Alaska Medicaid Pharmacy and Therapeutics Meeting

MINUTES OF MEETING
January 19, 2024

Committee Members Present:
John Riley, PA, Acting Chairman
Robert Carlson, MD
Sara Atchison, PharmD
Claudia Phillips, MD
Charles Ryan, MD
Trisha White, R.Ph.
Valarie Bixler, PharmD

Committee Members Absent:
Casey Gokey MD

Others Present:
Ryan Ruggles, Pharm D
Umang Patel
Charles Semling PharmD, DHSS
Matt Parrott
Greg Sexton, GSK
Ash Dave, AMGEN
Christine Dube, AstraZeneca
Long Nguyen, GSK
Hiren Kachhia, AMGEN
Erin Nowak, AbbVie
Shirley Quach, Novartis
Bernard Kim, AMGEN
Mariola Vasquez, Dermavant
Hiten Patadia, Incyte
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 (Blue); Glucocorticoids, Inhaled, Single Entity (Green); Glucocorticoids, Inhaled, Combined (Blue); Beta Agonists Bronchodilators, Long (Green); Beta Agonists Bronchodilators, Short (Green); Immunomodulators (Red)

Respiratory: COPD Agents (Blue)

Umang Patel gave the Magellan presentation for COPD Agents. He started off with the disease state description and stated that in the 2023 edition of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines described COPD as a heterogeneous lung condition characterized by chronic respiratory symptoms due to airway and/or alveoli abnormalities that cause persistent, often progressive, airflow obstruction. It is estimated that in the US there are approximately 16 million individuals with COPD and COPD is the third leading cause of death. Types of COPD include chronic bronchitis and pulmonary emphysema. Patients with chronic bronchitis experience intermittent airway inflammation and excessive mucus production that leads to frequent, prolonged episodes of productive cough. In its 2023 update GOLD revised the definition of COPD to include bronchitis and emphysema. He gave the GOLD guidelines for 2023. GOLD classifies patients separately by both their GOLD severity and exacerbation/symptom assessment.

In April 2023, the FDA announced the discontinuation of glycopyrrolate 25 mcg/mL nebulizer solution by Sunovion.

In April 2023, the FDA approved the first generic for tiotropium bromide inhalation powder 18 mcg/capsule (Spiriva HandiHaler) by Lupin.

Utilization was about 98% in line with PDL. Previous years motion Dr. Carlson moved the drugs in the class were therapeutic alternatives, seconded by Mrs. White. The motion passed unanimously.

DR. RYAN MOVED THAT THE DRUGS WERE THERAPEUTIC ALTERNATIVES, SECONDED BY VALARIE BIXLER. THE MOTION PASSED UNANIMOUSLY.

Respiratory: Glucocorticoids, Inhaled, Single Entity (Green Class)/Respiratory: Glucocorticoids, Inhaled, Combination (Blue Class)

Ryan Ruggles gave the Magellan presentation for glucocorticoids, inhaled, single entity as well as glucocorticoids, inhaled, combination. Given that one class was blue he allowed time for testimony. He then gave the disease state description for glucocorticoids, inhaled. The prevalence of asthma in the US continues to rise. Asthma is defined by the National Asthma Education and Prevention Program (NAEPP) as a chronic inflammatory disorder of the airways

in which may cells and cellular elements play a role. Studies have demonstrated the efficacy of inhaled corticosteroids in improving lung function, reducing symptoms, reducing frequency and severity of exacerbation, and improving the quality of life of patients with asthma.

In 2023, the GINA guidelines offer a control based management plan to adjust treatment in a continuous cycle of assessment, treatment, and review of the patients' responses as it related to symptom control, future risk of exacerbation, and side effects. Equally important in this process is identifying the patients' own goals regarding their asthma management to ensure improved outcomes 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 treatment can be stepped down to the lowest step and dosage that maintains control. Patients 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. Notably, reliever therapy can be considered for symptom management prior to exercise, if needed.

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 short acting beta agonist which is the alternative approach when track 1 is not an option or is not preferred for patient specific reasons.

In January 2023, the FDA approved a new combination of albuterol, a beta2-andrenergic agonist, and budesonide, a corticosteroid, indicated for as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in patients with asthma equal to or greater than 18 years of age. He gave the indications, precautions, dosage, and availability.

In May 2023, the maintenance treatment of asthma indication for Breo Ellipta 100/25 mcg has been expanded to include patients aged 12 – 17 years of age. Umang gave the indications, dosage, and availability.

In June 2023, the FDA posted that GSK would discontinue distribution of Flovent-HFA (44 mcg, 110 mcg, 220mcg) & Flovent Diskus (50 mcg, 100 mcg, 250 mcg). The last date for product ordering was 12/21/2023.

Utilization was 90.3% in line with PDL. Previous motion Dr. Carlson moved the drugs in the class were therapeutic alternatives, seconded by Dr. Doran-Atchison and passed unanimously.

DR. PHILLIPS STATED THAT SINCE THE CLASSES WERE COMBINED, SHE MOVED THAT THE DRUGS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE FROM EACH SUBCLASS, SECONDED BY DR. DORAN-ATCHION. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Glucocorticoids, Inhaled, Combination:

CRAIG SEXTON, GSK Regional Account Manager, gave testimony for Trelegy. He directed everyone to the full prescribing information for complete efficacy and safety. Trelegy was the

first and remains the only inhaler that combines the inhaled corticosteroid [unintelligible] and [unintelligible] with indications for both COPD and asthma. These three medications are delivered in an easy to use device that is always administered once daily with a single inhalation. As mentioned, the GOLD guidelines recommend triple therapy which has been shown to improve lung function, patient reported outcomes, and reduce exacerbations when compared to [unintelligible] alone, [unintelligible] or ICS combinations. Trelegy has enjoyed preferred status across 93 percent of all payers in the state of Alaska including the Alaksa PDL. They ask that Trelegy remain an option for patients and providers on the PDL in 2024.

Respiratory: Beta Agonists Bronchodilators, Short (Green Class)

Given that this is a green class Umang moved right into utilization which was 16.3% in line with PDL.

Previous motion Mrs. White moved a class effect to include both an inhaler and a nebulized product, seconded by Dr. Doran-Atchison. The motion passed unanimously.

Dr. Semling pointed out that this is actually the information for short acting which Umang apologized for getting them mixed up.

Dr. Semling stated that the utilization is low because most of the albuterol products the brand name is preferred. He stated that they do anticipate a shift on the next PDL. Matt Parrott stated that there has been significant discontinuations of the brand name products which will therefore drive some of the generic activity up.

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

Respiratory: Beta Agonists Bronchodilators, Long (Green Class)

This too was a green class so they moved right into utilization which was 100% in line with PDL.

Previous motion Dr. Doran-Atchison moved that the drugs were therapeutic alternatives, seconded by Dr. Gokey. The motion passed unanimously.

DR. PHILLIPS MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Respiratory: Immunomodulators (Red Class)

Umang Patel informed the committee that they updated the respiratory sub-classes to include asthma immunomodulators. He gave the Magellan presentation for immunomodulators. In February 2023, the FDA approved Tezepelumab-Ekko, Tezspire, a single-use 210 mg/1.9L mL

autoinjector for self or caregiver administration. He discussed the indications, precautions, contraindications, dosing, and formulations.

Given that this is the first time this has been reviewed there is no utilization or previous motion.

DR. PHILLIPS MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Immunomodulators

ASH DAVE, Medical Value and Access Director for AMGEN, gave testimony on TEZSPIRE. This is a first in class human monoclonal antibody that blocks the action of acute epithelial cytokine TSLP that acts as an upstream modulator of multiple inflammatory pathways. Tezspire is indicated for the add on treatment maintenance of severe asthma in adult and pediatric patients age 12 and older. Tezspire is given as a 210 mg dose subcutaneously once every four weeks by a healthcare provider or self-administration and is the first and only biologic for severe asthma without phenotypic or biomarker limitations within its approved label. Tezspire demonstrated significant reduction in annualized asthma exacerbation rates in two 52 week trials in patients with severe asthma receiving background therapy including medium or high dose inhaled corticosteroids. Tezspire is the only [unintelligible] biologic to demonstrate consistently significant reduction in asthma exacerbations regardless of a patient's biomarker status. Tezspire has an established safety profile with the most common adverse events reported being pharyngitis, arthralgia, and back pain. He provided the full label for reference. GINA recommends Tezspire as an add on biologic therapy option for patients with both type 2 and non-type 2 severe asthma. AMGEN respectfully requested that the committee offers Tezspire on the state PDL as the preferred agent with utilization criteria that continues to be aligned to its label. He opened the floor for any questions.

CHRISTINE DUBE, Clinical Account Director with AstraZeneca, gave testimony on Fasenra and its subcutaneous use. Fasenra was approved in 2017 as indicated for add on maintenance of patients with severe asthma 12 years of age or older with an eosinophilic phenotype. The recommended dose is 30 mg once every four weeks subcutaneously for the first three doses and then 30 mg every eight weeks thereafter by subcutaneous injection. It is not indicated for the treatment of other eosinophilic conditions or for acute bronchospasm or status epilepticus. She referred them to the full prescribing information. It is the only anti-eosinophil monoclonal antibody that binds directly to the IL-5 receptor alpha on eosinophils. It works rapidly to deplete eosinophils which can be a key cause of severe asthma. It is given again as a fixed dose with no weight base dosing maintenance administered subcutaneous every eight weeks after those first three doses. This is really important when you are modeling to understand that it is the only respiratory biologic that offers every eight week dosing having the fewest maintenance doses per year as either the 30 mg pre-filled or the self-administered auto injector pen. In the phase 3 registrational trials patients receiving Fasenra 30 mg versus placebo demonstrated significant reductions in asthma exacerbation, improved lung function, and reduced daily OCS use versus those on placebo. OCS dependent patients also demonstrated reduction in OCS dose while

maintaining asthma control. An open label safety study extension showed consistent safety. She referred them to the prescribing information for full safety profile. AstraZeneca respectfully requested that Fasenra be added on the preferred drug list for patients in the Alaska Medicaid program.

LONG NGUYEN, Field Medical Account Lead and Pharmacist with GSK, gave testimony on Nucala. He stated that he information he shared is not new but he just wanted to reinforce how important Nucala is to patients with eosinophilic disorders. Nucala is indicated for the maintenance treatment in patients with severe eosinophilic asthma, SEA, which is the largest population served by Nucala. It is given subcutaneously every four weeks without the need of a loading dose and it is the only [unintelligible] agent with a pediatric indication down to the age of 6. Nucala is available for both at home administration in pre-filled syringes or autoinjectors as well as in office dosage form to allow the flexibility for the patients to receive the medication whether they live in or close to a major metropolitan clinic or in a far hard to reach village. Since its approval in 2015, Nucala has a long standing history of safety and improved patient outcomes demonstrated by randomized clinical trials and open label studies. A recent prospective designed real-world evidence study using patient level data shows that Nucala reduced clinically significant exacerbations by 71 percent after 12 months and 74 percent after 24 months with continuing therapy. Those who are on maintenance oral corticosteroid in the study at baseline the median oral clinical steroid dose was reduced from 10 mg daily at baseline to zero and 57 percent of the patients discontinued their need of daily OCS at 24 months in the real-world study. Nucala is also indicated for other indications such as the treatment of chronic rhinosinusitis with nasal polyps and it is the only medication approved for the treatment of eosinophilic driven rare disease such as EGPA or [unintelligible] or HES. He asked the committee to make Nucala available and be added to the Alaska preferred drug list for patients with SEA.

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

Allergy: Epinephrine, Self-Injected (Green Class)

Given that this is a green class Umang moved directly into utilization.

Utilization was 99.7% in line with PDL. Previous motion Dr. Doran-Atchison moved that the drugs in the class were therapeutic alternatives, seconded by Dr. Carlson. The motion passed unanimously.

DR. DORAN-ATCHISON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Allergy: Intranasal Rhinitis Agents (Green Class)

This too is a green class so they moved directly to utilization. Utilization was 99.1% in line with PDL. Previous motion Dr. Ryan moved a class effect, seconded by Dr. Doran-Atchison. The motion passed unanimously.

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

Allergy: Leukotriene Modifiers (Green Class)

Given this is a green class they moved directly to utilization. Utilization was 99.8% in line with PDL. Previous motion Dr. Doran-Atchison moved a class effect to exclude Zileuton, seconded by Dr. Ryan. The motion passed unanimously.

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

Allergy: Antihistamines, Minimally Sedating (Green Class)

This is another green class so they moved directly to utilization. Utilization was 96.6% in line with PDL. Previous motion Dr. Ryan moved a class effect to include an oral syrup or a suspension for pediatric dosing, seconded by Dr. Doran-Atchison. The motion passed unanimously.

DR. RYAN MOVED A CLASS EFFECT TO INCLUDE AN ORAL SYRUP OR SUSPENSION FOR PEDIATRIC DOSING. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

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

Immunological: Cytokine & CAM Antagonists, Non-GI Indications (Red Class)

Umang Patel opened for testimony given this is a red class. He reminded the committee that they are only reviewing the non-GI indications as they reviewed the GI indications at the September meeting.

Public Comments for Cytokine & CAM Antagonists, Non-GI Indications

HIREN KACHHIA, Senior Medical Science Liaison for AMGEN, gave clinical updates on Otezla. AMGEN is requesting that the committee deem Otezla as a preferred drug on the state PDL. Otezla is a small molecule drug that inhibits the activity of [unintelligible] cells. It is indicated for the treatment of adult patients with oral ulcers associated with Behcet's disease, adult patients with active psoriatic arthritis, and adult patients with all severities of plaque psoriasis who are candidates for portal therapy or systemic therapy. Additional trials support the efficacy and safety of Otezla in adults with moderate to severe plaque psoriasis of the scalp and genitals. Otezla is administered orally 30 mg twice daily. It is not a biologic treatment requiring

injection and does not have a boxed warning for serious infections, malignancy, major adverse cardiovascular events, and thrombosis. The most common adverse reaction is greater than or equal to 5 percent for Otezla are diarrhea, nausea, and headache. The 2020 joint American Academy of Dermatology National Psoriasis Foundation Guidelines of Care for the management of psoriasis with systemic non-biological therapies recommends the use of Otezla for the treatment of moderate to severe psoriasis in adults. The 2018 American College of Rheumatology MPF Guideline for the treatment of psoriatic arthritis categorized Otezla as an oral small molecule and supports its use in defined patient populations.

SHIRLEY QUACH, Value Evidence Lead with Novartis, gave updated information for Cosentyx. Cosentyx is the first and only [unintelligible] human IL-17A inhibitor with over 8 years of market experience and spans across 8 approved inflammatory conditions. On October 21, 2023, the FDA approved Cosentyx as the first IL-17A biologic indicated for the treatment of adults with moderate to severe hidradenitis suppurativa or HS. Recommended dosage is 300 mg by sub-q injection at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter. If a patient does not adequately respond consider increasing the dosage to 300 mg every 2 weeks. The SUNSHINE and SUNRISE trials were the largest phase 3 program in HS with over 1,000 patients in 40 countries and evaluated the short and long term efficacy, safety, and tolerability of two dose regimens of Cosentyx in adults with moderate to severe HS. The onset of actions of Cosentyx occurred as early as week two and a statistically significantly higher proportion of patients treated with Cosentyx 300 mg every 2 weeks after the loading dosage achieved the primary endpoint high score of 50 response at week 16 compared with patients treated with placebo. High score values observed at week 16 following either dose regimen of Cosentyx were improved over time to week 52 with rapid improvement seen in patients who switched from placebo at week 16. Cosentyx safety profile in HS was consistent with the well established profile in other approved indications and no new safety signals were observed. HS is a painful, chronic, and [unintelligible] inflammatory skin disease that causes recurring boil like abscesses that burst and create open wounds in the most intimate parts of the body. It takes people living with HS an average of up to 10 years to get a correct diagnosis which results in disease progression and significantly impacts their quality of life. Prior to this approval there was only one approved treatment option available and there was a significant need for alternatives to reduce the disabling physical symptoms and improve the emotional burden of HS. Cosentyx can offer effective lasting relief from HS symptoms so that people with HS have a chance to live every day with confidence. To date, Cosentyx has been prescribed to over 1 million patients world-wide since its launch in 2015 with over 100 clinical studies and over 8 years of robust real-world clinical experience. She thanked the committee for their time.

BERNARD KIM, Regional Medical Director AMGEN, gave testimony on UPLIZNA or inebilizumab. UPLIZNA is used to treat neuromyelitis optica spectrum disorder (NMOSD). NMOSD is a rare autoimmune disorder characterized by repeated attacks of optic neuritis and transverse myelitis leading to accumulating and permanent disability including loss of vision and impairment and weakness in the extremities. Evidence has shown it is historically unlikely that NMOSD patients receive an accurate diagnosis within a year of initial symptom onset and over a third of patients will likely experience a delay in confirmed and accurate diagnosis of 3 to 5 years. NMOSD attacks are unpredictable and patients are likely to experience at least one attack yearly after diagnosis. Around 50 percent will also be hospitalized for attacks within the first

year of diagnosis. Given the high risk for permanent disability timely access to FDA approved treatments like inebilizumab or UPLIZNA is necessary. He asked the committee to consider the pivotal evidence which proved that the depletion of aquaporin-4 antibody producing plasma blasts is safe, effective, and well tolerated in NMOSD. He discussed trial information. The need for timely treatment in NMOSD is real. AMGEN asks that the committee consider current criteria and provide patients with prompt access to inebilizumab without barriers to access. He thanked the committee for their time.

ERIN NOWAK, Medical Outcomes and Science Liaison with AbbVie, gave testimony on risankizumab, Skyrizi, and upadacitinib, Rinvoq. She first spoke on risankizumab which is an IL-23 antagonist with preapproved indications for moderate to severe plaque psoriasis, psoriatic arthritis, and moderate to severe Crohn's disease. It is contraindicated in patients with a history of serious hypersensitivity to risankizumab or its excipients. She referred the committee to rxabbvie.com for full prescribing information. She asked the risankizumab, Skyrizi, be added to the preferred drug list for all indications. She next spoke about upadacitinib which is a JAK inhibitor and is approved for adult patients with the following indications who have an inadequate response or intolerance to one or more TNF blockers. The indications are moderate to severely active ulcerative colitis, Crohn's disease, rheumatoid arthritis, active psoriatic arthritis, ankylosing spondylitis, and non-radiographic axial spondylarthritis with objective [unintelligible] inflammation. It is indicated for patients 12 and older with refractory moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products or when those therapies are inadvisable. Both drugs offer rapid and durable response, demonstrate significant improvement in [unintelligible], and [unintelligible] across clinical programs, and are capable of helping patients achieve the recommended outcome. There is a favorable benefit risk profile. For upadacitinib this is evident through 25 clinical trials across 7 indications. To date there has been over 37,000 patient years of exposure, over 13,000 patients enrolled in clinical trials, and over 12 years of clinical trial experience showing a consistent safety profile. Of note, upadacitinib is an oral option which may be advantageous. It has a PDL therapy for Alaskan's living in rural areas. It may be beneficial where assistance for assistance and education on parental administration may be limited for patients. She respectfully asked that upadacitinib, Rinvoq, be added to the state preferred drug list for all indications given the clinical attributes, [unintelligible] indications, and being an oral therapy which may benefit Alaska patients. She thanked the committee for their time.

There were no other people wishing to give testimony. Umang then went into the disease state description on cytokines and cell-adhesion molecules (CAMs). They are chemical mediators involved in inflammatory processes throughout the body. He then went into some background and guidelines on Hidradenitis Suppurativa. Next, he gave background information and guidelines on uveitis. Then he gave the background and guidelines information for ankylosing spondylitis. The next topic he spoke on was recurrent pericarditis for which he gave the background and guideline information for. Next, he gave the background and guidelines for polymyalgia rheumatica (PR).

In 2023, the FDA approved sarilumab, Kevzara, as the first biologic for the treatment of adults with PMR who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

Lastly, he gave the background and guideline information on atopic dermatitis.

In February 2023, the FDA expanded the indication for abrocitinib, Cibinqo, to include pediatric patients greater than or equal to 12 years of age with moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable, previously approved only in adults. Hey then gave the indications, precautions, contraindications, dosing, and formulations for abrocitinib.

In March 2023, the FDA approved sarilumab, Kevzara, for the treatment of adults with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate a steroid taper. Previously approved for treatment of RA. He gave the indications, precautions, contraindications, dosing, and formulations.

In March 2023, the FDA approved Cyltezo, adalimumab-adbm (interchangeable Humira biosimilar), for the treatment of moderate to severe hidradenitis suppurative in adults. Previously approved indications include RA, JIA, PsA, AS, CD, UC, and PsO. In May 2023, the FDA approved a new 40 mg/0.8mL single dose prefilled autoinjector pen presentation. In July 2023, the FDA approved it for the treatment of non-infectious intermediate, posterior, and panuveitis in adults. Umang then gave the indications, precautions, contraindications, dosing, and formulations.

In July 2023, several adalimumab (Humira) biosimilars have launched per manufacturer press releases. These commercially available Humira biosimilars on the market include adalimumab-adbm (Cyltezo) from Boehringer Ingelheim, adalimumab-bwwd (Hadlima) from Organon, adalimumab-fkjp (Hulio) from Biocon, adalimumab-adaz (Hyrimoz) high concentration from Sandoz, adalimumab-aacf (Idacio) from Fresenius Kabi, adalimumab-aaty (Yuflyma) from Celltrion, and adalimumab-aqvh (Yusimry) from Coherus. All products are available as a low concentration formulation except Hyrimoz and Yuflyma. Hadlima, Hyrimoz, and Yufyma are available as high concentration formulations. Citrate-free formulations include Cyltezo, Hadlima (high concentration), Hulio, Hyrimoz (high concentration), Idacio, Yuflyma, and Yusimry. Cyltezo is interchangeable with Humira.

In June 2023, the FDA approved adalimumab-bwwd (Hadlima) for the treatment of moderate to severe hidradenitis suppurativa in adults. In July 2023, the FDA approved Hadlima for the treatment of non-infectious intermediate, posterior, and panuveitis in adults. Umang went over the indications, precautions, contraindications, dosing, and formulations.

In March 2023, the FDA approved Amjevita (Humira biosimilar) for the treatment of moderate to severe hidradenitis suppurativa in adults. In August 2023, the FDA approved new high-concentration presentations of 20 mg/0.2 mL, 40 mg/0.4 mL, and 80 mg/0.8 mL prefilled syringe; and 40 mg/0.4 mL and 80 mg/0.8 mL prefilled autoinjector. He then gave the indications, precautions, contraindications, dosing, and formulations.

In September 2023, the FDA approved Ilaris for gout flares in adults in whom NSAIDs and colchicine are contraindicated or not tolerated, or do not provide an adequate response and in

whom repeated courses of corticosteroids are not appropriate. Indications, precautions, dosing, and formulations were reviewed.

In September 2023, the FDA approved Hulio for the treatment of non-infectious intermediate, posterior, and panuveitis in adults. Indications, precautions, contraindications, dosing, and formulations were reviewed.

In March 2023, the FDA approved Yusimry (Humira biosimilar) as a single-dose 40 mg/0.8 mL prefilled autoinjector pen. Yusimry was previously approved as a prefilled syringe. In April 2023, the FDA approved Yusimry for the treatment of moderate to severe hidradenitis suppurativa in adults. In September 2023, the FDA approved Yusimry for the treatment of non-infectious intermediate, posterior, and panuveitis in adults. Indications, precautions, contraindications, dosing, and formulations were reviewed.

In March 2023, the FDA approved Hyrimoz (citrate-free Humira biosimilar) as a high-concentration formulation in the presentation of 10 mg/0.1 mL and 20mg/0.2 mL prefilled syringe as well as 40 mg/0.4 mL and 80 mg/0.4 mL prefilled syringe or autoinjector. In April 2023, the FDA approved Hyrimoz for the treatment of moderate to severe hidradenitis suppurativa in adults. In September 2023, the FDA approved Hyrimoz for the treatment of non-infectious intermediate, posterior, and panuveitis in adults. Indications, precautions, contraindications, dosing, and formulations were reviewed.

In May 2023, the FDA approved Yuflyma, a biosimilar to Humira. The indications are for RA, JIA, PsA, AS, CD, UC, Ps, and HS. There is a black box warning for serious infections as well as malignancy. Dosing is stratified by indication and can be found in TCR and/or PI. Formulations are injection as a single dose prefilled autoinjector 40 mg/0.4 mL, single dose prefilled syringe with safety guard 40 mg/0.4 mL, or single dose prefilled syringe 40 mg/0.4 mL.

In October 2023, the FDA approved tocilizumab-bavi (Tofidence) as the first biosimilar to Actemra. It is an IL-6 receptor antagonist indicated for certain adults with RA and patients greater than or equal to 2 years of age with polyarticular JIA or systemic JIA. Indications, precautions, contraindications, dosing, and formulations were given.

In June 2023, the FDA approved Abrilada for the treatment of moderate to severe hidradenitis suppurativa in adults. In August 2023, the FDA approved Abrilada for the treatment of non-infectious intermediate, posterior, and panuveitis in adults. In October 2023, Abrilada was designated by the FDA as an interchangeable biosimilar to the corresponding presentations of Humira. This interchangeable designation applies to all indications. Umang then gave the indications, dosing, and formulations.

In October 2023, the FDA approved ustekinumab-auub (Wezlana) as an interchangeable biosimilar to ustekinumab (Stelara). Indications, precautions, contraindications, dosing, and formulations were given.

In October 2023, the FDA approved bimekizumab-bkzx (Bimzelx) a humanized interleukin-17A and F antagonist indicated for the treatment of moderate to severe PsO in adults who are

candidates for systemic therapy or phototherapy. Indications, precautions, contraindications, dosing, and formulations were given.

In November 2023, the FDA approved ustekinumab (Wezlana) as an interchangeable biosimilar to ustekinumab (Stelara). Indications, precautions, contraindications, dosing, and formulations were given.

In November 2023, the FDA expanded the SC use of Orencia for the treatment of active PsA to include patients two years of age or older. There were no changes to the precautions or formulations. Dosing is weight based.

In October of 2023, the FDA approved Idacio for the treatment of moderate to severe hidradenitis suppurativa in adults. In November 2023, the FDA approved Idacio for the treatment of non-infectious intermediate, posterior, and panuveitis in adults. Indications, precautions, contraindications, dosing, and formulations were stated.

In October 2023, the FDA approved Cosentyx as the first IV formulation IL-17A antagonist for the treatment of adults with active PsA, active AS, and active non-radiographic axial spondylarthritis with objective signs of inflammation. In November 2023, the FDA approved Cosentyx for the treatment of moderate to severe hidradenitis suppurativa in adults. Indications, precautions, contraindications, dosing, and formulations were given.

Utilization was 72.8% in line with PDL.

Previous motion Dr. Ryan moved that the drugs were therapeutic alternatives, seconded by Mrs. White. The motion passed unanimously.

Dr. Phillips had a question. She stated that she noticed there are no oral preparations on the preferred drug list and asked if that is a need they are missing. [Unsure who spoke] replied stating that they are looking into that now. She is wondering if that should be added as part of the proposal.

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

Immunological: Immunosuppressants, Oral (Blue Class)

Umang Patel gave the Magellan presentation for Immunosuppressants, Oral. He gave the disease state description which included the sequence of events in graft rejection.

In September 2023, the FDA sent out a communication on tacrolimus stating that the therapeutic equivalence rating for tacrolimus oral capsules manufactured by Accord is being changed by the FDA from AB to BX due to concern for increased peak blood concentrations of the generic product compared to brand Prograf, which may increase toxicity risks. Accord's tacrolimus oral capsules are no longer recommended to be automatically substituted at the pharmacy for Prograf

oral capsules. FDA is not aware of post market safety or efficacy issues for Accord's tacrolimus oral capsules, and no significant difference in trough blood levels (no increased risk for organ rejection) were observed. Generic tacrolimus products by other manufacturers are not affected by this change.

Utilization was about 86.2% in line with PDL. Previous motion Dr. Ryan moved that the drugs be moved to therapeutic alternatives, seconded by Dr. Carlson. The motion passed unanimously.

DR. PHILLIPS MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNTIVES. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

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

Dermatological: Antipsoriatics, Topical (Blue Class)

Umang Patel gave the Magellan presentation on antipsoriatics, topical. He started by giving the disease state description of psoriasis.

In October 2023, the FDA approved roflumilast cream, 0.3% (Zoryve) for topical treatment of plaque psoriasis including intertriginous areas, in patients ages six to eleven years of age. Zoryve had previously been approved for patients greater than or equal to 12 years of age. Indication, dosage, warnings, precautions, and availability were given.

In March 2023, the FDA approved the first generic to Leo's Enstilar (calcipotriene/betamethasone dipropionate) topical foam from Glenmark.

Utilization was 85.6% in line with PDL. Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternative, seconded by Dr. Gokey. The motion passed unanimously.

DR. PHILLIPS MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY TRISH WHITE. THE MOTION PASSED UNANIMOUSLY.

Public Comments for antipsoriatics, topical

MARIOLA VAZQUEZ, Health Outcomes Director with Dermavant, gave testimony on Vtama, tapinarof 1% cream which is a once daily novel steroid free topical treatment option for adult patients with plaque psoriasis. Vtama is a therapeutic option that is a first in class topical [unintelligible] carbon receptor agonist. Vtama has been evaluated through a comprehensive clinical development program of over 1,000 patients with mild to severe plaque psoriasis which were enrolled into identical phase 3 trials that were each 12 weeks long and then followed by a 40 week open label long term extension trial. Vtama has demonstrated highly statistical clinical

significant efficacy across primary and key secondary endpoints. She discussed the trials in detail. Vtama cream offers patients and physicians a new highly efficacious safe, well-tolerated, potentially cost saving, therapeutic option that can be used long-term across the psoriasis disease spectrum. Vtama has no restrictions on application sites and provides a durable effect and may provide an effect of therapy for almost four months. They respectfully asked that the committee consider adding Vtama to the preferred drug list.

Dermatological: Immunomodulators, Atopic Dermatitis (Blue Class)

Umang Patel gave the Magellan presentation on immunomodulators, atopic dermatitis. He started with the disease state description of atopic dermatitis.

In 2023, The American Academy of Dermatology updated their guidelines. Umang discussed these guidelines.

Utilization was roughly 95% in line with PDL. Previous motion Dr. Doran-Atchison moved that the drugs in the class were therapeutic alternatives to include at least one pediatric approved preparation, seconded by Dr. Ryan. The motion passed unanimously.

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

Public Comments for immunomodulators, atopic dermatitis

HITEN PATADIA, Health Outcomes Liaison with Incyte, gave testimony on Opzelura. Incyte is respectfully requesting that Opzelura be made available to patients in Alaska with similar steps for approval as other agents in atopic dermatitis. Incyte also respectfully requested that Opzelura be made available to patients with non-segmental vitiligo at an interval consistent with the assessment of the primary endpoint in the phase 3 clinical trial which was about 24 weeks and preferably longer. In the interest of time the committee was referred to the prescriber information for the full indication statement. He gave presentation on clinical trial data.

VALERIE NG, Director and Medical Outcomes Liaison with LEO Pharma, gave testimony on Adbry, tralokinumab. Adbry is the first biologic developed to specifically target and neutralized NR [unintelligible] which is a key cytokine that drives inflammation in atopic dermatitis, AD. With this targeted mechanism of action Adbry has been prescribed for over 12,000 patients. Most recently two separate guidelines which are the 2023 American Academy of Dermatology and the 2023 American Academy of Allergy, Asthma, and Immunology guidelines for the systemic treatment of AD included a strong recommendation for Adbry as a first line systemic treatment for moderate to severe AD. Most recently Adbry has received FDA approval for the treatment of moderate to severe AD in patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. The approved dose for patients ages 12 – 17 is different than that of the adult. She

referred the committee to the full prescribing information for the dosing recommendation. She then went on to give the open label extension data. The monthly dosing option may lead to a reduction of dose volume and acquisition cost over time and is now further supported by real-world evidence with results ranging from 14 – 32 percent of patients switching from every 2 weeks to every 4 weeks. They asked the committee to consider adding Adbry to the PDL as a preferred product for patients 12 years of age and older suffering from moderate to severe AD who have had an inadequate response to topical prescription therapies.

Dermatological: Topical Steroids, Low Potency (Green Class)

Given that this is a green class they went straight into utilization.

Utilization was 90.9% in line with PDL.

Dermatological: Topical Steroids, Medium Potency (Green Class)

Given that this is a green class they moved right to utilization.

Utilization was approximately 81% in line with PDL.

Dermatological: Topical Steroids, High Potency (Green Class)

Another green class so they moved right into utilization.

Utilization was 95.7% in line with PDL.

Dermatological: Topical Steroids, Very High Potency (Green Class)

Utilization was 95.4% in line with PDL.

Umang bundled all of the topical steroids into one group since they are all the same just different potencies.

Previous motion Dr. Ryan moved a class effect within each potency group and 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. Gokey and passed unanimously.

DR. PHILLIPS MOVED A CLASS EFFECT WITHIN EACH POTENCY GROUP AND TO INCLUDE AT LEAST ONE OINTMENT, ONE CREAM, AND ONE PEDIATRIC FORMULATION FROM EACH POTENCY GROUP. SECONDED BY TRISH WHITE. THE MOTION PASSED UNANIMOUSLY.

Dermatological: Acne, Topical (Blue Class)

Umang Patel gave the Magellan presentation on acne, topical. He gave the disease state description on acne vulgaris.

In October 2023, the FDA approved Cabtreo, a topical gel comprised of clindamycin 1.2%, and adapalene 0.15%, benzoyl peroxide 3.1%; first triple-combination topical treatment for acne vulgaris. Indications, warnings, precautions, dosing, and availability were given.

In September 2023, the DFA approved the first generic for Retin-A-Micro 0.08% topical gel by Encube.

Utilization was approximately 84% in line with PDL. Prior motion Dr. Doran-Atchison moved the drugs in the class were therapeutic alternatives to include at least one drug from each subclass and at least one combination benzoyl peroxide and antibiotic, seconded by Dr. Ryan. The motion passed unanimously.

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

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

Ophthalmics: Allergic Conjunctivitis (Blue Class)

Umang Patel gave the Magellan presentation on ophthalmics, allergic conjunctivitis. He gave the disease state description for allergic conjunctivitis to include conjunctivitis and vernal keratoconjunctivitis (VKC).

In July 2023, the FDA approved the first generic for OTC Lastacraft (alcaftadine) 0.25% ophthalmic solution by Eugia.

Utilization was roughly 79% in line with the PDL. Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives, seconded by Mrs. White. The motion passed unanimously.

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

Ophthalmics: Antibiotics (Green Class)

Given that this is a green class they moved directly to utilization.

Utilization was 94.5% in line with PDL.

Ophthalmics: Antibiotics-Steroid Combination (Green Class)

Utilization was 96.8% in line with PDL.

Previous motions: Dr. Ryan moved a class effect for each subclass of the ophthalmic antibiotics and that the drugs in the ophthalmic antibiotics-steroid combination were therapeutic alternatives, seconded by Dr. Doran-Atchison. The motion passed unanimously.

DR. RYAN MOVED A CLASS EFFECT FOR EACH SUBCLASS OF THE OPHTHALMIC ANTIBIOTICS AND THAT THE DRUGS IN THE OPHTHALMIC ANTIBIOTICS-STEROID COMBINATION WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Ophthalmics: Anti-Inflammatory (Green Class)

Utilization was 92.5% in line with PDL. Previous motion 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.

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.

Ophthalmics: Glaucoma Agents (Red Class)

Umang Patel gave the Magellan presentation on ophthalmics, glaucoma agents. He gave the disease state description on glaucoma. Approximately 3 million people in the US suffer from glaucoma. 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 common cause of blindness in African Americans. Two major types of glaucoma have been identified as open-angle and closed-angle. In open-angle glaucoma there is reduced flow through the trabecular meshwork. Open-angle glaucoma accounts for the majority of cases. In close-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, advancing age (greater than 60 years of age), family history of glaucoma, and African American (greater than 40 years of age) or Hispanic descent. The goal of treatment 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 their lifetime. Patients with primary open-angle glaucoma commonly have untreated IOP that is within the normal range however decreasing pressure is still beneficial in these patients.

In January 2023, the FDA has approved the first generic to Allergan's Alphagan P from Apotex as brimonidine tartrate.

In March 2023, Apotex is voluntarily recalling six lots of brimonidine tartrate 0.15% ophthalmic solution due to cracks in some of the caps on bottles.

In October 2023, the FDA approved pilocarpine HCI (Qlosi) a cholinergic agonist, indicated for the treatment of presbyopia in adults. Warnings, indications, precautions, dosage, and availability were given.

Utilization was 91% in line with PDL.

Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives to include at least one drug from each subclass, seconded by Dr. Doran-Atchison. The motion passed unanimously.

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

Ophthalmics: Immunomodulators (Blue Class)

Umang Patel gave the Magellan presentation on ophthalmics, immunomodulators. He went ahead and gave the disease state description for keratoconjunctivitis sicca (KCS).

In June 2023, the FDA approved cyclosporine ophthalmic solution 0.1% (Vevye) for treatment of dry eye disease in adults. Indication, warnings, precautions, dosage, and availability were given.

Utilization was 31.9% in line with PDL. Umang stated that the reason for the utilization being that low is that there is generic medication that is non-preferred that shifted the utilization as a class.

Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives, seconded by Dr. Gokey. The motion passed unanimously.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RYAN. THE MOTION PASSES WITH 1 NAY.

TRISH WHITE stated that she is voting nay because the challenges when there is a generic available is inventory and when you are a small community pharmacy and so when you have to carry a supply that satisfies depending on who the payer is and she just wants to go on the record that is a challenge so she is saying nay.

5. End of Public Meeting
6. Review meeting minutes from November 2023

There were no changes to the meeting minutes of November 2023.

DR. PHILLIPS MOVED TO APPROVE THE MEETING MINUTES OF NOVEMBER 2023. SECONDED BY DR. DORAN ATCHISON. THE MOTION WAS PASSED BY ALL MEMBERS.