinra or abatacept can increase the risk of serious infections.

The FDA issued a safety announcement regarding Xeljanz/Xeljanz XR in September 2019. An ongoing clinical trial found there was an increased risk of blood clots in the lungs and death when a 10-milligram, twice-daily dose was tofacitinib was used in patients with RA, which is not an FDA-approved dose of for rheumatoid arthritis. Patients should be monitored for PE and advised to seek medical attention is symptoms of a PE occur. The trial is expected to be completed by the end of 2019 with patients assigned the higher dose switched to a lower dose.

The utilization report was reviewed, and 73.2% of the prescriptions were for preferred products. At the last review a motion of 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.

DR. LILJEGREN 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, WITH A GRANDFATHERING CLAUSE FOR PATIENTS WHO HAVE PREVIOUSLY RESPONDED TO OTHER AGENTS.

In response to Mr. Greear, Dr. Semling said many of the drugs in this class cost $7,500 per month or more, which triggers prior authorization.

After discussion, the committee determined that there were no oral agents available in this class, so it was unnecessary to include that in the motion.

DR. LILJEGREN AMENDED THE MOTION TO MOVE THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE FORMULATION FOR PEDIATRICS, ONE FOR ARTHRITIS AND ONE FOR PSORIASIS, WITH A GRANDFATHERING CLAUSE FOR PATIENTS WHO HAVE PREVIOUSLY RESPONDED TO OTHER AGENTS.

In response to Dr. Liljegren, Dr. Umang Patel said the cytokine and CAM antagonists for the GI indications were reviewed in the fall and were a separate class.

SECONDED BY MR. GREEAR. THE MOTION PASSED UNANIMOUSLY.

Break from 10:20 a.m. to 10:33 a.m.

Chair Hiestand called the meeting back to order at 10:33 a.m. The roll call was taken, and all the participants were present.

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 antibody is 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 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 any time after transplantation. 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 the changes in organ function are not usually reversible.

The sequence of events in grant rejection is (1) recognition of donor's histocompatibility differences by the recipient's immune system, (2) recruitment of activated lymphocytes, (3) initiation of immune effector mechanisms, (4) destruction of the graft. These events can take place at varying rates and may involve differing effects or mechanisms. Therefore, rejection of the transplanted tissue can take place any anytime following surgery. The immunosuppressive drugs and dosing used in the maintenance of transplanted organs varies, but the regimens generally follow the same principles. Following the 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-mediating mechanisms of action and may also allow for the use of lower doses of individual agents in order to minimize toxicity.

Tacrolimus ER (Astagraf XL) received an expanded indication by the FDA in December 2018 to include pediatric patients less than 16 years of age. Additional boxes warnings include the increased mortality in female liver transplant recipients for tacrolimus ER, and the increased risk of developing serious infections and malignancies with Astagraf XL or other immunosuppressants that may lead to hospitalization or death. Compared to Caucasian patients, African American patients may need to be titrated to higher doses to attain comparable concentrations.

Tacolimus ER (Envarsus XR) received a new indication by the FDA in December 2018 to prevent organ rejection in de novo kidney transplant patients in combination with other immunosuppressants. There is an increased risk for developing serious infections and malignancies with Envarsus XR or other immunosuppressants that may lead to hospitalization or death. This medication may also cause an insulin-dependent post-transplant diabetes mellitus in as many as 11-22% of transplant patients. It can also induce nephrotoxicity, which was reported in about 36-59% of transplantation patients. To avoid nephrotoxicity, this medication should not be used within 24 hours of tacrolimus. Pregnant women should be advices of a potential risk to the fetus. Dosage recommendations were reviewed.

Mycophenolate mofetil had a Class 2 recall due to discovery of a glass fragment within the reconstituted vial. Par Pharmaceutical issued a voluntary recall of one lot of injectable mycophenolate mofetil distributed between January 23, 2019 and February 11, 2019, packaged in cartons of four single-use vials. There were no reports of adverse events related to this recall.

The utilization report was reviewed, and 77.4% of the prescriptions were for preferred products. At the last review, a motion of class effect passed unanimously.

MR. RILEY MOVED A CLASS EFFECT. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY (with Dr. Liljegren not responding).

4-D. Dermatological: Antipsoriatics, Topical (Red 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 (Green Class); Acne, Topical (Red Class)

Public Comments for Dermatological: Antipsoriatics, Topical (Red Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Dermatological: Antipsoriatics, Topical. Psoriasis is a common chronic, inflammatory, multisystem condition with predominantly skin and joint manifestations. It is characterized by erythematous plaques with silvery scales that negatively impacts the quality of life. It is estimated that over 8 million people in the U.S. have psoriasis. The prevalence of psoriasis is 1.9% in African Americans, 1% in Hispanics, and 3.6% in Caucasians. It usually presents between the ages of 15 to 35, but it can develop at any age. There are five types of psoriasis: plaque, guttate, inverse, pustular, and erythrodermic. The most common type is plaque psoriasis in which patches or lesions of skin becomes 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. Mild to moderate psoriasis is generally treated with topical agents. Phototherapy is used when the disease is widespread and unresponsive to topical agents. Systemic agents, including biologic drugs, are usually reserved for patients with moderate to severe disease or those with psoriatic arthritis. Moderate to severe psoriasis is defined as involvement of more than 5-10% of the body surface area or involvement of the face, palm or sole, or disease that is otherwise disabling. Patients with moderate to severe disease are generally candidates for systemic therapy. Options for systemic therapy include methotrexate, cyclosporine, retinoids, biologics, and methoxsalen plus ultraviolet A (UVA) radiation.

Guidelines from the American Academy of Dermatology (AAD), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the National Psoriasis Foundation were reviewed.

Halobetasol propionate/tazarotene (Duobrii) was approved by the FDA in April 2019. It is a combination of a topical corticosteroid and a topical retinoid indicated for the topical treatment of plaque psoriasis in adults. The most common adverse reactions reported in clinical trials include contact dermatitis, application site pain, folliculitis, skin atrophy, and excoriation. Dosage recommendations were reviewed.

Calipotriene (Sorilux) was approved by the FDA in November 2019. It is indicated for the topical treatment of plaque psoriasis of the scalp and body in adults and pediatric patients 4 years of age and older. Do not use in patients with known hypercalcemia. Adverse reactions reported in about 1% of subjects treated with this medication were application site erythema and application site pain. Elevation of serum calcium has occurred with use of this medication. If elevated in serum calcium is

outside the normal range, treatment should be discontinued until normal calcium levels are restored. Dosage recommendations were reviewed.

Calcipotriene/betamethasone dipropionate (Taclonex Topical Suspension) received an expanded indication by the FDA in July 2019 for the topical treatment of plaque psoriasis of the scalp and body in patients 12 years of age and older. Previously, it was approved for plaque psoriasis of the scalp in patients 12 to 17 years of age, and of both the scalp and body in adults. Dosage recommendations were reviewed.

Calcipotriene/betamethasone dipropionate (Enstilar) received an expanded indication from the FDA in July 2019 for the topical treatment of plaque psoriasis in patients 12 years and older. Previously, it was approved for adults only. Dosage recommendations were reviewed.

The utilization report was reviewed, and 75.5 percent of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

Dr. Liljegren noted that she had technical problems and had not been present for the last vote, but now she was back.

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

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

BRANDON YIP, a representative of Sanofi Genzyme, discussed Dupixent. It is in IL4 receptor antagonist. It is indicated for chronic rhinosinusitis with nasal polyps. It is available in a prefilled, single-dose syringe for subcutaneous self-administrated injection. Dosage recommendations were reviewed. Several studies and their outcomes were reviewed.

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." It affects about 17.8 million Americans and accounts for 10-20% of all visits to the 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 inside of the elbows, behind the knees, and on the face, hands, and feet. In response to intensive itching, patients may scratch or rub the affect 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 dermatologic condition, there may be periods of the disease when the skin improves and periods when it 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."

Guidelines from the American Academy of Dermatology (AAD) and the American Academy of Allergy, Asthma, and Immunology (AAAAI) were reviewed.

Dupilumab (Dupixent) received a new indication from the FDA in June 2019 for the treatment of adults with nasal polyps accompanied by chronic rhinosinusitis. In March 2019, it received an expanded indication for the treatment of patients 12 years of age and older with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable (with or without topical corticosteroids). Previously, it was only approved for adults for this indication. Dosing recommendations were reviewed.

In January 2019, Pimecrolimus, the first generic for Elidel cream by Actavis/Teva Pharmaceuticals was approved. It is indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable. The FDA issued a public health advisory in 2006 to inform healthcare providers and patients about the potential cancer risk associated with the use of Elidel and Protopic. It has a boxed warning regarding the long-term safety of topical calcineurin inhibitors, which has not been established. It should not be used in immunocompromised adult and pediatric patients. It is pregnancy category C. There is insufficient data in patients with renal or hepatic impairment.

The utilization report was reviewed, and 56% of prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives passed unanimously.

DR. RUGGLES MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RYAN. 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)
Dermatological: Topical Steroids Very High Potency (Green Class)

Dr. Umang Patel gave the Magellan presentation on Dermatological: Topical Steroids Low Potency, Medium Potency, High Potency, and Very High Potency.

The utilization reports for topical steroids were reviewed. Low potency: 90.3% of prescriptions were for preferred product. Medium potency: 76.8% of prescriptions were for preferred products. High potency: 96.4% of prescriptions were for preferred products. Very high potency: 91% of prescriptions were for preferred products.

At the last review, a single motion for class effect within each potency group and to include at least one ointment and one cream from each potency group passed unanimously.

MR. 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 MS. WHITE. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Dermatological: Acne, Topical (Red 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 U.S. 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 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 include 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 consists 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. 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 include more than 125 lesions consisting of comedones, papules, and pustules.

Guidelines from the Global Alliance to Improve Outcomes in Acne were reviewed.

Minocycline (Amzeeq) was approved by the FDA in November 2019. It is a tetracycline-class drug indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris inpatients 9 years of age and older. Patients should avoid smoking and exposure to flames during and immediately following application as the propellant in this canister is flammable. Use may result in overgrowth of bacteria and fungi that are not susceptible to minocycline topical foam. It carries warnings associated with tetracycline class antibiotics, including teratogenic effects, permanent tooth discoloration, and inhibition of bone growth with oral tetracyclines in the 2nd and 3rd trimesters of pregnancy and up to 8 years of age. Dosing recommendations were reviewed. The launch for this medication is anticipated in 2020.

Trifarotene (Aklief) was approved by the FDA in October 2019 as a retinoid for topical treatment of acne vulgaris in patients 9 years of age and older. Patients 65 years of age and older were not included in clinical trials; therefore, response differences are unknown. Clinical trial data regarding use of this medication in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Dosage recommendations were reviewed.

Dapsone (Aczone 7.5%) received an expanded indication by the FDA in September 2019 for the use of acne vulgaris in patients 9 years of age and older. Previously, it was approved only in patients 12 years of age and older. This medication is pregnancy category C.

Discontinuations were reviewed. In August 2019, Biofrontera announced the discontinuation of Aktipak until further notice due to technical challenges with the manufacturing process that cannot be remedied in the short term. In July 2019, GlaxoSmithKline announced the discontinuation distribution of Duac due to business reasons. The effective date was about November 2019.

The utilization report was reviewed, and 52% of 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.

The committee discussed last year's motion in relation to the utilization report. Now that there is a generic available, it will be taken into consideration when the PDL is formulated.

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 MR. RILEY. THE MOTION PASSED UNANIMOUSLY.

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

Ophthalmics: Ophthalmic, Allergic Conjunctivitis (Green Class)

Dr. Umang Patel gave the Magellan presentation on Ophthalmics: Ophthalmic, Allergic Conjunctivitis. The utilization report was reviewed, and 94.8% of the prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives passed unanimously.

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

Ophthalmics: Ophthalmic, Antibiotics (Green Class)
Ophthalmics: Antibiotics-Steroid Combination (Green Class)

Dr. Umang Patel gave the Magellan presentation on Ophthalmics: Antibiotics and Antibiotics-Steroid Combination. The utilization report was reviewed. For Antibiotics: 98.7% of the prescriptions were for preferred products. For Antibiotics-Steroid Combination: 75.5% of the prescriptions were for preferred products.

At the last review, a single motion of class effect for each subclass of the ophthalmic, antibiotics; and that the drugs in the ophthalmic, antibiotic-steroid combinations were therapeutic alternatives passed unanimously.

DR. RYAN 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 MR. GREEAR. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Ophthalmics: Ophthalmic, Anti-inflammatory (Blue Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Ophthalmics: 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 is caused by eye trauma, secondary to autoimmune disease 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 flares, due to cellular infiltration and protein exudation into the anterior chamber, are seen as spots and haze on slit-beam examinations, and both are signs are ocular inflammation. If left untreated, it can lead to glaucoma, cataract, or retinal edema, and ultimately loss of vision. Initial treatment typically includes ophthalmic corticosteroids 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 this 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.

Guidelines from the American Academy of Ophthalmology were reviewed.

Dexamethasone (Dextenza) received an expanded indication from the FDA in June 2019 to include treatment of ocular inflammation following ocular surgery. It had already been indicated to treat ocular pain following ocular surgery.

The utilization report was reviewed, and 89.1% of the prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives to include one drug from each subgroup passed unanimously.

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

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

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Ophthalmics: Ophthalmic, Glaucoma Agents. Approximately 2.7 million people in the U.S. suffer from glaucoma. It is the second most common cause of permanent blindness in the U.S. and the most common cause among African Americans and Hispanics. Risk factors for the development of glaucoma include elevated IOP, advancing age, family history, 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. In closed-angle glaucoma, the iris is pushed forward against the trabecular meshwork, blocking fluid from escaping. Reduction of IOP may be achieved 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 guidelines from the American Academy of Ophthalmology were reviewed.

Netarsudil/Latanoprost (Rocklatan) was approved by the FDA in March 2019. It is a fixed dose combination of a Rho kinase inhibitor and a prostaglandin F2-alpha analogue indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Reactivation of herpes simplex keratitis has been reported during treatment with Latanoprost. Ophthalmic products containing thimerosal should be administered at least five minutes apart from latanoprost as precipitation has been reported. Using a combination of two or more prostaglandins or prostaglandin analogs is not recommended. Adverse effects include eyelash growth, eyelash or eyelid darkening, corneal verticillate, and conjunctival hemorrhage.

The utilization report was reviewed, and 77% of prescriptions were for preferred agents. At the last review, a motion of therapeutic alternatives to include at least one drug from each subclass passed unanimously.

MR. GREEAR MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE DRUG FROM EACH SUBCLASS. SECONDED BY DR. DORAN-ATCHISON.

The committee discussed last year's motion, which included at least one drug from each subclass, but no Rho kinase inhibitors were on the PDL. Dr. Doran-Atchison said the medically necessary clause could be utilized. Dr. Liljegren wanted to hear an ophthalmologist's opinion on Rho kinase inhibitors.

DR. RUGGLES OFFERED A FRIENDLY AMENDMENT THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE FROM EACH SUBCLASS. THE MAKER OF THE MOTION AND THE SECOND ACCEPTED THE FRIENDLY AMENDMENT. THE MOTION PASSED UNANIMOUSLY.

Ophthalmics: Ophthalmic, Immunomodulators (Green Class)

Dr. Umang Patel gave the Magellan presentation on Ophthalmics: Immunomodulators. The utilization report was reviewed, and 88.6% 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. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

The public session ended at 11:49 a.m. and the committee moved into executive session.

5. Review Minutes from November 2019

6. Comments from Committee Members or Chair

7. Adjourn