Alaska Medicaid Pharmacy and Therapeutics Meeting

MINUTES OF MEETING
January 21, 2022

Committee Members Present:
John Riley, PA, Acting Chairman
Robert Carlson, MD
Diane Liljegren, R.Ph.
Sarah Doran-Atchison, PharmD
Claudia Phillips, MD
Jonathan Harrison, PharmD
Charles Ryan, MD
Trisha White, R.Ph.
Matthew Begay-Bruno, PharmD

Others Present:
Umang Patel, Pharm D, R.Ph., Magellan Medical Administration
Charles Semling PharmD, DHSS
Erin Narus PharmD, MSJ, DHSS
Jennifer Schreiter, PhD., Teva Field Medical Affairs
Carrie Johnson, PharmD, Amgen Medical Affairs
Phil Wettestad, Medical Science Liaison, Novartis
Anthony Hager, PharmD and Medical Liaison, Bristol-Myers Squibb
Margaret Olmon, PharmD, Medical Affairs, AbbVie

1. Call to Order – Chair

MEETING BEGAN WITH A MOTION PRESENTED BY DR. RYAN. DR. LILJEGREN SECONDED THAT. THE MOTION WAS PASSED UNANIMOUSLY.

2. Roll Call

Meeting began with motion as stated above.

3. Public Comments – Local Public/Health Practitioners

None.

4. Class Review, Discussion & Vote

4-A. Asthma/Allergy: Glucocorticoids (Blue); Glucocorticoid Inhaled Combinations (Green); Long-Acting Beta-Agonist Bronchodilator (Green); Short-Acting Beta-Agonist

Bronchodilator (Green); Epinephrine (Green); Intranasal Rhinitis (Blue); Minimally Sedating Antihistamines (Green); Cytokine Antagonist (Blue)

Glucocorticoids (Blue Class)

Dr. Umang Patel gave the Magellan presentation for Glucocorticoids. The prevalence of asthma in the United States continues to rise. More than 25 million Americans have asthma and over 5 million of these are children. The National Asthma Education and Prevention Program has defined asthma as a chronic inflammatory disorder of the airways in which many cells and cellular elements played 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. And the inflammation also causes an increase in bronchial hyperresponsiveness to a variety of sickness.

Studies have demonstrated the efficacy of inhaled corticosteroids in improving the lung function, reducing symptoms, reducing frequency and severity of exacerbation and improving quality of life in patients with asthma. The 2007 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 patients with asthma should receive inhaled corticosteroid-containing controller treatment to reduce the risk of serious exacerbation and to control symptoms.

An update by the Global Initiative for Asthma or the GINA guidelines offers a control-based management plan to adjust treatments in a continuous cycle of assessment, treatment and review of the patient's response as it relates to symptom controls, future risk of exacerbations and side effects.

Equally important in the process of identifying the patient's own goal regarding their asthma management to ensure improved outcomes. In patients whose asthma is not adequately controlled on the first controller despite good adherence and correct technique, a step up and treatment may be added until control is achieved. This can be a short term or sustained step up in therapy, and if control is maintained for at least three months with the current regimen, treatment can be stepped down to the low steps and dosage that maintains control. Patient should be started on treatment based on symptoms with infrequent symptoms beginning at step 1 and patients with the most frequent, severe or debilitating symptoms beginning at step 4.

The GINA 2021 guidelines describe two treatment tracks, track 1 and track 2. In track 1, the reliever is as-needed, low-dose ICS formoterol, and in track 2, the reliever is an as-needed SABA, which is the alternative approach when track 1 is not an option or is not preferred for patient specifically.

The CHEST guidelines and the National Asthma Education and Prevention Guidelines from 2020 state that they have a report on chronic cough due to asthma and non-asthmatic eosinophilic bronchitis in adults and adolescents, address the role of ICS in these patients. For patients with chronic cough due to asthma as a unique system such as a cough-variant asthma,

they would recommend ICS as first line. If this is inadequate, the dose may be increased, treatment can be switched to a leukotriene inhibitor or an ICS/LABA can be considered. An ICS are also recommended as first line for chronic cough using NAEB, although they are not FDA approved for this use.

Per the National Asthma Education and Prevention Program guidelines, they recommended similar classification of asthma severity and control to guide in the initiation and adjustment therapy respectively. Asthma severity and control are defined in terms of two domains, which is impairment and risks. So the distinction between these domains emphasizes the need to consider separately asthma's effect on quality of life and functional capacity on an ongoing basis along with risk factors for adverse events, exacerbations and progressive loss of pulmonary function.

The group recommends a stepwise approach to asthma management which is detailed in the table that is in the TCR. In addition, all asthma patients should have a SABA inhaler for use on an as-needed basis. And as-needed ICS with formoterol is recommended instead for patients 5 to 11 years of age as step 3 and 4, but the SABA is recommended as an alternative. And lastly for combinations of an ICS and LABA for patients 5 years of age or older, the group states the single inhaler is preferred.

In July 2021, FDA approved ArmonAir RespiClick for the maintenance treatment of asthma as a prophylactic therapy in patients 4 to 11 years old. Previously, it was only for patients 12 years or older. Again, there is no change in terms of precautions, dosage or availability, just the age for indication has now gotten wider.

For the glucocorticoid inhaled single entity, 85% is in line with the PDL. Previous year's motion for single entity glucocorticoid was Mr. Riley moved the class effect to include one high potency product, one low-to-medium potency, and a budesonide product. This was seconded by Dr. Ryan and it passed unanimously.

Public Comments on Glucocorticoids (Blue Class)

JENNIFER SCHREITER, a representative from Teva Field Medical Affairs, discussed the ArmonAir Digihaler. ArmonAir Digihaler is a drug product containing an inhaled corticosteroid indicated for maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older. Now ArmonAir Digihaler is not indicative for the relief of acute bronchospasm. It is available as inhalation powder with 55 mcg of fluticasone propionate in each actuation and also available in 113 mcg and 232 mcg. ArmonAir Digihaler contains a built-in electronic module. The safety and efficacy of fluticasone propionate inhalation powder was evaluated in over 2000 patients with asthma. The efficacy of ArmonAir Digihaler is supported by the ArmonAir RespiClick clinical development program, which included two confirmatory trials of 12 weeks' duration and a 26-week safety trial and two dose ranging trials.

Real-world feasibility studies are investigating the impact of the Digihaler system that includes the rescue medication use and rescue plus maintenance on patient's overall ACT score. These studies and their protocols can be found on clinical trials.gov under the following titles Connect 1 and Connect 2.

The Digihaler portfolio includes a ProAir Digihaler ArmonAir Digihaler and AirDuo Digihaler. Each Digihaler contains a built-in electronic module, which detects, records and stores data on inhaler events including peak respiratory flow for transmission to the mobile app. Several notifications, messages and reports are provided to users based on Digihaler events and this includes inhalation events, high-dose notification for the ProAir Digihaler which is the rescue inhaler, twice daily reminders to take medication for maintenance inhalers, inhalation technique notification, refill notification. Tracks up to seven inhalers at once including five rescue and two maintenance inhalers. The app also provides daily and weekly reports, and these reports can be used to support consultations between patients and healthcare professionals. The breath-actuated device does not require use of a spacer. Objective inhaler data collected by the Digihaler system can be used to track the patient's inhaler use, including poor technique issues, rescue medication overuse and controller medication adherence and may help patients and providers make more informed treatment decisions.

TRISHA 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 SO, MEDICALLY NECESSARY WOULD PROBABLY BE ADEQUATE NOW. DR. CARLSON SECONDED THAT MOTION. MOTION WAS UNANIMOUS WITH ONE ABSTINATION.

Glucocorticoid Inhaled Combinations (Green Class)

Dr. Umang Patel gave the Magellan presentation for Glucocorticoid Inhaled Combinations. The previous year's motion, Dr. Ryan moved the class effect into one high potency, one medium potency products. This was seconded by Mr. Riley and passed unanimously.

DR. RYAN MOVED THE SAME MOTION AS LAST YEAR. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANMOUSLY.

Long-Acting Beta-Agonist Bronchodilator (Green Class)

Dr. Umang Patel gave the Magellan presentation for Long-Acting Beta-Agonist Bronchodilators. The utilization report was reviewed and roughly about some 4% in line with PDL. Previous year's motion, Mr. Riley moved the class effect to include both an inhaler and a nebulized product, and this was seconded by Dr. Ryan and passed unanimously.

DR. RYAN MOVED THE SAME MOTION AS LAST YEAR. SECONDED BY DR. WHITE. TH MOTION PASSED UNANIMOUSLY.

Short-Acting Beta-Agonist Bronchodilator (Green Class)

Dr. Umang Patel gave the Magellan presentation on Short-Acting Beta-Agonist Bronchodilator. The utilization report was reviewed and roughly about 79% was in line with the PDL. Previous year's motion shows Mr. Greer moved the class effect to include at least one albuterol inhaled product and a nebulized solution, and this was seconded by Dr. Ryan and passed unanimously.

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

Epinephrine (Green Class)

Dr. Umang Patel gave the Magellan presentation for Epinephrine. Previous year's motion shows that roughly 99% is in line with the PDL. On previous year's motion, Dr. Ryan moved the class effect to include at least one 0.15 mg and one 0.3 mg auto-injecting product. This was seconded by Mr. Riley and passed unanimously.

DR. RYAN MOVED THE SAME MOTION THAT WAS PASSED LAST YEAR. DR. LILJEGREN SECONDED THAT MOTION. THE MOTION WAS PASSED UNANIMOUSLY.

Intranasal Rhinitis (Blue Class)

Dr. Umang Patel gave the Magellan presentation for Intranasal Rhinitis. Allergic rhinitis is constellation of symptoms affecting about 7.7% of adults and 7.2% of children in the United States, characterized by sneezing; itching of the eyes, nose, palate and rhinorrhea and nasal obstruction. It is often associated with postnasal drip, cough, irritability and fatigue. Symptoms develop when patients inhale airborne antigens to which they have previously been exposed and made antibody. Antibodies bind to receptors on mast cells in respiratory mucosa and basophils and peripheral blood. These release pre-formed and granule-associated chemical mediators and they also generate other inflammatory mediators and cytokines which lead to nasal inflammation with continued allergen exposure chronic symptoms.

Perennial allergic rhinitis is an IgE-mediated reaction to allergens with little or no seasonal variation, and it has persistent chronic and generally less severe than seasonal allergic rhinitis. Vasomotor rhinitis or irritant rhinitis is a condition of unknown origin. It is aggravated by fumes, odors, temperature, atmospheric changes, smoke and other irritants. And this form of rhinitis, generally conditions diagnosed in adults causes a year round symptoms that include congestion and headache.

There was a guideline update from the American Academy of Allergy, Asthma and Immunology in 2020. They recommend inhaled antihistamines as first line for seasonal allergic rhinitis, intermittent rhinitis and non-allergic rhinitis. Intranasal corticosteroids are the preferred monotherapy for persistent allergic rhinitis. These guidelines suggest combination of an intranasal corticosteroid and an intranasal antihistamines for moderate or severe cases of SAR

and PAR that is resistant to monotherapy and resistant to NAR. An alternative option for rhinorrhea that persists while on intranasal corticosteroid is the addition of an intranasal ipratropium. If nasal congestion persists despite treatment with an intranasal corticosteroid with or without an intranasal antihistamine, addition of an intranasal decongestant for up to 4 weeks may be considered. The guidelines also provide pharmacotherapy recommendation 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.

There were a few updates for medications. First being for azelastine hydrochloride. FDA approved this for the maintenance treatment of asthma as prophylactic therapy in patients 4 to 11 years old. Previously, was only approved in patients 12 years of age or older. They approved this nasal spray 0.15% for OTC use for seasonal and perennial allergic rhinitis in adults and children 6 years or older. This is considered a partial prescription to non-prescription switch because of the 0.1% strength, which includes the perennial allergy indication for children 6 months to 6 years and seasonal allergy indication for children 2 to 6 years old will remain prescription based. And Astepro Allergy will be available in Q1 of 2022.

And lastly, there was a discontinuation for Nasonex in June 2021. FDA posted that Merck will discontinue distribution of Nasonex nasal sprays. However, generic versions are available.

On the next and final slide, roughly 99% is in line with the PDL. Previous motion, Mr. Riley moved the drugs in the class of therapeutic alternatives to include one anticholinergic, one antihistamine and one corticosteroid. This was seconded by Dr. Ryan and passed unanimously.

DR. LILJEGREN MOTIONED THE SAME MOTION AS LAST YEAR. SECONDED BY DR. CARLSON. THE MOTION WAS PASSED UNANIMOUSLY.

Leukotriene Modifiers (Green Class)

Dr. Umang Patel gave the Magellan presentation on Leukotriene Modifiers. The utilization report was reviewed and the drugs were 100% in line with PDLs. Previous motion, Mr. Riley moved the class effects to exclude zileuton. This was seconded by Mr. Greer and it passed unanimously.

Dr. Ryan asked why zileuton was excluded again.

Dr. Doran-Atchison believed that it was due to its poor side effect profile compared to the other leukotriene modifier.

Dr. Ryan stated that it was unusual to exclude a specific brand name.

Dr. Doran-Atchison stated that it was not a good drug.

Dr. Ryan stated that Dr. Jeff Demain was adamantly against it. Dr. Doran-Atchison supported Dr. Demain's claim.

Dr. Patel stated that in 2017 and 2018, when the drug was reviewed, the committee had discussed hepatotoxicity and side effects regarding the liver. And since then, it has been kind of carried over.

Dr. Ryan stated that it was Strange that the drug was still available.

DR. CARLSON MOVED TO KEEP THE SAME MOTION AS PREVIOUSLY DECIDED. DR. LILJEGREN SECONDED THIS. THE MOTION WAS PASSED UNANIMOUSLY.

Minimally Sedating Antihistamines (Green Class)

Dr. Umang Patel gave the Magellan presentation on Minimally Sedating Antihistamines. The utilization report was reviewed and stats that these drugs were roughly 96% in line with PDL. Previous year's motion, Dr. Ryan moved the class effects to include an oral syrup for a suspension for pediatric dosing. This was seconded by Dr. Doran-Atchison and the motion passed unanimously.

DR. RYAN MOVED SAME AS LAST YEAR. DR. DORAN-ATCHISON SECONDED IT. THE MOTION WAS PASSED UNANIMOUSLY.

Cytokine Antagonist (Blue Class)

Public Comments on Cytokine Antagonist (Blue Class)

CARRIE JOHNSON, a representative from Amgen Medical Affairs discussed Otezla or apremilast. Apremilast was FDA approved in 2014 and is indicated for the treatment of adult patients with active psoriatic arthritis, treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy and the treatment of adult patients with oral ulcers associated with the Behcet's disease. Warnings and precautions include diarrhea, nausea, vomiting, weight decrease, depression and drug interactions. Please see the full prescribing information at amgen.com for further information.

Apremilast is not a biologic and recent published guidelines separated out from biologics, the AAD-NPF psoriasis guidelines and the ACR-NPF psoriatic arthritis guidelines.

Apremilast is an orally administered small molecule that works intracellularly to inhibit phosphodiesterase-4. This reduces immune cell production of proinflammatory cytokines and increases production of anti-inflammatory cytokines. Apremilast works intracellularly to modulate the future production of cytokines, so unique mechanism of action. Importantly, apremilast has no black box warnings and no requirement for laboratory monitoring or premedication screening. Additionally, there are no warnings or precautions related to infection or malignancy. As an oral small molecule, it does not induce the production of anti-drug antibodies.

As of December 20, 2021, Otezla is now the first and only oral treatment approved in adult patients with plaque psoriasis across all severity including mild, moderate and severe psoriasis. This FDA approval is based on the findings from the phase 3 advanced trials in which five times as many adults with mild-to-moderate plaque psoriasis receiving Otezla 30 mg twice daily achieved the primary endpoint of Static Physician's Global Assessment response at week 16 compared to placebo, a difference that was statistically significant. Otezla also demonstrated statistically significant improvements in key symptoms such as whole body itch and the difficult-to-treat area of the scalp as measured by the Scalp Physician's Global Assessment response at week 16 compared to placebo.

Second label update that occurred in 2020. Scalp psoriasis occurs in over 90% of psoriasis patients at some point in the disease course and is considered a difficult-to-treat area. In the phase 3 style study, apremilast demonstrates significantly greater improvements in scalp psoriasis, scalp and full body itch and quality of life versus placebo at week 16 with improvements continuing out to week 35. Most common adverse events were diarrhea, nausea and vomiting. These data were fully published, and they were added to the label.

Additionally, long-term data are published after five years in psoriatic arthritis and over three years in psoriasis. These data show no increase in the incidents or severity of the adverse events with no new safety signal. Apremilast is not a biologic and placed in a separate category. Apremilast does not have black box warning or premedication screening or laboratory monitoring and now is the first and only treatment approved for adult patients across all severities. Please consider adding apremilast to the PDL as an oral nonbiologic option for your adult patients with active psoriatic arthritis, plaque psoriasis or candidates for phototherapy or systemic therapy and for your adult patients with oral ulcer associated with Behcet's disease.

PHIL WETTESTAD, a representative from Novartis discussed Cosentyx, secukinumab, the first and only fully human interleukin inhibitor indicated for plaque psoriasis, psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondylarthritis, a group of related diseases driven by interleukin-17A. On December 23, 2021, the FDA approved Cosentyx for the treatment of active psoriatic arthritis in patients 2 years of age and older and active enthesitis-related arthritis in patients 4 years of age and older. Cosentyx is the only biologic treatment approved for children and adolescents for both enthesitis-related arthritis and psoriatic arthritis in the US. The approval is based on data from the phase 3 JUNIPERA study, a two-year, three-part, double-blind, placebo-controlled, randomized, even- driven, treatment-withdrawal study that evaluated the efficacy and safety of Cosentyx using a flare-prevention design and enrolled 86 children and adolescents aged 2 to 18 years old with a confirmed diagnosis of enthesitis-related arthritis or juvenile psoriatic arthritis. The primary objective of this study was to demonstrate that the time to flare and treatment period too was longer with Cosentyx for combined enthesitis-related arthritis and juvenile psoriatic arthritis groups than with placebo.

The JUNIPERA study demonstrated that patients with active juvenile psoriatic arthritis treated with Cosentyx had a longer time to flare showing an 85% reduction in the risk of flare versus placebo. The study also demonstrated that patients with active enthesitis-related arthritis treated with Cosentyx had a significantly longer time to flare, showing a 53% reduction in the risk of

flare versus placebo. Safety in these pediatric populations was consistent with the known safety profile of Cosentyx.

In summary, Cosentyx has been prescribed to more than 500,000 patients worldwide since launch, with more than five years of consistent long-term efficacy and safety data, more than 100 clinical studies and a comprehensive head-to-head clinical trial program.

ANTHONY HAGER, a representative Bristol-Myers Squibb discussed Orencia, abatacept. Orencia is labeled, indications include RA, PsA and GI and those have not changed recently. It does have a new indication which I wanted to highlight. That is for prophylaxis of acute GVHD. This is in combination with a calcineurin inhibitor and methotrexate in adult and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation from a matched or one of the [Inaudible: 39:30] old mismatched unrelated donor. Orencia continues to have no black box warnings in its label and remains the only molecule in its mechanism class with T-cell co-simulation modulator. The most commonly reported AEs in clinical trials that occurred in at least 10% of Orencia-treated patients are headache, URTI, nasal pharyngitis and nausea.

Recently, Bristol-Myers in collaboration with Rheumatology Community has uncovered evidence of a clinically meaningful serum biomarker predicting treatment response to Orencia in adult patients with RA. This biomarker ACPA is an autoantibody that is commonly utilized with diagnostic and prognostic value in RA. However, it has recently been shown to correlate with enhanced treatment response to Orencia. For example, in the ample study, which was published in 2014, this was a phase 3 head-to-head randomized control non-inferiority study of subcutaneous abatacept compared to subcutaneous adalimumab in biologic-naive methotrexate [Inaudible: 40:30] medical responder RA patient. It is still non-inferiority per the primary endpoint as well as the post hoc analysis which show that the subcutaneous abatacept cohort with the highest ACPA concentrations. Quartile 4 had a higher response in patients with lower concentration with quartile 1 through 3. This association was not observed in the subcutaneous adalimumab cohort and that was published in 2016.

Similar results were found in a subsequent head-to-head phase 4 clinical trial in which numerically greater Orencia-treated patients achieved an ACR 50 response in week 24 versus Humira, 73% versus 45% in an early dual-seropositive RA cohort and these patients were both ACPA and rheumatoid factor positive, now published in 2021.

MARGARET OLMON, a representative from AbbVie, discussed Skyrizi, which is risankizumab and Rinvoq, which is upadacitinib and answer any questions you might have. Please see the full prescribing information at rxabbvie.com for comprehensive safety and efficacy data.

Skyrizi is an IL-23 inhibitor indicated for the treatment of moderate-to-severe plaque psoriasis in adults and has given us a 150 mg subcutaneous injection at week 0 for and then every 12 weeks. In the four phase 3 clinical trials that met all primary and ranked secondary endpoints, Skyrizi showed superior efficacy to Stelara in both PASI 90 and PASI 100 responses at week 16 and 52 weeks. After two doses, 75% of Skyrizi patients had at least a 90% improvement in their PASI

score. The incidents of adverse reactions were similar with Skyrizi, Humira and Stelara in both the long and short term. There were no unexpected safety findings, and there are no contraindications to Skyrizi treatment.

Rinvoq is an oral JAK inhibitor indicated after an adequate response to one or more TNF blockers for both treatment of adults with moderately to severely active rheumatoid arthritis and adults with active psoriatic arthritis. A recommended dose for either condition is 15 mg taken orally once daily. The phase 3 clinical program in RA consisted of five studies in over 4300 patients. Rinvoq met all primary and ranked secondary endpoints in all five clinical trials, and significantly more patients achieved DAS28 remission and low disease activity versus controls in each trial.

The most common adverse reactions in the upadacitinib RA trials were upper respiratory tract infections, nausea, cough and fever. In the two phase 3 studies in psoriatic arthritis, over 1800 patients were treated with Rinvoq. Overall, the safety profile observed in patients with active PsA was consistent with that seen in patients with RA. In both PsA studies, Rinvoq-treated patients met all primary, ranked secondary outcomes and achieved a statistically higher ACR20, ACR50 and ACR70 response at 12 weeks compared to placebo.

At week 12, Rinvoq patients showed significant improvement in physical function and health-related quality of life. Treatment with Rinvoq inhibited progression of structural joint damage compared with placebo when patients were assessed at week 24.

Dr. Umang Patel stated as an FYI for the newest member, Dr. Begay-Bruno, that Alaska P&T does break cytokinin and CAM antagonist into two reviews. One during this P&T meeting where we review non-GI indications and one in September where it is for GI indications.

Cytokines and cell adhesion molecules are chemical mediators involved in inflammatory processes throughout the body. Cytokines are small proteins secreted in response to an immune stimulus for the purpose of mediating and regulating immunity, inflammation and hematopoiesis. 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 collagen matrix. The proinflammatory cytokines; TNF, interleukin 1 are involved in tissue destruction in many chronic inflammatory diseases affecting various organs.

Cell adhesion molecules are cell surface proteins that are involved in the binding of cells, usually leukocytes to each other, endothelial cells or extracellular matrix. Specific signals produced in response to wounds and infection control the expression and activation of these molecules, and most of the cell adhesion molecules fall into three general families of protein. They are immunoglobulin superfamily that essentially binds and integrin leukocytes and mediates their flattening. Integrin family that has the alpha-beta chain then mediates cell-to-cell interactions and this [Inaudible 48:01] that is involved in the adhesion of leukocytes to activated endothelium followed by extravasation through the blood vessel walls.

A different CAM has been implicated in inflammatory, fibrotic, and autoimmune diseases. I am going to cite here this is just here for, as you can imagine, there are a lot of different disease

states that fall under non-GI cytokine and CAM [Inaudible: 48:27] antagonists. So, I have done my best to keep the relevant various disease state guidelines here. There is some in the appendix as well, but anything that is over 12 or 13 months, I will not review just for respect of the committee's time.

Ankylosing spondylitis was discussed. So, axial spondylarthritis is an inflammatory condition generally affecting the spine and can be further subdivided into ankylosing spondylitis, radiographic ankylosing spondylitis, and non-radiographic ankylosing spondylitis. The American College of Rheumatology, Spondylitis Association of America and Spondylarthritis Research and Treatment Network published 2019 update on the treatment of this. Again, it is over 2 years old, here for the Committee's sake, but they do provide recommendations on these broken down subclasses here.

On the next slide here, we have recurrent pericarditis. And just to let the committee know the reason I have chosen specific disease state to review are either new guidelines or their new drug-specific updates. And so I wanted to give a little bit of background for those disease states. So for recurrent pericarditis, the acute pericarditis with the inflammation of the pericardium and symptoms can include chest pain, ECG changes, pericardial effusion and pericardial friction rub. It typically lasts up to six weeks, although symptoms may recur and recurrence may be as high as 15% to 30% in selected patients with idiopathic pericarditis. In recurrent pericarditis, these symptoms return after a symptom-free period about four to six weeks. Symptoms of recurrent pericarditis include psoriatic chest pain with fever, pleuritic rub, ECG changes, new or worsening pericardial effusions, and/or elevation of markers of inflammation. Patients may feel well in between attacks and others may have a more persistent disease.

Studies have suggested that many cases of recurrent pericarditis are caused by autoimmune disorder, although other causes are possible [Inaudible: 51:03] infection. There is no well-established predicators of recurrence. In terms of treatment, the pharmacological treatment of recurrent pericarditis is similar to the treatment of acute pericarditis, NSAIDs or aspirin plus colchicine as typical first-line agents. Steroids or combination therapy may be considered, and other agents that may be used for treatment in late-line therapy includes rilonacept and the off label use of a few medication like anakinra, azathioprine or [Inaudible: 51:36] immunoglobulins. Pericardiectomy may also be considered in select patients as well.

Moving onward to drug-specific updates, first one we have here is Arcalyst. In March 2021, FDA approved the expanded indications for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years of age or older. Again, no changes to any of the precautions, dosage, or availability with just the indication has been expanded into the pediatric realm [Inaudible: 52:11] as well.

Just to pause right here for a second. To give more information about our special populations here first, based on animal data, it may cause fetal harm, so keep an eye out if the patients are of productive potential age. And no studies have been conducted to evaluate the PK in patients with hepatic and renal impairment, so there is no specific recommendations.

On the next slide here, we have Cosentyx. In 2021, the FDA expanded the use from moderate-to-severe plaque psoriasis to patients who are candidates for systemic therapy or phototherapy to include patients 6 years of age or older. Again, this used to only be in adults. So, of late, it has expanded into the pediatric realm as well. No changes to indications, precautions, dosage or availability for this medication. In terms of specialized population, there is limited available human data in patients who are pregnant, but there is insufficient data to inform a drug associated risk of adverse development. And again, no formal studies for hepatic or renal impairment here.

On the next slide, we have Actemra. In June 2021, the FDA issued an emergency use authorization for this medication for the treatment of hospitalized adults, pediatric patients 2 years of age or older for COVID-19 who are receiving systemic corticosteroid and require supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation. It is already approved for the treatment of select patients with rheumatoid arthritis, interstitial lung disease, giant cell arteritis and juvenile idiopathic arthritis. Again, given the last two years in the pandemic, nothing has changed in terms of the FDA-approved indication, just a new emergency use authorization has been activated for Actemra for patients with COVID-19 that are hospitalized.

On the next slide here, we have Cyltezo. In October 2021, the FDA approved the first interchangeable biosimilar to Humira, and it was first approved in August of 2017, but it was not being interchangeable. In October 2021, again, the juvenile idiopathic arthritis indication was expanded to include reducing signs and symptoms of moderate to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age or older. Previously, it was only indicated for patients 4 years. As you can see, has a litany of other indications that are listed here. Two main updates here, expanded indication for juvenile idiopathic arthritis and it has now been approved as the first interchangeable biosimilar to Humira. No changes in precautions, dosage or availability here.

On the next slide, we have Ruxience. In November 2021, FDA approved for the treatment of rheumatoid arthritis in combination with methotrexate in adult patients with moderate-to-severe active rheumatoid arthritis who have inadequate response to one or more TNF antagonists. Again, no update to any of the other litany of indications that we can see here that are outside of the scope of the update. No changes to precautions, dosage, or availability.

Okay, we will move onto drug communications, essentially FDA communications for Xeljanz and Xeljanz XR. In February 2021, FDA is alerting the public that preliminary results from a safety clinical trial showed an increased risk of serious heart-related problems and cancer with tofacitinib compared to TNF inhibitors. They advise patients should not stop taking prescribed tofacitinib without consulting the physician and FDA will communicate final conclusions and recommendations once they are [Inaudible: 56:38].

In September 2021, FDA [Inaudible: 56:43] to the box labels for Xeljanz, Olumiant, and Rinvoq to include information about the increased risk of serious heart-related events, cancer, blood clots and deaths. All this change is based on data from clinical trials [Inaudible: 57:00] Xeljanz and Xeljanz XR in treating rheumatoid arthritis and ulcerative colitis. Olumiant and Rinvoq are

included in the action based on their shared mechanism of action with Xeljanz, and FDA considers that these medicines may have similar risks. This action by the FDA does not apply to other JAK inhibitors which are used in the oncology settings. FDA is also limiting all approved uses of Xeljanz and Xeljanz XR, Olumiant, Rinvoq to certain patients who have not responded or cannot tolerate at least one of the TNF blockers.

On the next and final slide for updates, we have REMS update and a drug shortage update. First in February 2021, for brodalumab, various updates to the REMS material including conversion of the documents to a new format, removal of programs from the title of the REMS materials was completed. Additionally, changes were made to the stakeholder enrollment form and patient enrollment form as well as to the REMS materials aligned with changes to REMS document.

In August 2021, FDA reported that Actemra 200 mg/mL, 400 mg/mL, and 80 mg/4 mL vial are unavailable. ASHP also reports shortage of 162 mg/0.9 mL prefilled syringe and 152 mg/0.9 mL ACTPen is available on allocations and shortages [Inaudible: 58:38].

Moving onto the next and final slide for cytokine and CAM antagonists on GI indication. Roughly 80% is in line with the PDL. Previous year's motion, Dr. Phillips moved the drugs in the class of therapeutic alternatives to include at least one oral preparation, one formulation for pediatrics, one for arthritis, one for psoriasis and the grandfather clause for patients who previously responded to other agents. This was seconded by Mr. Greer in the past meeting.

DR. LILJEGREN MOVED TO MOTION THE SAME AS LAST YEAR. DR. RYAN SECONDED IT. THE MOTION PASSED UNANIMOUSLY.

4-B. ***Immunosuppressant Medications***

Dr. Umang Patel gave the Magellan presentation on Immunosuppressant Medications. Immunosuppressive therapy after organ transplantations prevent organ rejection, prolonged graft and patient survival by providing an environment of permanent acceptance or tolerance for the new organ and recognize that self by the host immune system. Rejection can be classified as hyper-acute, acute or chronic. Hyper-acute may occur when donor-specific antibodies are present in the recipient at the time of transplant. It often occurs within minutes of transplant or may occur anytime within the first two weeks following surgeries. Autoreactive T-lymphocytes that appear in circulation infiltrate the allograft through the vascular endothelium and mediate acute cellular rejections. This type of rejection may occur as early as a few days postoperatively. However, it can occur any time after transplant. And the process of chronic rejection is poorly understood, although it may simply be a slow form of cellular rejection.

Clinical presentation is dependent on the organ grafted and generally presents as normal organ aging. The onset of chronic rejection is very slow. The changes in organ function are not I believe reversible. The sequence of events in graft rejection is; one, recognition of donor's histocompatibility difference by the recipient's immune system; two, recruitment of activated lymphocytes; three, initiation of immune-effective mechanisms and four, destruction of the graft. These events can take place at varying rates and they often involve differing effective mechanisms. Therefore, rejection of the transplanted tissues can take place at anytime following

surgery. Immunosuppressive drugs and dosing used in the maintenance of transplanted organ varies, but the regimens generally follow the same principle. Following induction therapy at the time of surgery, transplant recipients are started on drug regimens that consist of several categories that hopefully capitalizes on the different immune-mediated mechanisms of action and may also allow for the use of lower doses individually in order to minimize toxicity.

Dr. Patel discussed Prograf, where in July of 2021, FDA approved for the prevention of rejection in lung transplantations in combination with other immunosuppressants. As you can see, add a litany of other indications already, such as liver, kidney, heart transplant as well. So, just an expanded indication here, no changes to any of the black box warnings, precautions, dosing or availability. As you can imagine, the dosing is stratified by indication, specifically [Inaudible: 1:04:22] set of organ that has been transplanted. And so the specific dosing instructions are available in the package insert or in the CCR for the committee to see.

For specialized populations for Prograf, first pregnancy, it can cause fetal harm, advise pregnant women of the potential risk to the fetus. In terms of hepatic impairment, due to reduced clearance and prolonged half-life, patients with severe hepatic impairments defined as Child-Pugh greater than or equal to 10 may require lower dose of Prograf. Close monitoring of blood concentration is warranted. And renal impairment, there is a chance for nephrotoxicity. So, there is a dose adjustment recommended in patients who do have renal impairment.

Dr. Patel discussed Jakafi. In September 2021, FDA approved oral Jakafi for chronic graft versus host disease after failure of one or two lines of systemic therapy in adults and pediatric patients 12 years of age and older. This was already indicated for steroid refractory acute graft versus host disease in the same age group and for select patients with myelofibrosis and polycythemia vera. Similar to the previous slide, no changes to the other indications it has along with warnings, precautions. The dosing for the new indication as you can see is here 10 mg orally twice daily and the other dosages are stratified by indication as well and no changes to availability here as well.

One thing to note with Jakafi, is when pregnant rats and rabbits were administered with this during the period of organogenesis, adverse developmental outcomes did occur at doses associated with maternal toxicity. There are no doses in pregnant women to inform a drug-associated risk. However, animal studies have shown some form of adverse events.

And lastly, there is a REMS update for mycophenolic acid delayed-release tablets, such as the CellCept and Myfortic. REMS update [Inaudible: 1:06:40] with more patients from the language eliminated the patient prescriber acknowledgement form, revision of training documents, and inclusion of a list of professional medical society. In May 2021, REMS modified to update the non-continuing education website screenshots into the hyperlink on the website for the CE request. And in August 2021, mycophenolate shared REMS update with REMS website screenshots updated to align the Data Insight section of the patient overview with the Data Insights from the patient brochure.

Moving to the next slide here, you can see that the utilization was in line with the PDL. Previous year's motion, Mr. Riley moved the class effect. This was seconded by Dr. Ryan and passed unanimously.

DR. LILJEGREN MOVED THAT THE DRUGS BE MOVED TO THERAPEUTIC ALTERNATIVES. DR. DORAN-ATCHISON SECONDED THAT. THE MOTION PASSED UNANIMOUSLY.

4-C. ***Antipsoriatics (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Antipsoriatics. The utilization report stated that roughly 82% was in line with PDL. Previous year's motion, Mr. Riley moved the drugs in the class of therapeutic alternatives, seconded by Dr. Ryan and passed unanimously.

DR. RYAN MOVED FOR THE SAME MOTION FROM LAST YEAR. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

4-D. ***Immunomodulators, Atopic Dermatitis (Blue Class)***

Public Comments on Immunomodulators, Atopic Dermatitis (Blue Class)

BRANDON YIP, a representative from Sanofi Genzyme, discussed dupilumab and atopic dermatitis. And one of the things I wanted to also highlight for the committee was the recent ICER report that came out on dupilumab and atopic dermatitis towards the end of 2021. And it kind of outlines the additional safety information post launch in 2017. It has done a great job in just outlining the great safety story that we have established dupilumab in atopic dermatitis and along with the other indications in asthma and CRS with NP. So, I am just pleased, just wanted to bring some attention to that leave behind so you have access to that. So please, if there is any questions, you guys know how to reach me or if there is any questions now, feel free to ask them and I can answer them.

MARGARET OLMON, a representative from AbbVie, discussed upadacitinib with the brand name Rinvoq. My focus at this time is on the newest indication. Rinvoq has been FDA approved to treat patients 12 years and older with refractory moderate-to-severe atopic dermatitis, not adequately controlled with other systemic medications or when the use of those therapies is inadvisable. Treatment should be initiated with 15 mg taken orally once daily. If an adequate response is not achieved, provider should consider increasing the dose to 30 mg daily.

Atopic dermatitis is the most common and most severe type of eczema and is characterized by itching and inflamed skin. Providers and patients with moderate-to-severe AD are looking for a treatment that will offer rapid reduction in itch and pain along with lessening of inflammation, redness, and thickening of the skin. Rinvoq has differentiated itself from other medications currently available for the treatment of AD. Rinvoq at both 15 and 30 mg daily doses, met all primary and ranked secondary endpoints in three pivotal trials. Measure of 1 and 2 looked at monotherapy treatment, and ADF was a trial that evaluated Rinvoq in combination with topical corticosteroids. In these studies, the investigators noted a rapid onset of action. Over two-thirds

of patients saw statistically significant 75% improvement in skin symptoms after 16 weeks and a significant reduction in itch was seen as early as day 2 with Rinvoq 30 mg and day 3 with 15 mg.

In all three studies, Rinvoq demonstrated disease control for adults and adolescents throughout the double blind period with and without the use of topical corticosteroids. Rinvoq has a well-studied clinical profile with over 7500 patients studied in rheumatoid arthritis and psoriatic arthritis. And now with over 3200 additional patients in the AD phase 3 program. The safety of the AD studies was consistent with previous trials in RA and PsA. The most common adverse events seen in AD were upper respiratory tract infection, acne, headache, and nasal pharyngitis. No MACE or VT events were reported in the upadacitinib treatment groups.

AbbVie will continue to observe patients to determine long-term safety with upadacitinib across all indications. This has been only a short review. Please refer to the prescribing information for full efficacy and safety information online at rxabbvie.com. I want to close by respectfully asking that Rinvoq be added to the state-preferred drug list for all indications including atopic dermatitis.

Dr. Umang Patel gave the Magellan presentation for Atopic Dermatitis. Atopic dermatitis is a chronic non-contagious inflammatory disease of the skin resulting from a combination of genetic and environmental factors. Less than 70% of patients diagnosed have a positive family history. The odds of developing atopic dermatitis 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. It often refers to as eczema, and it affects about 18 million Americans and accounts for 10% to 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 5-1/2, 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 the intense itching, patients may scratch or rub the affected areas which leads to further irritation and inflammation. As skin loses moisture from the epidermal layer, it becomes increasingly dry and may begin to crack, leak, crust and scale. The damage to the integrity of the skin renders it less effective and more prone to infection. And despite the chronic nature of the dermatologic condition, there may be periods of the disease when the skin improves and present periods where 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 and cause flare ups.

On the next slide here, we have Dupixent. So in terms of, again, for this class, the guidelines are greater than a year and can be found in the appendix. Dupixent had two updates last year. First, in June 2021, where the FDA approved a single-dose autoinjector prefilled pen for use in patients 12 years of age or older. It was already approved as a prefilled syringe and an autoinjector in different strengths and prefilled syringe as well. And in October 2021, FDA expanded the indication of add-on maintenance treatment with moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid-dependent asthma to patients 6 years of age or older. Previously, this was only 12 years of age and older. So, expanded even further into the pediatric realm. No other updates to its other indications listed here. So, dosage again is stratified by

indication, age and weight. So, the different dosing instructions are available in the CCR [Inaudible: 1: 19:40]. And as I mentioned earlier, there was a new availability, the 200 mg/1.14 mL solution can now be found already within a single dose. It was already in a syringe with a needle shield, and now, it is also available in a single dose.

The utilization report was reviewed and roughly 50% is in line with the PDL, where in the previous year's motion, Dr. Liljegren moved the drugs in the class of therapeutic alternatives to include at least one pediatric-approved preparation and this was seconded by Mr. Riley and passed unanimously.

Dr. Liljegren asked why there were so many non-PDL prescriptions.

Dr. Patel stated that it was primarily due to Dupixent.

Dr. Liljegren asked if when the PDL chooses its drugs, does it take into any account the utilization or is it strictly price based.

Dr. Semling stated that the decision was based off of clinical outcomes, based on the will of the committee, and partially based on costs.

Dr. Liljegren asked Dr. Patel to clarify the name of the drug that was responsible for most of the non-PDL.

Dr. Patel and Dr. Ryan both clarified that it was Dupixent.

Dr. Liljegren asked that if the same motion was made, if there would be a reasonable likelihood that the decision on which drugs to include would be based then as well looking at what was prescribed last year.

Dr. Semling stated that everything would be taken into consideration and that there had been a major market shift to Dupixent, since it is fairly new.

DR. LILJEGREN MOVED THAT THE THERAPEUTIC ALTERNATIVES INCLUDE AT LEAST ONE PEDIATRIC-APPROVED PREPARATION. SECONDED BY DR. RYAN. THE MOTION PASSED WITH ONE ABSTENTION.

4-E. Topical Steroids: Low Potency Topical Steroids (Green); Medium Potency Topical Steroids (Green); High Potency Topical Steroids (Green); Very High Potency Topical Steroids (Blue)

Low Potency Topical Steroids (Green Class)

Dr. Umang Patel gave the Magellan presentation on Low Potency Topical Steroids. The utilization records were reviewed and it was revealed that for low potency, roughly 89% of utilization is in line with PDLs.

Medium Potency Topical Steroids (Green Class)

Dr. Umang Patel gave the Magellan presentation on Medium Potency Topical Steroids. The utilization records were reviewed and it was revealed that for medium potency, about 88% is in line with PDL.

High Potency Topical Steroids

Dr. Umang Patel gave the Magellan presentation on High Potency Topical Steroids. The utilization reports were reviewed and it was revealed that for high potency, 96% is in line with PDL.

Very High Potency Topical Steroids

Dr. Umang Patel gave the Magellan presentation on Very High Potency Topical Steroids. There drugs were in a Blue Class due to drug update for Lexuss. In August 2021, the FDA approved and expanded indication for the topical treatment of plaque psoriasis to pediatric patients 12 years of age or older. Previously, it was indicated for the treatment of plaque psoriasis in patients 18 years of age or older, but now they are in the pediatric realm as well. Again, no changes to warnings, dosing, availability, and there is no available data on Lexuss and its effect on women who are pregnant to inform a drug-associated risk.

The utilization reports were reviewed and roughly 93% were in line with PDL. Previous year's motion, Mr. Riley moved the class effect within each potency group and include at least one ointment and one cream from each potency group. Dr. Liljegren moved 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. Ryan and passed unanimously.

DR. RYAN MOVED FOR THE SAME MOTION THAT WAS OUTLINED LAST YEAR. SECONDED BY DR. LILJEGREN. THE MOTION PASSED WITH ONE ABSTENTION.

4-F. ***Topical Acne Agents (Red Class)***

Dr. Umang Patel gave the Magellan presentation on Topical Acne Agents. So, acne vulgaris is the most common cutaneous condition in the United States for disorder that affects primarily teenagers and young adults, but it can sometimes persist beyond young adults. In adolescents, sebaceous glands increase sebum release after puberty and small cysts called comedones-forming hair follicles due to blockage of the foreign-simulated sebum and keratinous material. Bacteria, most often P. acnes, releases free fatty acids and sebum within the comedones, which causes inflammation to form cysts. So, this results in a rupture in cyst wall and subsequent inflammatory reaction due to extrusion of [Inaudible: 1:28:46] terrigenous debris from the cyst.

There are three categories of the severity of acne, and since either acne occur in the face or trunks of body, these categories are graded as mild to moderate or severe depending on the

presence and number of lesions, which contains comedones, papules, pustules and/or cysts. Mild was defined as the presence of less than 20 comedones, 15 papules or fewer than 30 lesions consistent with the combination of comedones and papules. Moderate is 15 to 20 papules and pustules in addition to comedones and various cysts and the total number of lesions can range from 30 to 125. And severe is defined by the presence of mostly inflamed nodules and cysts and includes more than 125 lesions consisting of comedones, papules and pustules.

There are no clinical updates or guidelines that can be found in the appendix. Moving right to the new medication here, we have Twyneo. In December 2021, FDA approved medications which is combination of a tretinoin or a retin-A and benzoyl peroxide indicated for the treatment of acne vulgaris in pediatric patients 9 years of age or older. In terms of warnings and precautions, there is a hypersensitivity warning here, which includes anaphylaxis and angioedema that have been reported with the use of benzoyl peroxide products. As one can imagine, skin irritation can be a warning in precautions, and it is recommended to avoid application to cuts, abrasions and sunburned skin and photosensitivity. So, it is recommended to use sunscreen and protective clothing when sun exposure cannot be avoided against topical agent, so the dosing was just a thin layer topically to the affected areas once daily and it is available as a cream that is 0.1% tretinoin and 3% benzoyl peroxide. One other clinical update that is not related to this medication is for clindamycin phosphate which is the 1% gel. In September 2021, FDA approved the first time generic of Clindagel [Inaudible: 1:31:05].

The utilization records were reviewed and were roughly 84% in line with the PDL. And previous motion, Dr. Ryan moved the drugs in the class of therapeutic alternatives to include at least one drug from each subclass and at least one combination benzoyl peroxide and antibiotic. This was seconded by Mr. Riley and passed unanimously.

DR. LILJEGREN MOVED THE PREVIOUS MOTION. DR. WHITE SECONDED IT. THE MOTION WAS PASSED UNANIMOUSLY.

4-G. ***Ophthalmic Allergic Conjunctivitis (Green Class)***

Dr. Umang Patel gave the Magellan presentation on Ophthalmic Allergic Conjunctivitis. The utilization records were reviewed and roughly 91% of utilization is in line with PDL. Previous motion, Dr. Ryan moved the drugs in the class of therapeutic alternatives, seconded by Mr. Riley and passed unanimously.

DR. RYAN RENEWED THE MOTION. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

4-H. OPHTHALMIC DRUGS: Ophthalmic Antibiotics (Green); Antibiotic Steroid Combinations (Green); Ophthalmic Anti-Inflammatory (Blue); Ophthalmic Glaucoma Agents (Green)

Ophthalmic Antibiotics (Green Class)

Dr. Umang Patel gave the Magellan presentation for Ophthalmic Antibiotics. The utilization records were reviewed and utilization is roughly 98%.

Antibiotic Steroid Combinations (Green Class)

Dr. Umang Patel gave the Magellan presentation for Antibiotic Steroid Combinations. The utilization records were reviewed and the utilization is roughly at 85%. And so previous motion, Dr. Ryan moved the class effect for each subclass of the ophthalmic antibiotics and of the drugs in the ophthalmic antibiotic steroid combinations with therapeutic alternatives. It was seconded by Mr. Riley and passed unanimously.

DR. RYAN MOVED THE SAME AS LAST YEAR. SECONDED BY DR. LILJEGREN. THE MOTION WAS PASSED UNANIMOUSLY.

Ophthalmic Anti-Inflammatory (Blue Class)

Dr. Umang Patel gave the Magellan presentation for Ophthalmic Anti-Inflammatory. Uveitis is an inflammation of the middle layer of the eye or uvea consisting of the iris, ciliary body and choroid caused by eye trauma secondary to autoimmune diseases or infection and maybe idiopathic in nature. It may present as acute, chronic or recurrent attacks with unilateral pain or photophobia. Aqueous cells and flare due to cellular infiltration and protein exudation into the anterior chamber are seen as spots and [Inaudible: 1:37:04] on fluorescein examination. Both are signs of ocular inflammation. If left untreated, uveitis can lead to glaucoma, cataracts, or retinal edema and ultimately loss of vision.

Initial treatment of uveitis typically includes ophthalmic corticosteroids, such as topical drops or intravitreal implants with these pain and inflammation. Temporal arteritis affecting the superficial temporal arteries as a systemic inflammation, inflammatory vasculitis of unknown etiology that occurs in older individuals and can result in systemic, neurologic and ophthalmologic complications. Permanent visual impairments is estimated in up to 20% of patients with the condition. Timely initiation of therapy may prevent irreversible damage including blindness and the mainstay of therapy includes corticosteroids, which are typically prescribed for up to two years.

In October 2021, FDA approved Dextenza ophthalmic inserts for the treatment of ocular itching associated with allergic conjunctivitis. Previously, it was approved only for the treatment of ocular inflammation and pain following ophthalmic surgery. Again, it is just an expanded indication. No other updates to warnings, precautions, dosage or availability here.

In October 2021, FDA approved this medication for the treatment of macular edema associated with uveitis and approved as a 40 mg/mL single dose vial.

A few other updates, first being a discontinuation. In September 2021, the FDA has announced discontinuation of the fluorometholone ointment 0.1% as AbbVie Allergan have discontinued manufacturing the drugs. And in August 2021, there is a new generic, the FDA approved first generic of Novartis' Durezol which is difluprednate and this is made by Cipla Pharmaceuticals.

The utilization reports were reviewed and were roughly 92% is in line with PDL. Previous motion, Dr. Ryan moved the drugs in the class of therapeutic alternatives to include one drug from each subclass, seconded by Mr. Riley and passed unanimously.

DR. RYAN MOVED FOR LAST YEAR'S MOTION, SECONDED BY DR. LILJEGREN. THE MOTION WAS PASSED UNANIMOUSLY.

Ophthalmic Glaucoma Agents (Green Class)

Dr. Umang Patel gave the Magellan presentation on Ophthalmic Glaucoma Agents. The utilization was roughly 85% is in line with PDL. Dr. Ryan moved the drugs in the class for therapeutic alternatives to include at least one drug from each subclass, seconded by Mr. Riley and passed unanimously.

DR. RYAN MOVED FOR THE SAME MOTION AS LAST YEAR, SECONDED BY DR. DORAN-ATCHISON. THE MOTION WAS PASSED UNANIMOUSLY.

Ophthalmic Immune Modulators (Red Class)

Dr. Umang Patel gave the Magellan presentation on Ophthalmic Immune Modulators. Keratoconjunctivitis sicca (KCS) is defined as a dry-eye disease related to either decreased tear volume or rapid evaporative loss due to poor tear quality. Both of these conditions may be present in dry eye syndrome. The term dry eye syndrome [Inaudible 1:43:20], KCS and keratoconjunctivitis sicca are often used interchangeably with the term keratoconjunctivitis sicca being in all other terms. There is considerable overlap with other ophthalmic conditions such as meibomian gland dysfunction. This does affect approximately 10% to 13% of US population and occurs more commonly in patients over 50 years of age with approximately twice as many women as men affected, probably due to increased use of soft contact lenses, frequent smartphone and computer usage. The prevalence is increasing among young adults aged 18 years or before. Patients with KCS may have the following complaints such as sensation of ocular dryness, grittiness, a foreign body or irritation, hyperemia, mucoid discharge, excessive tearing, photophobia and blurry vision.

On the next slide here, we have Verkazia where in June 2021, FDA approved this new medication which is a calcineurin inhibitor immunosuppressant for the treatment of vernal keratoconjunctivitis in children and adults. Some warnings and precautions to avoid the potential of eye injury and contamination, it is recommended to advise patients not to touch the tip of the vials to the eye or other surfaces. The dosing for this is 1 drop four times daily in each affected eye. And again, this is an ophthalmic emulsion of 0.1% of cyclosporine.

On the next slide here, we have Tyrvaya. In October 2021, FDA approved this nasal spray formulation of varenicline indicated for the treatment of signs and symptoms of dry eye. It is a cholinergic agonist, and the warnings and precautions are similar to the previous medication to avoid touching the vial tip to the eye or other surfaces. The dosage is one spray in each nostril twice daily, about 12 hours apart. [Inaudible: 1:45:29] There is a prime first seven actuations for

use and you can use a three prime with one actuation [Inaudible] for more than five days. And it is a nasal spray delivering 0.03 mg of varenicline in each spray.

The utilization report was reviewed and roughly 84% is in line with PDL. Previous year's motion, Dr. Ryan moved the drug in the class of therapeutic alternatives, seconded by Mr. Greer and it passed unanimously.

DR. RYAN MOVED FOR THE SAME MOTION AS LAST YEAR, SECONDED BY DR. LILJEGREN. THE MOTION WAS PASSED UNANIMOUSLY.

5. Review Minutes from November 2021.

None.

6. Other Business

Dr. Umang Patel stated the Committee is required to do a new procurement for stenographer, and that they were still working on that. Dr. Patel stated that everything was recorded and that as soon as the procurement process went through, the recording would be converted to minutes. This was acknowledged by Dr. Riley.

7. End of public meeting.

8. Comments from Committee Members or Chair

MR. RILEY MOVED TO ADJOURN THE MEETING. THE NEXT MEETING WAS SCHEDULE FOR APRIL 15, 2022. WITHOUT OBJECTION, THE MEETING WAS ADJOURNED.