Alaska Medicaid Pharmacy and Therapeutics Meeting

MINUTES OF MEETING
January 17, 2025

Committee Members Present:
Charles Semling PharmD, DHSS
John Riley, PA, Acting Chairman
Robert Carlson, MD
Anna Breckheisen (phonetic)
Sarah Doran-Atchison, PharmD
Casey Gokey
Valarie Bixler, PharmD
Charles Ryan, MD

Committee Members Absent:
Claudia Phillips, MD

Others Present:
Nina Huynh, PharmD, BCPS
Umang Patel
Matthew Parrot
Dr. Jeff Dumane (phonetic)
Christine Dubay (phonetic), Pharmacist AstraZeneca
Shannon DeBartolo (phonetic), Amgen
Bill Nubek (phonetic), ARS
Carla McSpadden (phonetic), Galderma
Dr. Melinda Turkington (phonetic), UCB
Joe Cirincione (phonetic), Incyte

1. Call to Order – Chair

Mr. Riley called the meeting to order at * a.m.

2. Roll Call

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

3. Public Comments - Local Public/Health Practitioners

JEFF DUMANE (phonetic), said that he was calling in support of the inclusion of neffy, self-administered intranasal epinephrine on the Medicaid formulary. He has practiced in Alaska for over 30 years. He is speaking for himself as well as representing AAFA Foundation. The AAFA chapter provides anaphylaxis and epinephrine training throughout the state. It is not for profit and there is no charge for the training. They have been doing it for several years. He speaks on anaphylaxis nationally and regionally mainly focused on insect stings and macrocytosis issues. Neffy was recently approved by the FDA for patients greater than or equal to 30 kg with a 2 mg dose which can be repeated in 5 – 10 minutes, similar to the intramuscular epinephrine. It has a comparable pharmacokinetic and pharmacodynamic as they see with the intramuscular epinephrine as well as the self-administered auto injector. It also has the benefit of a 30 month shelf life. In his practice and throughout the world lifetime prevalence of anaphylaxis has increased and it is now estimated between 1.6 and 5.1 percent of the population. The incidence of anaphylaxis is growing globally in hospitalizations due to anaphylaxis. Fortunately, fatalities have flattened however the most robust database was the European anaphylaxis registry from 1998 – 2022 and showed that fatalities have increased 3.7 fold. This is likely similar to the increase rate they are seeing in food allergy which is one of the primary reasons for fatal anaphylaxis. When they look at epinephrine therapy there are certain barriers and hurdles that they have to overcome. The first is not carrying the epinephrine pen and the second is reluctance to administer a shot. Very often they person is trying to see if it really is warranted. He has treated multiple cases of anaphylaxis and stated that people would be surprised with the patients that are having clinical significant problems and they are trying to talk the provider out of giving them epinephrine. The third is accessibility. It has improved and it should be available for everyone but unfortunately it is not. (unintelligible) published a study of a series of 32 adolescent and adult deaths related to food allergy. Of those 32 deaths 29 or 90 percent either did not have their epinephrine with them or did not administer the epinephrine. Recent data reports that only 34 percent of adolescents age 18 and younger carry their epinephrine even knowing that they have severe or potentially fatal food allergy. What is important is the convenience of a smaller, needle free, and portable device with ease of use may help solve some of these issues and provide ease of carrying through a small carrying case, compact size. There is a decrease of reluctance to use it because it is needle free. It has an extended shelf life of 30 months and it does not have intolerance to wide temperature fluctuation, making it superior to epinephrine in that way. His point is not to suggest that nasal epinephrine is superior nor should it replace self-administered IM epinephrine but rather he recommends that the P&T committee support the addition of neffy to the medical formulary as an alternative delivery device that is safe and effective. What the company is doing right now, ARS, they are

launching this month. They have already contact them at AAFA to help distribute it. This is going to be eligible to K-12 public and private schools throughout Alaska and each of those schools will receive two 2 packs and AAFA will be involved with the training of its use. He is happy to answer any questions that anyone may have.

4. Class Review, Discussion & Vote

4-A. Respiratory/Allergy: COPD Agents (Red); Glucocorticoids, Inhaled, Single Entity & Combination (Green); Beta Agonists Bronchodilators, Long (Green); Beta Agonists Bronchodilators, Short (Green); Immunomodulators, Asthma (Blue); Epinephrine, Self-injected (Red); Intranasal Rhinitis Agents (Blue); Leukotriene Modifiers (Green); Antihistamines, Minimally-Sedating (Green)

COPD Agents (Red Class)

There was no one wishing to provide testimony.

Nina gave the presentation for COPD agents. She gave the disease class description for COPD, Chronic Obstructive Pulmonary Disease. She then also gave the GOLD Global Initiative for COPD guidelines for 2024.

In June 2024, the FDA approved Ohtuvayre, ensifentrine, a first in class selective dual inhibitor of PDE3 inhibitor and PED4 for maintenance treatment of COPD in adults. She gave the warnings, dosage, and availability for this medication.

Utilization was 95.3 percent in line with PDL.

Previous motion Dr. Ryan moved for therapeutic alternatives. Seconded by Valarie Bixler. The motion passed unanimously.

DR. RYAN MOVED FOR THERAPEUTIC ALTERNATIVES. SECONDED BY SARAH DOREN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Glucocorticoids, Inhaled, Single Entity & Combination (Green Class)

May 2024, Teva discontinued the manufacture of ArmonAir Digihaler 55 mcg, 113 mcg, and 232 mcg metered powder inhaler.

May 2024, Teva discontinued the manufacture of AirDuo Digihaler 55 mcg/14 mcg, 113 mcg/14 mcg, and 232 mcg/14 mcg metered powder inhaler.

Utilization for the single entity products was 91 percent in line with PDL.

Utilization for the combination products was 35.6 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives to include at least one from each subclass. Seconded by Sarah Doran-Atchison. Motion passed unanimously.

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

Beta Agonists Bronchodilators, Long (Green Class)

Utilization was 83.3 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives. Seconded by Sarah Doran-Atchison. The motion passed unanimously.

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

Beta Agonists Bronchodilators, Short (Green Class)

May 2024, Teva discontinued the manufacture of ProAir Digihaler 90 mcg metered powder inhaler.

Utilization was 89.4 percent in line with PDL.

Previous motion Dr. Ryan moved a class effect to include both an inhaler and a nebulized product. Seconded by Dr. Carlson. The motion passed unanimously.

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

Immunomodulators, Asthma (Blue Class)

CHRISTINE DUBAY, with AstraZeneca, presented information on Fasenra. The information she gave was provided to support the maintenance of Fasenra on the PDL. Its indicated ages was recently updated for add-on maintenance treatment for patients with severe asthma ages six or older and with an (unintelligible). It is administered by subcutaneous injection every four weeks for the first three doses then every eight weeks thereafter. The recommended dose for patients 12 and older or patients ages six to 11 that weigh 35 kg or more is 30 mg as a prefilled single dose syringe or single dose autoinjector. The recommended dose for patients age six to 11 or who weigh less than 35 kg is a 10 mg dose in a prefilled single dose syringe. Fasenra is most recently approved for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis knows as EGPA, administered by subcutaneous injection 30 mg every four weeks.

Fasenra is not indicated for other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus. She referred the panel to their prescribing information for more complete product warnings and precautions. Fasenra is the only anti-eosinophilic monoclonal antibody that binds directly to the IL receptor alpha (unintelligible). It works rapidly to deplete the eosinophils which can be a key cause of asthma. Fasenra is the only biologic for severe asthma maintenance dosed subcutaneously every eight weeks after the first three doses every four weeks. EGPA, Fasenra, is administered subcutaneously as a single 30 mg injection once every four weeks. It is the only respiratory biologic that has the two administration options, either a prefilled syringe or autoinjector and offers every eight week dosing for asthma and every four weeks for EGPA. The most common adverse effects of phase two trials for asthma (unintelligible) more than three percent incidence from Fasenra to placebo include headache, eight to six percent, pyrexia, three versus two percent, pharyngitis, five versus three percent, and hypersensitivity (unintelligible), which were equal at three percent each. In EGPA the adverse events were consistent with those reported in asthma with the exception of headache which occurred in 17 percent of Fasenra treated patients. No new adverse events for EGPA were identified. They requested the Fasenra remain on the Alaska PDL as a preferred option for patients with severe eosinophilic asthma and EGPA.

SHANNON DEBARTOLO, Amgen, gave testimony for Tezspire and asked the committee to add Tezspire to the state PDL as a preferred agent. Tezspire is a first in class human monoclonal antibody that blocks TSPL. It is approved as an add-on maintenance treatment for severe asthma in patients who are 12 and older. Tezspire is the only biologic for severe asthma with no phenotypic or biomarker restrictions. Severe asthma is a heterogeneous disease with overlapping phenotypes. In 2021, the International Severe Asthma Registry reported that severe asthma patients often exhibit multiple inflammatory phenotypes with 59 percent showing significant overlap and at risk to phenotypic biomarkers. Tezspire received breakthrough therapy designation based on the PATHWAY trial and priority review status based on the NAVIGATOR study. These studies demonstrated reductions in annualized asthma exacerbation rates as well as ER visits and hospitalizations. The most common adverse events reported during the trials were pharyngitis, arthralgia, and back pain. A post-hoc pooled analysis of NAVIGATOR and PATHWAY demonstrated annualized asthma exacerbation rate reductions for Tezspire versus placebo across asthma phenotypes and irrespective of biomarker levels. Tezspire is included on the Global Initiative for Asthma, or GINA, guidelines as an add-on therapy for patients with allergic eosinophilic and non-type II asthma not optimally controlled on maintenance therapy. Tezspire is the only biologic to consistently and significantly reduce asthma exacerbations across phase II and III clinical trials encompassing a broad population of asthma patients irrespective of key biomarkers. She asked the committee to include Tezspire on the state PDL as a preferred agent with utilization criteria aligned to its label and the GINA recommendations.

Nina then gave the presentation. She gave the disease state description for food allergies.

In February 2024, the FDA approved Xolair, for IgE-mediated food allergy in adults and pediatric patients aged one year and older for reduction of allergic reactions type II, including anaphylaxis, which may occur with accidental exposure to one or more foods, used in conjunction with food allergen avoidance. She gave the indications, limitations, warnings, dosage, and availability.

Nina then gave the presentation for the disease state description for asthma.

In 2024, the Global Initiative for Asthma stated that although most people will be able to achieve good asthma control with standard management strategies a subset of patients remain uncontrolled even when treatments are optimized. For a patient with type II inflammation a trial of non-biologic therapies is recommended as the first step in treatment with consideration of individual phenotypes. If non-biologic interventions are not effective targeted biologic treatment can be an option if available. Appropriate candidates have exacerbation and/or poor symptom control despite use of at least high dose ISC LABA therapy and should display allergic or eosinophilic biomarkers or new maintenance oral corticosteroids. There are no head to head trials directly comparing biologic agents for patients with severe asthma who are eligible for more than one product. After a biologic agent is started treatment should be given for three to four months in order to assess response. If the response is good treatment should be continued. If response is bad treatment should be stopped with consideration of a change to an alternative biologic agent. If the response is unclear a continued trial for an additional six to 12 months may be recommended.

Nina then gave the disease state description for eosinophilic granulomatosis with polyangiitis (EGPA).

In April 2024, the FDA approved Fasenra for the expanded indication to include pediatric patients ages six to 11 years old for add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype previously approved for patients 12 years and older for this indication.

In September 2024, the FDA approved Fasenra for the new indication for treatment of adults with eosinophilic granulomatosis with polyangiitis (EGPA).

The limitations, warnings, dosage, and availability for Fasenra were given.

Utilization was 65.8 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives. Seconded by Sarah Doran-Atchison. The motion passed unanimously.

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

Epinephrine, Self-Injected (Red Class)

BILL NUBEK, ARS, presented testimony for Neffy. Neffy is a 2 mg needle free intranasal epinephrine delivery option for patients 30 kg or greater with type I allergic reactions including anaphylaxis. Anaphylaxis requires immediate intervention with epinephrine however the fear of needles contributes to a 50 percent failure or delay in epinephrine delivery. Needle devices can

be risky with lacerations and accidental self-injections. Neffy eliminates these challenges with intranasal delivery of epinephrine. Rigorous FDA standards were met with both safety and efficacy studies for the approval of Neffy 2 mg. Side effects are mild and self-limiting such as throat irrigation. Neffy contains Intravail which is also the same excipient contained in Narcan. Neffy has a 30 month shelf life and reduces both delays and self-injection delivery mistakes of epinephrine treatment with improved clinical utility. They ask that Neffy is included and thanked the committee for their time.

Nina gave the presentation for Epinephrine, Self-injected. She first gave the disease state description for anaphylaxis.

In August 2024, the FDA approved Neffy which is the first nasal spray formulation of epinephrine. The indications, warnings, recommended dosage, and availability were given.

Utilization was 99.5 percent in line with PDL.

Previous motion Sarah Doran-Atchison moved the drugs in the class were therapeutic alternatives. Seconded by Dr. Phillips. The motion passed unanimously.

Dr. Ryan stated that he assumed that they were going to be looking at Neffy and seeing how it should fit into this scheme.

Charles Semling stated that they would be looking into all factors.

John Riley asked if they would say that a medication like Neffy, which is currently new and not preferred, that there would be … even though it could be prescribed as medically necessary would they say there are barriers to its availability?

Charles Semling stated that at present they do not believe that there are any barriers since it is non-reviewed and doesn't actually have a status yet. It depends on the will of the committee and other factors as to where it will be placed.

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

Intranasal Rhinitis Agents (Blue Class)

There was no one present that wished to provide testimony.

Nina gave the presentation for intranasal rhinitis. She started by giving the disease state description of chronic rhinitis.

In March 2024, the FDA approved Xhance for new indications of chronic rhinosinusitis without nasal polyps in adults. The indication, warnings, dosage, and availability were given.

Utilization was 99 percent in line with PDL.

Previous motion Sarah Doran-Atchison moved a class effect. Seconded by Dr. Phillips. The motion passed unanimously.

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

Leukotriene Modifiers (Green Class)

Utilization was 99.8 percent in line with PDL.

Previous motion Sarah Doran-Atchison moved a class effect to exclude Zileuton. Second by Dr. Phillips. The motion passed unanimously.

SARAH DORAN-ATCHISON MOVED A CLASS EFFECT TO EXCLUDE ZILEUTON. SECOND BY CASEY GOKEY. THE MOTION PASSED UNANIMOUSLY

Antihistamines, Minimally-Sedating (Green Class)

Utilization was 95.1 percent in line with PDL.

Previous motion Dr. Ryan moved a class effect to include an oral syrup or suspension for pediatric dosing. Second by Sarah Doran-Atchison. Seconded by Dr. Carlson. The motion passed unanimously.

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

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

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

CARLA MCSPADDEN, Galderma, gave testimony for nemolizumab-ilto which is the generic name for Nemluvio. Nemluvio is a new biologic in the dermatology category. It is an IL-31 receptor alpha-antagonist. It is the first drug approved that targets IL-31 which is a cytokine that is implicated in chronic itch, inflammation, skin barrier issues, and fibrosis. Galderma is asking for preferred status for Nemluvio on the PDL. It is indicated for two skin diseases. Initially it was approved in August for a rare but extremely itchy skin disease called prurigo nodularis (PN) and it was approved in December for adults and pediatric patients 12 years of age and older with moderate to severe atopic dermatitis in combination with topical corticosteroids and with calcineurin inhibitors when those don't adequately control the disease. In the trials prescription topical (unintelligible) but they could be adjusted or tapered by the HCP based on disease severity. Nemluvio has been studies in a large clinical development program for both disease

states, all primary and key secondary endpoints were statistically significant versus placebo. There were clinically significant improvements in itch and skin lesions in the PN studies and in the atopic dermatitis studies significant improvement in itch, skin lesions, and disease severity. There are a couple of post hoc analyses in both disease states where they saw statistically significant itch relief as early as 48 hours after the loading dose. As for safety it has shown a favorable safety profile including the long term extension studies that are still ongoing. AE rates were similar between Nemluvio and placebo. No box warnings or lab monitoring requirements. The full USPI is available online. It is a subcutaneous self-injectable product that requires a onetime loading dose of 60 mg for both indications and then 30 mg every four weeks. This is different than other biologics that have an additional maintenance dose every two weeks. For PN patients who weigh over 90 kg the maintenance dose is 60 mg but weight based dosing is not recommended in the larger indication atopic dermatitis. Also, in atopic dermatitis those who achieve clear or almost clear skin anytime after 16 weeks can extend their maintenance dose to every 8 weeks meaning half the number of doses and that flexibility was granted in the label based on seeing similar efficacy and safety between four and eight weeks in the maintenance phase. It has a unique mechanism of action, rapid itch relief, improved skin lesions, and it has favorable safety and extended dosing intervals every eight weeks.

DR. MELINDA TURKINGTON, UCB, gave testimony of Bimzelx. Bimzelx is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. It is now also indicated for the treatment of adult patients with active psoriatic arthritis, active non-radiographic axial spondylarthritis with objective signs of inflammation, active ankylosing spondylitis, and hidradenitis suppurative. The recommended dosing regimen for Bimzelx in psoriasis is 320 mg given as two separate 160 mg injections administered subcutaneously at week zero for a 12/16 and then every eight weeks thereafter for the patients that weigh less than or equal to 120 kg. Dosing for psoriatic arthritis, (unintelligible), and AS is 160 mg every four weeks. The caveat would be for that psoriatic arthritis patient that has clinically relevant psoriasis they would revert back to the psoriasis dosing. Dosing for HS is 320 mg every two weeks from week zero to 16 and then every four weeks. Bimzelx is available as a prefilled syringe and an autoinjector. It is a humanized immunoglobulin Igg1 monoclonal antibody with two identical antigen binding regions that selectively bind to IL-17a and IL-17f to inhibit those pro inflammatory cytokines and chemokines. Through three pivotal clinical trials on psoriasis Bimzelx demonstrated statistically significant improvement over placebo, adalimumab, ustekinumab, and through a head to head phase 3b study in psoriasis against secukinumab. There are no contraindications. Most common adverse reactions of greater than one percent are upper respiratory infections, oral candidiasis, and headache. It may increase the risk of suicidal ideation and behavior but no causal association between the treatment of Bimzelx and increased risk of SIB has been established. It may increase the risk of infections. Patients need to be evaluated for TB, liver enzymes should be tested at baseline, and periodically during the treatment. Cases of inflammatory bowel disease have also been reported in patients treated with IL-17 inhibitors. She referred them to the full prescribing information for the complete safety and efficacy profile. She included that at the end of last year they had a 2 mL syringe that has now been approved so while the psoriasis dose is two subcutaneous injections there is now the option of a singular injection for the psoriasis patients. The respectfully requested preferred status.

Nina then gave the presentation for this class. She gave the disease state description for uveitis.

She gave the 2019 American College of Rheumatology and Arthritis Foundation guidelines.

Next up she gave the disease state description for psoriasis and psoriatic arthritis as well as the American Academy of Dermatology and National Psoriasis Foundation guidelines from 2020. She gave the ACR and National Psoriasis Foundation guidelines from 2018.

The next disease state description she gave was for Juvenile idiopathic arthritis along with the ACR/Arthritis Foundation guidelines from 2019 and 2021.

The next disease state description given was for axial spondylarthritis. Nina also gave the Pan American League of Associations for Rheumatology 2023 guidelines.

The next disease state description given was for Giant cell arthritis (GCA). The 2021 joint guidelines regarding the treatment of GCA was given.

Disease state description for alopecia areata and hidradenitis suppurativa (HS) were given. The 2019 guidelines from the United States and Canada Hidradenitis Suppurativa Foundations were given.

In December 2023, the FDA approved new indication Yuflyma for treatment of non-infectious intermediate, posterior, and panuveitis in adults. Indications, warnings, dosing, and availability were given.

In March 2024, the FDA approved Tyenne as the new first approved biosimilar to Actemra with both intravenous and subcutaneous formulations. Indications, warnings, dosage, and availability were given.

In March 2024, the FDA approved an expanded indication for Spevigo, an IL-36 receptor antagonist to include pediatric patients 12 years of age and older and weighing at least 40 kg for the treatment of generalized pustular psoriasis and can now be administered subcutaneously. It was previously only indicated for flares in adults with generalized pustular psoriasis as an intravenous infusion. The indications, dosage, and availability were given.

In April 2024, the FDA approved Selarsdi as a biosimilar to Stelara. It carries all of the same indications as Stelara and those were given along with the warnings, dosage, and availability.

In May 2024, Rinvoq was updated for the indication for treatment of psoriatic arthritis and active polyarticular JIA in patients who have had an inadequate response or intolerance to one or more TNF blocker, have both been expanded to include patients 2 years of age and older and Rinvoq LQ oral solution has been approved for use in pediatric patients. It was previously approved for adults for these indications. The FDA indications, warnings, dosage, and availability were given.

In May 2024, the FDA approved the expanded indication of Otezla for the treatment of pediatric patients ages six to 17 years of age weighing at least 20 kg with moderate to severe plaque

psoriasis who are candidates for phototherapy or systemic therapy. This was previously approved for adults for this indication. Indications, dosage, and availability were given.

In June 2024, the FDA approved a new indication for Kevzara for the treatment of active polyarticular juvenile idiopathic arthritis in patients' weight 63 kg or greater. Indications, warnings, dosing, and availability were given.

In July 2024, the FDA approved Pyzchiva as an interchangeable biosimilar to Stelara. The indications, warnings, dosage, and availability were given.

In July 2024, the FDA approved Tofidence for new indications for adults with giant cell arteritis and hospitalized adults with coronavirus disease 2019 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation. Indications, warnings, dosage, and availability were given.

In July 2024, the FDA approved Leqselvi, a JAK inhibitor for the treatment of adults with severe alopecia areata. Indications, warnings, dosage, and availability were given.

In August 2024, the FDA approved Amjevita for new formulations of the following concentrations: 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL in a prefilled syringe and a 40 mg/0.8 mL in a prefilled autoinjector. Indications, warnings, dosage, and availability were given.

In September 2024, the FDA approved a new indication for Cimzia for the treatment of active polyarticular juvenile idiopathic arthritis for patients ages two years of age and older. Indications, warnings, dosage, and availability were given.

In September 2024, the FDA approved Otulfi as a biosimilar to Stelara. The indications, warnings, dosage, and availability were given.

In September 2024, the FDA approved Bimzelx for new indications for adults with active psoriatic arthritis, adults with active ankylosing spondylitis, and adults with active non-radiographic axial spondylarthritis with objective signs of inflammation. The indications, dosage, and availability were given.

In October 2024, the FDA approved Imuldosa as a biosimilar to Stelara. The indications, warnings, dosage, and availability were given.

In December 2024, the FDA approved Yesintek as a biosimilar to Stelara. The indications, warnings, dosage, and availability were given.

In December 2024, Boehringer Ingelheim discontinued adalimumab-adbm, unbranded version of Cyltezo, 40 mg/0.8 mL prefilled pen starter package for psoriasis, uveitis, and adalimumab-adbm 40 mg/0.8 mL prefilled pen starter kit package for CD, UC, and HS. All other formulations of both Cyltezo and unbranded adalimumab-adbm remain available.

Utilization was 69.5 percent in line with PDL.

Previous motion Dr. Phillips moved that the drugs in the class were therapeutic alternatives to include at least one oral preparation. Seconded by a Sarah Doran-Atchison. The motion passed unanimously.

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

Immunosuppressants, Oral (Blue Class)

There was no one wishing to give testimony.

Nina gave the presentation starting with the disease state description for organ rejection.

In May 2024, the FDA published a communication to warn health care professionals of rare risk of intrahepatic cholestasis of pregnancy (ICP) associated with the use of thiopurines. The FDA is requiring manufactures to update labeling to indicate ICP warning and pregnant patients should stop thiopurines if they develop ICP.

In August 2024, Novartis discontinued Sandimmune 100 mg/mL oral solution due to business decisions. Sandimmune oral capsules and solution for IV infusion remain available.

In December 2024, AbbVie made a business decision to permanently discontinue Gengraf oral solution 100 mg/mL. Generic remains available.

In May 2024, the FDA approved Myhibbin, a ready to use oral suspension formulation of mycophenolate mofetil indicated for the prophylaxis of organ rejection in adult and pediatric recipients 3 months of age and older of allogenic kidney, heart, or liver transplants in combination with other immunosuppressants. The warnings, including a black box warning, dosage, and availability were given.

Utilization was 87.2 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives. Seconded by Dr. Carlson. The motion passed unanimously.

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

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

Antipsoriatics, Topical (Green Class)

Utilization for the triptans was 86.5 percent in line with PDL.

Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives. Second by Trish White. The motion passed unanimously.

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

Immunomodulators, Atopic Dermatitis (Red Class)

JOE CIRINCIONE, pharmacist and health outcomes liaison with Incyte, gave testimony for Opzelura. Opzelura is approved for the topical short term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Opzelura is also approved for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older. The use of Opzelura in combination with therapeutic biologics, other JAK inhibitors, or (unintelligible) suppressants is not recommended. As for atopic dermatitis the following information is new and was not reviewed for the most recently published guidelines. After the eight week primary endpoint in Opzelura's two phase III clinical trials patients could enter into a follow up open labeled safety extension period in which patients were treating their atopic dermatitis with Opzelura as needed for 44 weeks. During this time, the safety profile remained consistent through the 44 week follow up period and no new safety signals were observed compared with the eight week vehicle control period. (Unintelligible) studied the results from an indirect number needed to treat comparison showed that Opzelura has a lower number needed to treat compared to (unintelligible) as well as dupilumab and a similar or lower number needed to treat to oral JAK inhibitors. In a real world claims analysis of Opzelura utilization results from the 12 month follow up period after the first Opzelura claim shoed patients had an average of 2.1 fills of Opzelura in 12 months. About 92 percent of biologic naive patients at baseline did not receive biologics during the 12 month follow up period and of those who had previous biologic experience at baseline 16 percent did not continue biologic therapy during the six month follow up period, and 26.4 percent did not continue biologic therapy in months seven through 12. Lastly, a post-market safety analysis of Opzelura encompassing nearly 14,000 patient years of treatment during the first year of market approval was completed. A total of 589 adverse events were identified. 99.3 percent of events were non-serious and four were considered serious however none of the serious adverse events contained sufficient information for assessment of possible relatedness to Opzelura. There are no fatal adverse events. For safety, the prescribing information for Opzelura contains the box warning for risk of serious infections, mortality, malignancy, major cardiovascular events, and thrombosis. The most common adverse events

occurring in greater than or equal to one percent of patients were nasopharyngitis, diarrhea, bronchitis, ear infection, (unintelligible) count increase, urticaria, folliculitis, tonsilitis, and rhinorrhea. In conclusion, Incyte respectfully requests that Opzelura be a preferred agent on the PDL with a single step (unintelligible) topical product for atopic dermatitis. They also respectfully request coverage for nonsegmental vitiligo (unintelligible) a label of this indication since Opzelura is the only FDA approved topical treatment for the condition.

CARLA MCSPADDEN, Galderma, said that she already testified and must have presented early. She thought she saw atopic dermatitis on the slide earlier. She apologized for presenting ahead of time.

Nina gave the presentation on immunomodulators, atopic dermatitis. She started with the disease state description for atopic dermatitis. She also gave the American Academy of Allergy and Immunology/American College of Allergy, Asthma, and Immunology (AAAI/ACAAI) joint taskforce guidelines from 2023. Nina then gave the American Academy of Dermatology guidelines from 2023.

In December 2023, the FDA approved the expanded indication of Adbry for moderate to severe atopic dermatitis to include patients ages 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. In June 2024, a new formulation of Adbry was made available for 300 mg/2mL single dose autoinjector for use in adults only. The indications, warnings, and availability were given.

In December 2023, the FDA approved the expanded indication for Zoryve for 0.3% foam to include pediatric patients ages nine years of age and older for topical treatment of seborrheic dermatitis, previously only approved for use in adults. In July 2024, the FDA approved a 0.15% cream for the topical treatment of mild to moderate atopic dermatitis in adults and pediatric patients six years of age and older. The indications, warnings, dosage, and availability were given.

In February 2024, the FDA approved expanded indications for Dupixent, for the treatment of eosinophilic esophagitis to include pediatric patients ages one year of age and older, weighing at least 15 kg. Previously this indication was only approved for adult and pediatric patients ages 12 years of age and older weighing at least 40 kg. In September 2024, the FDA approved the expanded indication for add-on maintenance treatment of inadequately controlled chronic rhinosinusitis with nasal polyps to include pediatric patients ages 12 years of age and older previously this indication was only approved in adults. In October 2024, the FDA approved new indication as an add-on maintenance treatment for adults with inadequately controlled COPD and an eosinophilic phenotype. The indications, warnings, dosage, and availability were given.

In September 2024, the FDA approved Ebglyss, an interleukin-13 antagonist indicated for the treatment of adult and pediatric patients ages 12 years of age and older who weigh at least 40 kg with moderate to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable; can be used with or without topical corticosteroids. Warnings, dosage, and availability were given.

Utilization was 96 percent in line with PDL.

Previous motion Dr. Carlson moved the drugs in the class were therapeutic alternatives to include at least one pediatric approved preparation. Seconded by Sarah Doran-Atchison. The motion passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE PEDIATRIC APPROVED PREPARATION. SECONDED BY ANNA BRECKHEISEN. THE MOTION PASSED UNANIMOUSLY.

Topical Steroids – Low, Medium, High, Very High Potency (Green Class)

In July 2024, the FDA approved the first generic to Sun's Halog 0.1% topical solution from Encube.

In August 2024, ANI has discontinued the manufacture of Pandel 1 mg/g cream due to a business decision.

Utilization for the low group was 91 percent in line with PDL.

Utilization for the medium group was 87.4 percent in line with PDL.

Utilization for the high group was 95 percent in line with PDL.

Utilization for the very high group was 93.7 percent in line with PDL.

Previous motion 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.

DR. RYAN 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 ANNA BRECKHEISEN. THE MOTION PASSED UNANIMOUSLY.

Acne, Topical (Blue Class)

There was no one who wished to give testimony.

Nina gave the presentation for acne topical. She first started with giving the disease state description for acne vulgaris. She gave the American Academy of Dermatology 2024 guidelines.

Utilization was 84.8 percent in line with PDL.

Previous motion Sarah 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. Phillips. The motion passed unanimously.

DR. RYAN 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 SARAH DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

4-D. Ophthalmics: Ophthalmic, Allergic Conjunctivitis (Green); Ophthalmic, Antibiotics (Green); Ophthalmic, Antibiotics – Steroid Combination (Green); Ophthalmic, Anti-Inflammatory (Blue); Ophthalmic, Glaucoma Agents (Blue); Ophthalmic, Immunomodulators (Green)

Ophthalmic, Allergic Conjunctivitis (Green Class)

In December 2024, Novartis announced permanent discontinuation of Alomide 1 mg/mL ophthalmic solution due to a business decision which included manufacturing concerns. Short-dated material will be available until January 2025.

Utilization was 94.1 percent in line with PDL.

Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives. Seconded by Dr. Phillips. The motion passed unanimously.

DR. RYAN MOVED THERAPEUTIC ALTERNATIVES. SECONDED BY SARAH DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Ophthalmic, Antibiotics (Green Class) and Ophthalmic, Antibiotics – Steroid Combination (Green Class)

Utilization for the antibiotics group was 99 percent in line with PDL.

Utilization for the antibiotics, steroid combination group was 92.6 percent in line with PDL.

Previous motion 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.

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 CASEY GOKEY. THE MOTION PASSED UNANIMOUSLY.

Ophthalmic, Anti-Inflammatory (Blue Class)

There was no one who wished to give testimony.

Nina gave the disease state description for ophthalmic anti-inflammatories.

In January 2024, the FDA approved the first generic to AbbVie's FML 0.1% ophthalmic drops from Amneal.

In March 2024, the FDA approved the first generic to Sun's BromSite 0.015% ophthalmic drops from Lupin.

In October 2024, Lupin launched the first generic for Pred Forte 1% ophthalmic suspension.

In March 2024, the FDA approved the corticosteroid clobetasol propionate as a 0.05% ophthalmic suspension for treatment of post operative inflammation and pain following ocular surgery. The warnings, dosage, and availability were given.

Utilization was 94.3 percent in line with PDL.

Previous motion Dr. Ryan moved that the drugs in the class were therapeutic alternatives. Seconded by Sarah Doran-Atchison. The motion passed unanimously.

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

Ophthalmic, Glaucoma Agents (Blue Class)

There was no one who wished to give testimony.

Nina gave the disease state description for glaucoma along with the American Academy of Ophthalmology guidelines from 2020.

In December 2023, the FDA approved iDose TR, a prostaglandin analog indicated for the reduction of intraocular pressure in patients with ocular hypertension or open-angle glaucoma. The warnings, dosage, and availability were given.

In July 2024, the FDA announced Novartis will permanently discontinue Betopic S ophthalmic suspension 0.25%. Discontinuation is not due to manufacturing, product quality, safety, or efficacy concerns.

Utilization was 93.5 percent in line with PDL.

Previous motion Dr. Ryan moved that 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.

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

Ophthalmic, Immunomodulators (Green Class)

Utilization was 26.8 percent in line with PDL.

Previous motion Dr. Phillips moved that the drugs in the class were therapeutic alternatives. Seconded by Dr. Ryan. The motion passed with one nay.

Charles Semling said that the utilization was so low due to the generic Restasis. Currently Restasis brand name is actually more beneficial to the state versus the generic. That is why there is a shift.

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

5. End of Public Meeting

6. Comments From Committee Members

7. Adjourn

THE NEXT MEETING WAS SCHEDULE FOR APRIL 18, 2025.