Alaska Medicaid Pharmacy and Therapeutics Meeting

MINUTES OF MEETING
January 20,2023

Committee Members Present:
John Riley, PA, Acting Chairman
Robert Carlson, MD
Sarah Doran-Atchison, PharmD
Charles Ryan, MD
Trisha White, R.Ph.
Casey Gokey, MD
Valerie Bixler, PharmD

Committee Members Absent:
Matthew Begay-Bruno, PharmD
Claudia Phillips, MD

Others Present:
Umang Patel, PharmD
Ryan Ruggles, PharmD
Charles Semling PharmD, DHSS
Matthew Parrott PharmD, DHSS
Victoria Romo-LeTourneau, PharmD, Pfizer
Shirley Quach, Novartis
Erin Nowak, AbbVie
Andrew Delgado, Bristol Myers Squibb
Valerie Ng, LEO Pharma

1. Call to Order – Chair

Mr. Riley called the meeting to order.

2. Roll Call

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

3. Public Comments - Local Public/Health Practitioners

None.

4. Class Review, Discussion & Vote

4-A. Respiratory: COPD Agents (Green); Inhaled Glucocorticoids (Blue); Pancreatic Enzymes (Green)

Respiratory: COPD agents (Green)

Umang Patel gave the Magellan presentation for COPD agents. Being that this is a green class there are no changes. Therefore, Umang went right into the utilization. 99.5% is in line with the PDL.

Previous years motion, Mr. Greear moved the drug in the class were therapeutic alternatives which was seconded by Dr. Ryan. It was passed unanimously.

Definition was given to differentiate therapeutic alternatives versus class effect for those that are new to the committee.

DR. CARLSON MOVED THAT THE DRUGS WERE THERAPEUTIC ALTERNATIVES, SECONDED BY MRS. WHITE. THE MOTION PASSED UNANIMOUSLY.

Respiratory: Inhaled Glucocorticoids (Blue Class)

Umang Patel gave the Magellan presentation for Respiratory: Inhaled Glucocorticoids. The single entity and combination were combined due to the background and guidelines being one in the same. The prevalence of asthma in the United States continues to rise. More than 25 million Americans have asthma and over 4 million are children. The national asthma, education and prevention program has defined asthma as the 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 hyperresponsiveness to a variety of stimuli.

Studies have demonstrated that the efficacy of inhaled corticosteroids in improving lung function, reducing symptoms, reducing frequency and severity of exacerbations and improving quality of life of patients with asthma.

In 2007 the National Heart Lung and Blood Institute states that inhaled corticosteroids 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 inhaled corticosteroids containing controller treatment to reduce the risk of serious exacerbation and to control symptoms. Updated GINA guidelines offer controlled based management plan to adjust to treatment in a continuous cycle of assessment, treatment and review of the patient's response as it related to symptom, control, future risk of exacerbations and side effects.

Equally important in this process is identifying the patients' own goals regarding their asthma management to ensure improved outcomes. Patients whose asthma is not adequately controlled on the preferred controller, despite good adherence and control, a step up in treatment may be

added until control is achieved. This can be a short term or sustained step-up therapy. If control is maintained for at least 3 months on the current regimen than treatment can be stepped down to the low step of dosage that maintains control.

Patients should be started on treatment based on symptoms with infrequent symptoms beginning at step 1 and more frequent, severe and debilitating symptoms beginning at step 4. Notably, reliever therapy can be considered for symptom management prior to exercise if needed.

The 2021 GINA guidelines described a 2-treatment track. All the verbiage behind this process was discussed.

In March 2022 a new generic was released, breyna. This was the first FDA approved generic for Symbicort. This will be marketed under the trade name Breyna for which the launch was anticipated for last year.

In April of 2022 the FDA approved ArmonAir Digihaler for the maintenance treatment of asthma as prophylactic therapy in adults and pediatric patients 4 years of age or older. It was previously prescribed for 12 years and older. There were no changes to precautions, dosage or availability.

First discussed the single entity utilization. 88% is in line with the PDL. Previous years motion Trish White stated that she would move a slight change with the information about the new FDA approval of drugs for kids under and would change the inhaled single entity to class effect including one high potency product, one low to medium potency product and one product approved for children under 5 because she thought that the approval of fluticasone for younger children now will make it much more uncommon to need an alternative non-formulary treatment like budesonide. Dr. Carlson seconded that motion and the motion passed with one abstination.

DR. CARLSON MOVED THAT THE DRUGS WERE THERAPEUTIC ALTERNATIVES, SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Respiratory: Combination Medications (Green Class)

Umang Patel discussed combination medication utilization. It is roughly 79-78% in line with PDL. Previous years motion Dr. Ryan moved to class effect to include one high potency product, one low to medium potency product and a budesonide product. This was seconded by Dr. Lilijegren and passed unanimously.

DR. DORAN-ATCHISON MOVED THAT THE DRUGS WERE THERAPEUTIC ALTERNATIVES, SECONDED BY MRS. WHITE. THE MOTION PASSED UNANIMOUSLY.

Respiratory: Bronchodilators (Green Class)

Umang Patel discussed the utilization for bronchodilators. This was about 88% in line with PDL. Previous motion was Dr. Ryan moved to class effect, to include both an inhaler and nebulized product. This was seconded by Mrs. White and passed unanimously.

DR. DORAN-ATCHISON MOVED THAT THE DRUGS WERE THERAPEUTIC ALTERNATIVES, SECONDED BY DR. GOKEY. THE MOTION PASSED UNANIMOUSLY.

Respiratory: Bronchodilators – long acting (Green Class)

Umang Patel discussed the utilization of long-acting bronchodilators. It is roughly 81% in line with PDL. Previous years motion Mrs. White moved a class effect to include at least one inhaled product in a nebulae solution. This was seconded by Dr. Ryan and passed unanimously.

MRS. WHITE MOVED THAT THE DRUGS WERE THERAPEUTIC ALTERNATIVES, SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Respiratory: Epinephrine (Green Class)

Umang Patel discussed the utilization of epinephrine, self-injected. It is 100% in line with PDL. Previous years motion Dr. Ryan moved to class effect to include at least one 0.15 mg and one 0.3 mg auto injecting product. This was seconded by Dr. Lilijegren and passed unanimously.

DR. DORAN-ATCHISON MOVED THAT THE DRUGS WERE THERAPEUTIC ALTERNATIVES, SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Respiratory: Inhaled Glucocorticoids (Blue Class)

VICTORIA ROMO-LETOURNEAU, from Pharm D representing Pfizer gave testimony for abrositinib, brand name Cibinqo. This is a JAK inhibitor for atopic dermatitis.

UMANG PATEL let her know that would be under the category of cytokine inhibitors. She stated that she was just wanting to remedy the technical difficulties she was having.

Respiratory: Intranasal rhinitis (Blue Class)

Umang Patel gave the Magellan presentation for intranasal rhinitis. This affects approximately 8% of adults and 7% of children in the United States. It is characterized by sneezing as well as itching of the eyes, nose, palette, 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. Antibodies bind to the receptors on the mass cells in respiratory mucosa and the basal cells in the peripheral blood. Mass cells release pre-formed and granule associated chemical mediators and mass cells generate other inflammatory mediators and cytokines which lead to nasal inflammation and with continued allergen exposure chronic symptoms. Perennial allergic rhinitis is an IGE mediated

reaction to allergens with little or no seasonal variation. This is typically persistent, chronic and generally less severe than seasonal allergic rhinitis. Irritant rhinitis is a condition of unknown origin. It is aggravated by various things such as fumes and odors, temperature and atmosphere changes, smoke and other irritants. This form of rhinitis is generally found in adults and causes year-round symptoms that include congestion and headache.

In 2020 the American Academy of Allergy, Asthma and Immunology recommended inhaled antihistamines as first line for seasonal allergic rhinitis, intermittent allergic rhinitis and non-allergic rhinitis. Intranasal corticosteroids are the preferred monotherapy for persistent allergic rhinitis. Those guidelines suggest combination of an intranasal corticosteroid and intranasal antihistamine for moderate or severe cases in patients 12 years of age or older in seasonal allergic rhinitis, and perennial allergic rhinitis, that is resistance to monotherapy and resistant non-allergic rhinitis. An alternative option for rhinorrhea that persists while on intranasal corticosteroids is the addition of intranasal ipratropium. If nasal congestion persists despite treatment with an intranasal corticosteroid, with or without an intranasal antihistamine, addition of an intranasal decongestion for up to 4 weeks may be considered. The guidelines also provide pharmacotherapy recommendations using oral agents and strongly recommend use of an oral second-generation antihistamine and against prescribing an oral first-generation antihistamine for the treatment of allergic rhinitis.

In January of 2022 the FDA approved a new combination medication of olopatadine, a H1 receptor inhibitor and mometasone furoate a corticosteroid indicated for the treatment of symptoms of seasonal allergic rhinitis is adults and pediatric patients 12 years of age or older.

Precautions were discussed. Dosage was also discussed.

Nasonex 24-hour allergy was updated in March 2022. The FDA approved this for OTC use for temporary relief of symptoms of hay fever and other upper respiratory allergies such as nasal congestion, sneezing, runny nose and itchy nose in those 2 years of age and older. This is considered a partial prescription that OTC switch. For adults and children 12 years of age or older they would do 2 sprays in each nostril once daily while sniffing gently. For children 2 to 11 years of age they would do 1 spray in each nostril once daily. In July 2022 Nasonex for the treatment of nasal symptoms of allergic rhinitis and nasal congestion associated with seasonal allergic rhinitis in patients 2 years of age or older has been removed from the RX labeling.

The OTC version of Perrigo, which has not yet been launched, is labeled for the removed indications. RX Nasonex is listed as discontinued by the federal register however NDC still remain in first databank.

In June 2022 Patanase was discontinued. The FDA has reported that Novartis made a business decision to discontinue both brand Patanase and the authorized generic version of this product.

The utilization report was reviewed and stated that they are roughly 99% is in line with the PDL. Previous years motion Dr. Lilijegren moved that the drugs in the class were therapeutic alternatives to include one anticholinergic, one antihistamine and one corticosteroid. This was seconded by Dr. Carlson and passed unanimously.

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

Respiratory: Leukotriene modifiers (Green Class)

The utilization report was reviewed and stated that they are roughly 99.9% is in line with the PDL. Previous years motion Dr. Carlson moved a class effect to exclude Zileuton. This was seconded by Dr. Lilijegren and passed unanimously.

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

Respiratory: Antihistamines (Green Class)

The utilization report was reviewed and stated that they are roughly 94% is in line with the PDL. Previous years motion Dr. Ryan moved a class effect to include an oral syrup or a suspension for pediatric dosing. Seconded by Dr. Doran-Atchison and passed unanimously.

DR. RYAN MOVED A CLASS EFFECT WITH ORAL SYRUP OR A SUSPENSION FOR PEDIATRIC DOSING. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

4-B. Cytokine and CAM antagonists, non-GI indications (Red class)

Public Comments for Cytokine and CAM antagonists, non-GI indications (Red Class)

SHIRLEY QUACH, a representative from Novartis, stated that last year updates were given on Cosentyx and that since then there have been no new updates.

ERIN NOWAK, a representative from AbbVie, provided some information regarding Rinvoq and Skyrizi.

First you have had an upadacitinib with the tradename Rinvoq. It is an oral JAK inhibitor that has 6 approved indications. Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, atopic dermatitis and non-radiographic axial spondylarthritis. Rinvoq has important safety considerations and a black box warning for serious infection, mortality, malignancies, MACE, thrombosis, hypersensitivity reactions and other serious adverse reactions such as gastrointestinal operations and laboratory abnormalities.

The committee was referred to rxabbvie.com for the full prescribing and safety information.

Remote safety is well studies with clinical trial experience in over 9,900 patients since 2012. The overall safety profile is consistent across all indications and both safety and advocacy continue to

be studied in a comprehensive phase 3 clinical trial program. The benefits and potential risks should be considered with all immunomodulators.

She asked that Rinvoq be added to the state preferred drug list for all 6 indications.

The next product that she discussed was Skyrizi. This is an IL-23 antagonist that has 3 approved indications.

The first indication is for the treatment of moderate to severe plaque psoriasis in adults with dose administration of 150 milligrams by subcutaneous injection at week 0, week 4 and every 12 weeks thereafter.

The second indication is for the treatment of active psoriatic arthritis in adults at the same dose and administration as plaque psoriasis.

Also, Skyrizi may be administered alone or in combination with non-biologic DMARDs for psoriatic arthritis.

The third is for the treatment of moderate to severe active Crohn's disease in adults. The recommended dosing for Skyrizi is unique and starts with 3 induction infusions of 600 milligrams given IV at week 0, week 4 and week 8. The recommended maintenance dosage is 180 or 360 milligrams, self-administered, by subcutaneous injection starting up with 12 and every 8 weeks thereafter. For Crohn's disease it is recommended to provide or obtain liver enzymes and bilirubin levels prior to initiating treatment. The committee is referred to rxabbvie.com for the full prescribing information.

The committee was asked to add Skyrizi to the state approved drug list for all 3 indications.

ANDREW DELGADO, from Bristol Myers Squibb, spoke today on regarding deucravacitinib which received FDA approval on September 9, 2022 for adult patients with moderate to severe plaque psoriasis who were candidates for systemic therapy or phototherapy.

As we know, psoriasis can be a challenging disease to manage with observational studies suggesting a variety of barriers including limited persistence with current therapies, a high rate of discontinuation with about 42% and 59% of the patients reports discontinuing an oral or biologic treatment respectively over a 24 month period and a high rate of switching with more than half of patients switching to other therapies over 24 months of observation. These challenges underscore the continued unmet need in this therapeutic space. This is the first and only oral once daily selective tyrosine kinase 2 inhibitor with a distinct mechanism of action. Two different studies were discussed with the committee as well as safety.

Umang Patel gave the Magellan presentation on cytokine and CAM antagonists, non-GI indications. The members were advised to look at the appendix listed in SharePoint for the indications on these medications.

Cytokines and CAM 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. Cytokines are widely buried and they contribute to the fibrosis and tissue degeneration associated with chronic inflammation primarily by introducing the proliferation of fibroblasts and collagen.

Most CAMs are categorized into 3 general families of protein. First is the immunoglobulin super family. These are the adhesion molecules that bind integrins to leukocytes and mediate their flattening into the blood vessel wall. Second is the integrated family consisting of an alpha and beta chain that mediates cell to cell interaction. Lastly is the selected family which is involved in the adhesion of leukocytes. Different CAMs have been implicated in inflammatory and vibrant and autoimmune diseases.

A slide was then shown for the ACR Arthritis Foundation from 2019 for referral back to the guidelines on many of the drugs that will be discussed.

Regarding traditional DMARDs for polyarthritis methotrexate is conditionally recommended over leflunomide of sulfasalazine. Subcutaneous methotrexate is conditionally recommended over oral methotrexate. For biologic DMARDs in patients with polyarthritis combination therapy with a DMARD is conditionally recommended over biologic monotherapy when initiating treatment with a biologic.

Only the pertinent recommendations were discussed as there are a lot of recommendations and committee members were urged to ask questions if they had any regarding the recommendations that were not discussed. Guidelines were also discussed for the cytokine and CAM antagonists, non-GI indications. Again, committee members could look back to the SharePoint for the recommendations and guidelines.

The utilization showed that roughly 77.7% was in line with PDL. During this year's motion Dr. Liljegren moved that the drugs in the class were therapeutic alternatives to include at least one oral preparation, one formulation for pediatrics, one for arthritis, one for psoriasis and a grandfather clause for patients who previously responded to other agents. This was seconded by Dr. Ryan and passed unanimously.

Charles Ryan discussed that he did not think there was a reason to have a grandfather clause anymore. He also stated he did not know if it was necessary to single out arthritis and psoriasis since there are so many indications.

DR. RYAN MOVED THAT THE DRUGS WERE THERAPEUTIC ALERNATIVES, SECONDED BY MRS. WHITE. THE MOTION WAS PASSED UNANIMOUSLY.

4-C. Immunosuppressants

Immunosuppressants (Blue Class)

Umang Patel gave the Magellan presentation on immunosuppressants.

The open goal of immunosuppressive therapy after organ transplantation is to prevent organ rejection for long-graft and patient survival by providing an environment of permanent acceptance of tolerance. Where the new organ is recognized as self by the host immune system projection can be classified by hyperacute, acute cellular or chronic. Hyperacute 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 2 weeks following surgery. Acute cellular 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, rapid, 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.

They next discussed the sequence of events of rejection of a donor system. These events can take place at varying rates and may involve differing effects or mechanisms. Therefore, rejection of the transplant to tissues can take place at any time following surgery. The immunosuppressive drugs and dosing used in maintenance of transplanted organs varies but the regimens generally follow the same 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 and the mediated mechanisms of action and they allow for the use of lower doses of individual agents in order to minimize toxicity.

In June 2022 the FDA expanded Cellcept's indication for mycophenolate mofetil for the prophylaxis of organ rejection to include pediatric patients of allogenic heart and liver transplants. Previously safety and efficacy for pediatric use in allogenic heart or liver transplants had not been established but use had been established in pediatric patients 3 months or older for prophylaxis of kidney rejection after allogenic kidney transplant as well as for prevention of organ rejection in adults with allogenic heart or liver transplants. The expanded indication includes use for prophylaxis of organ rejection in adults and pediatric recipients 3 months of age or older for allogenic kidney, heart or liver transplant in combination with other immunosuppressants. No changes to any warnings, precautions, black box warnings or availability. The dosing is stratified by the organ that is being transplanted. For pediatric heart or liver transplant recipients the recommended starting dose is 600 mg per meter squared orally twice daily up to a maximum of 900 mg per meter squared twice daily. This will be 3 grams or 15 ml of the oral suspension.

We have the utilization where roughly 84% is in line with the PDL. Previous years motion Dr. Liljegren moved the drugs be therapeutic alternatives and was seconded by Dr. Doran-Atchison. This passed unanimously.

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

4-D. Dermatologic Agents: Topical Antipsoriatics (Red Class), Immunomodulators (Red Class)

Dermatologic Agents: Topical antipsoriatics (Red Class)

Umang Patel gave the Magellan presentation on dermatologic agents, topical antipsoriatics.

Psoriasis is a common chronic inflammatory multi-system condition with predominantly skin and joint defined as arthritis manifestation. It is characterized by arithmetic plaques with silvery scales which negatively impacts quality of life. It is estimated that over 8 million people in the US have psoriasis. Prevalence of psoriasis is 2% in African Americans, 1.6% in Hispanics and 3.6% in Caucasians. It usually presents between the ages of 15 and 35 but actually can onset at any age. There are 5 types of psoriasis plaque, guttate, inverse, pustular and erythrodermic. Most common type is plaque psoriasis or plaque 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. Mild to moderate psoriasis is generally treated with topical agents. Phototherapy is used when the disease is widespread or unresponsive to topical agents. Systemic agents including biologic drugs are usually reserved for patients with moderate to severe disease for those of psoriatic arthritis. Moderate to severe psoriasis is defined as an involvement of more than 5-10 % of the body surface area of involvement of face, palms or sole or disease that is otherwise disabling. Patients with moderate to severe disease are generally candidates for systemic therapy. Options for systemic therapy can include methotrexate, cyclosporin, retinoids, biologics and methoxatin plus UV radiation.

The guidelines for this subclass are all over a year. They're found in the appendix for any committee members that would like to look at them.

In May 2022 the FDA approved Vtama which is an aerial hydrocarbon receptor agonist indicated for the topical treatment of plaques psoriasis in adults. Since this is topical the dosing is a thin layer to the affected area once daily. It is available in a 1% cream and each gram contains 10 mg of tapinarof.

In August 2022 the FDA approved Zoryve 0.3% cream, a phosphodiesterase 4 inhibitor, for treatment of psoriasis including intertriginous areas in patients 12 years of age or older. It is contraindicated in patients with moderate to severe liver impairment. Most common adverse reactions were diarrhea, headache and insomnia as well as site application pain, upper respiratory tract infection and urinary tract infection. Being a topical agent, it is applied once daily to the affected area and is a 0.3% cream of which 3 mg of roflumilast per gram and comes in a 60-gram tube.

Roughly about 83% of prescriptions were in line with the PDL. Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives. Seconded by Dr. Carlson and was passed unanimously.

DR. RYAN MOVED THE DRUGS WERE THERAPEUTIC ALTERNATIVES, SECONDED BY DR. GOKEY. THE MOTION WAS PASSED UNAMIMOUSLY.

Dermatologic Agents: Immunomodulators (Red Class)

Public Comments on Dermatologic Agents: Immunomodulators

ERIN NOWAK, a representative from AbbVie, spoke about Rinvoq. It was approved in January 2022 for atopic dermatitis. Given that this was reviewed in a prior class she gave her time back to the committee.

VALERIE NG, a representative from LEO Pharma, gave testimony on Adbry. It was approved in December 2021 by the FDA and it is the first and only human high affinity monoclonal antibody that specifically binds to and inhibits IL13. IL13 has been shown to be a cytokine driving inflammation in atopic dermatitis or AD skin. Adbry is indicated for the treatment of moderate to severe AD in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Adbry can be used with or without topical corticosteroids and the recommended dose, which is an initial dose of 600 mg via subcutaneous injection followed by 300 mg every other week. A dosage of 300 mg every 4 weeks, or monthly, may be considered for patients below 100 kg who achieve clear or almost clear skin after 16 weeks of treatment. Efficacy was assessed in over 1,900 adult patients in 3 pivotal trials where AD redemonstrated superiority over placebo for primary and secondary endpoints at week 16 and maintain those responses with long term treatment through 32 and 52 weeks. The monthly dosing option for eligible patients was also shown to be effective after 16 weeks of every 2 weeks treatment providing the lowest effective dose and fewer injections to maintain control of their chronic disease. Majority of the adverse events reported int eh trials were non-serious and mild or moderate in severity. Overall frequency of adverse events was comparable across treatment groups and did not increase during prolonged treatment of up to 52 weeks. A long-term extension trial to evaluate the safety and efficacy of every patient who participated in previous clinical trials is currently ongoing with interim data available for patients who receive Adbry for up to 3 and a half years. We would like for the committee to consider adding Adbry to the PDL as a preferred product for adult patients suffering from moderate to severe atopic dermatitis who had an inadequate response to topical prescription therapies.

VICTORIA ROMO-LETOURNEAU, a representative from Pharm D and Pfizer, gave testimony on Cibinqo, a JAK inhibitor indicated for the treatment of adults with refractory moderate to severe atopic dermatitis. This disease is not adequately controlled with other systemic drug products including biologics or when use of those therapies is inadvisable. The efficacy of Cibinqo as monotherapy and in combination with topical corticosteroids was evaluated in 3 randomized double-blind placebo-controlled trials and over 1,600 patients, 12 years of age and older, with moderate to severe atopic dermatitis.

In the 2 monotherapy trials the patients with an IGA score of clear or almost clear scans and at least a 75% improvement in eczema areas and severity index was statistically higher in both treatment arms of abrositinib compared to placebo. The proportion of subjects achieving an itch improvement at week 2 was higher in the patients treated with Cibinqo in both treatment arms compared to placebo in all 3 trials. Please do refer to the full prescribing information. There is a boxed warning for JAK inhibitors for serious infections, mortality, malignancy and major adverse cardiovascular events and thrombosis. These events have occurred in a trial involving

another JAK inhibitor used in rheumatoid arthritis patients. Note that Cibinqo is not approved for use in RA patients. Cibinqo is contraindicated in patients taking antiplatelet therapy except for low dose aspirin during the first three months of treatment. Some of the most common adverse reactions in the clinical trials were nasal pharyngitis, nausea, headache and acne.

In conclusion, atopic dermatitis continues to have a high unmet medical need and adding an orally administered medication offers an additional treatment option for patients with atopic dermatitis. Based on the efficacy and safety of Cibinqo we request that you consider adding Cibinqo to the PDL. Thank you to the committee for their time.

Umang Patel gave the Magellan presentation on dermatologic agents: immunomodulators. Atopic dermatitis is a chronic non-contagious inflammatory disease of the skin resulting from a combination of genetic and environmental factors. 70% of patients diagnosed with atopic dermatitis have a positive family history of the disease. The odds of developing are 2 to 3 times higher in children with one atopic parent and 3 to 5 times higher if both parents are atopic. It affects approximately 18 million Americans and accounts for 10 to 20% of all visits to the dermatologists. Although symptoms can develop at any age it has been estimated that 50% of patients develop symptoms in the first year of life while 90% develop symptoms before the age of 5 and a half.

Atopic dermatitis is characterized by extremely dry itchy skin on the insides of elbows, behind the knees, on the face, hands and feet. In response to the intense itching patients may scratch or rub the affected area which will lead to further irritation and inflammation. As the skin loses moisture of the epidermal layer it becomes increasingly dry and may start to crack, leave crust and scale. The damage to the integrity of the skin renders it less protective and more prone to infection. Despite the chronic nature of this dermatologic condition where there may be periods of the disease when skin improves and periods when skin worsens. Irritants such as detergents, perfumes, tobacco smoke and alcohol containing skin products as well as allergens like dust mites, pollen and animal dander may exacerbate or cause flare ups.

In December 2021 the FDA approved Adbry, an IL13 antagonist indicated for the treatment of moderate to severe atopic dermatitis in patients who were not adequately controlled with topical prescription therapies or when those therapies are not advisable. Therapy can be used with or without topical corticosteroids.

In terms of warnings and precautions conjunctivitis keratitis has been seen as well as parasitic helmet infections and risk of infection with live vaccines.

The dosage is an initial dose of 600 mg or 150 mg injection followed by 300 mg administered every other week. A dosage of 300 mg every 4 weeks may be considered for patients below 100 kg to achieve clear or almost clear skin. After 16 weeks of treatment the availability is 150 mg per milliliter solution in a single dose prefilled syringe with a needle guard for an injection.

There were a lot of updates for Dupixent. Due to the numerous updates, it is presented differently with only the respective updates.

In May 2022 the FDA approved Dupixent for the treatment of adult and pediatric patients 12 years of age or older weighing over 40 kg or more with eosinophilic esophagitis. It was already indicated for atopic dermatitis, asthma and chronic rhinosinusitis with nasal polyps.

In June 2022 the FDA expanded the age range for atopic dermatitis indication to the treatment of patients 6 months of age or older with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Previously it was indicated for treatment of atopic dermatitis in patients 6 years of age or older.

In September 2022 the FDA granted approval under priority review for the treatment of adults with prurigo nodularis at a recommended dose of 600 mg followed by 300 mg every other week by subcutaneous injection.

In November 2022, the FDA authorized use of a single dose prefilled pen in patients 6 months to less than 12 years of age when administered by a caregiver. Previously only the prefilled syringe was approved for use in this age. The pens deliver 100 mg, 200 mg and 300 mg and pediatric indications impacted are severe atopic dermatitis and severe asthma which are approved for patients as young as 6 months and 6 years respectively. As you can imagine dosage is stratified by indicated, age and weight. The availability was updated in November for the single dose, prefilled pen and syringe.

Lastly, we observe Opzelura. In July 2022 they indicated Opzelura topical treatment of non-segmental vitiligo in adults and pediatric patients 12 years of age or older. No changes to warnings and precautions. Dosing again, this is a topical treatment. No changes to availability.

When we look at utilization, you can see about 96% is in line with a PDL. Last years motion Dr. Liljegren moved the drugs in the class for therapeutic alternatives to include at least one pediatric approved preparation. Seconded by Dr. Ryan and passed unanimously.

DR. DORAN-ATCHISON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE AT LEAST ONE PEDIATRIC APPROVED PREPARATION, SECONDED BY DR. RYAN. THE MOTION WAS PASSED UNANIMOUSLY.

4-E. Dermatitis: Topical steroids (Green Class), Acne (Red Class)

Dermatitis: Topical steroids (Green Class)

Umang Patel gave the Magellan presentation on topical steroids. As you can see topical steroids is stratified by potency of low, medium, high and very high. All of these classes are green. The motion for all subclasses is one motion so we will go right through to utilization.

In regards to utilization for low potency roughly 80% was in line with PDL. For medium potency it was about 85% in line with the PDL. High potency was roughly 96% in line with PDL. Very high potency was 93% in line with the PDL. The previous motion Dr. Ryan moved a class effect

within each potency group to include at least one ointment and one cream from each potency group and to amend the motion to a class effect within each potency group and to include at least one ointment, one cream and one pediatric formulation from each potency group. This was seconded by Dr. Liljegren and passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE AT LEAST ONE OINTMENT AND ONE CREAM FROM EACH POTENCY GROUP AND TO INCLUDE AT LEAST ONE PEDIATRIC FORMULATION FROM EACH POTENCY GROUP, SECONDED BY DR. GOKEY. THE MOTION PASSED UNANIMOUSLY.

Dermatitis: Acne (Red Class)

Umang Patel gave the Magellan presentation on acne. Acne vulgaris is the most common cutaneous condition in the United States. It's a disorder that primarily affects teenagers and young adults but it can sometimes persist beyond young adulthood and adolescents. Sebaceous glands increase sebum release after puberty. Comedones form in the hair follicles due to blockage of the pore from accumulated sebum and keratinous material. Bacteria release free fatty acids from sebum within the comedone which cause inflammation to form a cyst. This results in a rupture of a cyst wall and subsequent inflammatory reaction due to extrusion of oily and keratinous debris from the sieve. There are 3 categories of severity of acne to include either acne occurring on the face or trunk of the body. These categories are created 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 of comedone and papules. Moderate acne is defined as 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.

In December 2021 the FDA approved Twyneo. This medication is a combination of tretinoin retinoid and benzyl peroxide indicated for the topical treatment of acne vulgaris in adult and pediatric patients 9 years of age and older. In terms of warnings, hypersensitivity, reactions have occurred including anaphylaxis and angioedema. They have been reported with the use of benzyl peroxide. Skin irritations such as pain, dryness, exfoliation, erythema and irritation may occur with use. Photosensitivity is also possible due to the retinoid combination. For dosage apply a thin layer to the affected area once daily. The availability is a 0.1% tretinoin and 3% benzyl peroxide cream combination.

There were a few generics. In February 2022 clindamycin phosphate and tretinoin was the first generic from Almirell's Veltin from Solaris. In September 2022 the FDA approved tazarotene as a generic to Allergan's Tazorac topical gel 0.1% from Cosette.

In regards to utilization 85% are in line with the PDL. Previous years motion Dr. Liljegren moved the drugs in the class to therapeutic alternatives to include one drug from each subclass and at least one combination benzyl peroxide and antibiotics. Seconded by Mrs. White and passed unanimously.

DR. DORAN-ATCHISON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE DRUG FROM EACH SUBCLASS AND AT LEAST ONE COMBINATION BENZYL PEROXIDE AND ANTIBIOTICS. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

4-F. Ophthalmic Agents: Allergic conjunctivitis (Blue Class), Antibiotics (Green Class), Antibiotic Steroids (Green Class), Anti-Inflammatory offline agents (Green Class), Glaucoma (Red Class)

Ophthalmic Agents: Allergic Conjunctivitis (Blue Class)

Umang Patel gave the Magellan presentation on ophthalmic agents: allergic conjunctivitis. Conjunctivitis is the inflammation of the conjunctiva which may occur secondary to infections or non-infectious stimuli. Seasonal, vernal, atopic and giant papillary conjunctivitis are non-infectious types of conjunctivitis. Infectious types include viral and bacterial. Estimated prevalence of seasonal allergic conjunctivitis is 15%. The condition occurs in both adults and children and is one of the most common reasons for patient's self-referral. Signs and symptoms of the disorder may cause extreme discomfort. Seasonal allergic conjunctivitis usually presents bilaterally and occurs during seasonal exposure to allergens such as ragweed. Perennial has a similar initiated presentation however symptoms do not have a seasonal variation and the range of symptoms varies from itching to redness, swelling, excessive lacrimation and mucous discharge. As with allergic rhinitis avoidance of identified allergens is part of comprehensive therapy for allergic conjunctivitis. Vernal keratoconjunctivitis is an unusually severe chronic condition of exacerbations during spring and summer months. It is more common in children and young adults and is more prevalent in hot, dry climates. Patients present with severe eye itching, discharge and photophobia. Eyelid thickening, ptosis, corneal ulceration and infection can occur. If it is left untreated and is severe it can lead to permanent vision loss.

Common therapies include topical antihistamines and topical mass cell stabilizers. Topical corticosteroids are usually needed to reduce inflammation. Topical cyclosporin 0.25% or tacrolimus 0.1% can be added to reduce the required dose of corticosteroid, particularly in severe cases.

In December 2021 the FDA approved this for OTC use in adults and pediatric patients ages 2 years and older. It contains the same 0.25% strength and is indicated for temporary relief of itchy eyes due to pollen, ragweed, grass, animal hair and dander. The dosage is 1 drop in the affected eye once daily.

There was a discontinuation of Alocril in May 2022. Allergen reported to the FDA the discontinuation of Alocril 2% and no generic products are available.

Roughly 89% of the utilization was in line with PDL. Previous motion Dr. Ryan moved the drugs in the class with therapeutic alternatives. Seconded by Dr. Doran-Atchison and passed unanimously.

DR. RYAN MOVED FOR THERAPEUTIC ALTERNATIVES, SECONDED BY MRS. WHITE. THE MOTION PASSED UNANIMOUSLY.

Ophthalmic Agents: Antibiotics (Green Class), Antibiotic Steroids (Green Class)

Umang Patel moved directly to utilization for antibiotics as well as antibiotic steroid due to them both being a green class. In terms of utilization for antibiotics roughly 98% of the utilization is in line with PDL. For antibiotic steroids roughly 97% of the utilization is in line with the PDL. Previous motion Dr. Ryan moved a class effect for each subclass of ophthalmic antibiotics and that the drugs and ophthalmic antibiotic steroid combinations were therapeutic alternatives. This was seconded by Dr. Liljegren and passed unanimously.

DR. RYAN MOVED THE CLASS EFFECT FOR EACH SUBCLASS OF OPTHALMIC ANTIBIOTICS AND THAT THE DRUGS AND OPTHALMIC ANTIBIOTIC STEROID COMBINATIONS WERE THERAPEUTIC ALTERNATIVES. THIS WAS SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Ophthalmic Agents: Anti-inflammatory Offline Agents (Green Class)

Uman Patel moved directly to utilization for this due to it being a green class. It is 92% in line with PDL. Previous motion Dr. Ryan moved the drugs in the class with therapeutic alternatives to include one drug from each subclass. Seconded by Dr. Liljegren and passed unanimously.

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

Ophthalmic Agents: Glaucoma (Red Class)

Public Comments on Ophthalmic Agents: Glaucoma

ERIN NOWAK, a representative from AbbVie, gave testimony on Lumigan 0.1% ophthalmic solution. This is indicated for the reduction of elevated interocular pressure in patients with open-angle glaucoma and ocular hypertension. She acknowledged that the committee already reviewed them in detail so she touched on a few key points. First, Lumigan has 2 modes of action. While the mechanism of action is not fully characterized it is believed to lower interocular pressure by increasing outflow of aqueous humor through both the trabecular meshwork and uveoscleral route. It selectively mimics the effects of the naturally occurring process. Next, she brought attention to the fact that it has a lower concentration and produced equitable interocular pressure lowering efficacy across the 12-month study while cutting the treatment related adverse effects to one-third and the discontinuation over time due to ocular adverse events was also significantly lower. This class may be valuable for patients who are not

reaching their treatment goal with an initial therapy. This allows a patient to stay on a single medication used once daily at bedtime and continued a simplified eye drop regimen by not requiring wait time between different eyes.

The most common adverse event was conductible hyperemia in the pivotal study. Approximately 1.6% of patients discontinued therapy for this reason. She directed committee members to rxabbvie.com for full prescribing information.

Uman Patel gave the Magellan presentation on glaucoma. Glaucoma affects approximately 3 million people in the United States. It is the second most common cause of permanent blindness in the US. It is the leading cause of blindness among Hispanics and the second most among African Americans. Increased IOP, intraocular pressure, 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. Some patients, however, with glaucoma have normal IOP and many patients with the elevated IOP do not have glaucoma. IOP alone is no longer considered a diagnostic criterion for glaucoma. Major types of glaucoma have been identified as open angle and closed. In open angle there is reduced flow through the trabecular meshwork. Open angle glaucoma accounts for the majority of cases. In closed angle glaucoma the iris is pushed forward against the trabecular meshwork blocking fluid from escaping.

Risk factors for the development of glaucoma include elevated IOP, advanced staging, family history of glaucoma, African Americans over 40 years of age or Hispanic descent. The treatment goal is to maintain the IOP in a range at which the optic nerve, head and retinal nerve fiber layer are stable as well as preserve visual function and quality of life over the lifetime. Patients with primary open angle glaucoma commonly have untreated IOP that is within normal range, however, decreasing pressure is still beneficial in these patients.

In September 2022, the FDA approved Omlonti, a relatively selective prostaglandin E2 receptor for the reduction of elevated IOP in patients with open angle glaucoma or ocular hypertension. Warnings and precautions are fragmentation, eyelash changes, ocular inflammation or macular ischemia. The recommended dosage is one drop to the effected eye once daily in the evening. The availability are solutions containing 0.002% of the medication.

In April 2022 Merck reported to the FDA the discontinuation of Trusopt 2% ophthalmic solution. Generics remain available.

It is 93% in line with PDL. Previous motion Dr. Ryan moved the drugs in the class with therapeutic alternatives to include one drug from each subclass. Seconded by Dr. Doran-Atchison and passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE DRUG FROM EACH SUBCLASS. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Ophthalmic Agents: Immunomodulators (Blue Class)

Umang Patel gave the Magellan presentation on ophthalmic agents: immunomodulators. Keratoconjunctiva sicca, KCS, as discussed earlier, is defined as aqueous dry eye disease related to either decreased tear volume or rapid evaporative loss due to poor tear quality. These conditions may be present in dry eye syndrome. The term dry eye syndrome, or dry eye disease, keratoconjunctivitis sicca or keratitis sicca are often used interchangeably with the term keratoconjunctivitis sicca being an older term. There is considerable overlap with other optimal conditions such as meibomian gland dysfunction. This affects approximately 10 to 30% of the US population and occurs more commonly in patients over 50 years of age with approximately twice as many women as men affected. However, due to the use of soft contact lenses and frequent smartphone and computer usage the prevalence is increasing among young adults aged 18 to 34. Patients may have the following complaints: sensation of ocular dryness, grittiness, a foreign body, irritation, hyperemia, discharge, excess tearing, photophobia and/or blurry vision.

In February 2022, the FDA approved the first generic for Restasis, a cyclosporin ophthalmic emulsion 0.05% to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. It was labeled for approval under Verkazia.

On the next and final slide about 38% of utilization was in line with PDL. Previous motion Dr. Ryan moved the class with therapeutic alternatives. This was second by Dr. Liljegren and passed unanimously.

The primary reason the utilization is not in line with the PDL like other classes is a majority of the prescriptions were for the cyclosporin generic and authorized generic, which are not preferred.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, SECONDED BY DR. GOKEY. THE MOTION PASSED UNAIMOUSLY.

5. End of Public Meeting

6. Review Minutes from November 18, 2022.

There were no changes to the meeting minutes of November 18, 2022.

DR. DORAN-ATCHISON MOVED TO APPROVE THE MEETING MINUTES OF NOVEMBER 18, 2022. SECONDED BY MRS. WHITE. THE MOTION WAS PASSED BY ALL MEMBERS.

7. Comments From Committee Members
8. Adjourn

MRS. WHITE MOVED TO ADJOURN THE MEETING. THE NEXT MEETING WAS SCHEDULE FOR APRIL 21, 2023. WITHOUT OBJECTION, THE MEETING WAS ADJOURNED.