ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

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

MINUTES OF MEETING
January 19, 2018
8:00 a.m.

Committee Members Present:
Jeffrey Demain, MD, Chair
Robert Carlson, MD (telephonic)
Vincent Greear, R.Ph. (telephonic)
Jenna Hiestand, MD
Charles Ryan, MD (telephonic)
Claudia Phillips, MD (telephonic)
John Riley, PA (telephonic)
Ryan Ruggles, PharmD
Trish White, R.Ph. (telephonic)

Committee Members Absent:
Diane Liljegren, MD
Denise Evey, PharmD (excused)

Others Present:
John McCall, R.Ph., Magellan Medicaid Administration
Elaine Edwards, Magellan Medicaid Administration
Erin Narus, PharmD, State of Alaska
Colette Grower, Kron Associates

1. Call to Order – Chair

Dr. Demain called the meeting to order at 8:02 a.m. Industry comments would be taken on red and blue classes only and were limited to three minutes. John McCall has accepted another position and will be replaced by Elaine Edwards at the next meeting.

2. Roll Call

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

3. Public Comments - Local Public/Health Practitioners

There were no public comments.

4. Class Review, Discussion & Vote

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

Public Comments for Respiratory: COPD Agents (Blue Class)

Craig Peton (ph), a representative of GlaxoSmithKline, discussed the Ellipta portfolio of medications, focusing on Anora. Please refer to the full PI on www.gsksource.com for complete safety and efficacy information. According to the 2017 GOLD Guidelines for COPD, more than two-thirds of patients make at least one error using an inhalation device. All the medications in this class are long-acting, anticholinergic, LABA combinations. Several medications in the Ellipta portfolio were reviewed. Newly approved Trelegy Ellipta is the first and only single inhaler triple therapy. All these agents are delivered with one inhalation and once daily dosing via an Ellipta device. Only the Ellipta portfolio offers this continuity of dosing and device across COPD and asthma products and indications. Trelegy Ellipta was specifically approved by the FDA in 2017 as a combination of Fluticasone Furoate, Umeclidinium and Vilanterol. It is indicated for the long-term, once-daily maintenance treatment of COPD, including chronic bronchitis and emphysema, for patients who are on a fixed-dose combination of Fluticasone Furoate and Vilanterol for airflow obstruction and reducing exacerbations in whom additional treatment of airflow obstruction is desired, or for patients who are already receiving Umeclidinium and a fixed-dose combination of Fluticasone Furoate and Vilanterol. Trelegy is not indicated for relief of acute bronchospasm or the treatment of asthma. Several trials and their outcomes were reviewed.

In response to Craig Peton (ph), Erin Narus said the PDL was in the regulatory process and was waiting to be released for public comment.

Mr. McCall gave the Magellan presentation on COPD and asthma. COPD is projected to be the third leading cause of death by 2020. It is characterized by persistent respiratory symptoms and airflow limitation due to airway and/or alveolar abnormalities. Its onset is in midlife. The main risk factor for COPD is tobacco smoking, followed by environmental exposure. COPD is associated with significant concomitant chronic diseases. The GOLD Guidelines recommend long-acting anticholinergics, followed by anticholinergics combined with a beta agonist, and moving away from inhaled corticosteroids due to risk of pneumonia. Asthma symptoms can vary over time. The onset is generally early in life. It can be associated with flare-ups and factors that can trigger or worsen asthma symptoms. Other autoimmune diseases associated with asthma are eczema and nasal rhinitis. The GINA 2017 Guidelines recommend starting with a short-acting beta agonist, followed by low-dose corticosteroids, low-dose corticosteroids with a long-acting beta agonist, and finally Formoterol for maintenance and as a reliever. Inhaler delivery systems were reviewed. Utilization for both COPD and asthma agents were reviewed. At the last review, the motion was therapeutic alternatives to include at least one product from each subclass.

Dr. Demain said that since the last review, steroids have been deemphasized in the management of COPD. When they are used, they tend to be a step-three therapy and used in low doses. While there is overlap amongst asthma and COPD products, most of the products for asthma are no longer

appropriate for COPD because steroid doses are higher for asthma than COPD. Asthma and COPD Overlap Syndrome is new, and physicians must manage both disorders and maintain a fine balance. Now asthma therapies are more personalized due to the differences between phenotypes and endotypes, which are based on presentation, age of onset, exposure, and other issues. A physician may need to treat eight disorders for asthma, whereas COPD is more one-track.

The committee discussed a proposed motion. Dr. Demain said Spiriva, which was approved for asthma and COPD, was the most common long-acting muscarinic agent and should probably be included in the motion. The committee discussed possible motions that would ensure Anoro Ellipta on the PDL.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE PRODUCT FROM EACH SUBCLASS.

Dr. Demain suggested including Spiriva in the motion. Dr. Ruggles suggested a grandfather clause for patients already using Spiriva.

SECONDED BY DR. WHITE. THE MOTION PASSED UNANIMOUSLY.

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

There were no public testimonies.

Mr. McCall gave the Magellan presentation on Respiratory: Glucocorticoids, Inhaled, Single Entity. The FDA is removing the boxed warning for combination ICS/LABAs based on four trials with 40,000 asthma patients that compared LABA plus ICS to ICS monotherapy. It did not pose a greater risk for hospitalization, intubation, or mortality. Single agent LABAs remain associated with the risk of asthma-related mortality and will continue to carry the boxed warning for asthma patients. The FDA has approved the SmartTouch for the Symbicort inhaler monitoring device. Trelegy Ellipta, the first approved single-inhaler triple inhaler of Fluticasone Furoate, Umeclidinium and Vilanterol, is approved for the long-term maintenance treatment of COPD. Head-to-head trials showed superiority over dual therapy with Fluticasone Furoate and Vilanterol. The utilization for the class was reviewed. At the last review, the motion for single agent glucocorticoids was class effect to include one high-potency product, one low-to-medium product, and a Budesonide product.

Dr. Demain noted that Qvar changed their delivery device to a dry-powder delivery system called RediClick that works nicely. It has lower dosing due to the new delivery device, which provides better distribution of the topical steroid. It is in the low-potency category but achieves superior benefits in some patients due to its small particle size. Budesonide is the preferred agent for pregnancy. It is also preferred for infants with asthma and other respiratory conditions warranting steroids, because it is the only nebulized agent.

Dr. Greear said Budesonide was included in last year's motion because the committee wanted to include the Respules nebulizer, and not just the Pulmicort inhaler, on the PDL.

Dr. Demain said Fluticasone has two delivery devices, an HFA device with propellant and a dry-powder device. The HFA device is preferred for children 6 years of age and under, because the dry-

powder device is difficult for them to use. Patients do not like Flunisolide because it tastes bad and must be administered four times a day.

DR. RUGGLES MOVED A CLASS EFFECT TO INCLUDE ONE HIGH-POTENCY PRODUCT, ONE LOW- TO MEDIUM-POTENCY PRODUCT, AND A BUDESONIDE PRODUCT. SECONDED BY DR. HIESTAND. THE MOTION PASSED UNANIMOUSLY.

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

There were no public comments.

Mr. McCall gave the Magellan presentation on Respiratory: Glucocorticoids, Inhaled, Combination. The FDA is removing the boxed warning for combination ICS/LABAs. At the last review, the motion for multi-agent glucocorticoids was class effect to include one high-potency product and one low- to medium-potency product.

Dr. Demain said a new Fluticasone/Salmeterol generic was released this year called AirDuo. It comes in three different strengths, similar to Advair.

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

Respiratory: Beta Agonists Bronchodilators, Long (Green Class)

Mr. McCall gave the Magellan presentation on Respiratory: Beta Agonists Bronchodilators, Long. These agents are used for COPD. They are used in combination with an inhaled corticosteroid for asthma if an inhaled corticosteroid alone does not work. Asthma patients should never be on a LABA or long-acting beta agonist alone. At the last review, the motion was class effect.

Dr. Demain said it was important to note that this class included nebulized and dry-powder products. Utilization of the preferred products was 0 percent, possibly because the Foradil inhaler is difficult to use. Almost half of the utilization in this class was for a nebulized agent. This class is used for COPD, but not asthma unless you have a combined agent. Dr. Demain suggested considering having both a hand-held and nebulized agent on the PDL.

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

Mr. McCall noted that Foradil has been taken off the market for business-related reasons.

Respiratory: Beta Agonists Bronchodilators, Short (Green Class)

Mr. McCall gave the Magellan presentation on Respiratory: Beta Agonists Bronchodilators, Short. At the last review, the motion was class effect to include at least one Albuterol inhaled product and a nebulized solution.

DR. (UNIDENTIFIED) MOVED A CLASS EFFECT TO INCLUDE AT LEAST ONE ALBUTEROL INHALED PRODUCT AND A NEBULIZED SOLUTION. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

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

Public Comments for Allergy: Epinephrine, Self-Injected (Red Class)

There were no public comments.

Mr. McCall gave the Magellan presentation on Allergy: Epinephrine, Self-Injected. Anaphylaxis is a life-threatening allergic reaction caused by a variety of allergies. All patients at risk for anaphylaxis use self-injectable Epinephrine. Anaphylaxis has a rapid onset and multiple organ system involvement. Reactions are typically uniphasic, but about 20 percent of reactions are biphasic in nature. The second phase usually occurs after an asymptomatic period of one to eight hours but can be delayed as much as 24 hours. Utilization of the Epinephrine class was reviewed. SYMJEPI, a new agent approved by the FDA in June 2017 but not yet released, is a syringe prefilled with a standard dose of Epinephrine used for the emergency treatment of anaphylaxis. It is indicated for patients who weigh 40 kilograms or more and is injected intramuscularly or subcutaneously. At the last review, the motion was class effect to include a grandfathering clause for patients already trained on a specific device.

Dr. Demain reviewed the agents in the class. SYMJEPI is for adults only. It is called a prefilled syringe, but it is a fancy device in a case that has a plunger. Adrenaclick is the least expensive Epinephrine agent on the market and is well tolerated. With all these devices, patient education is a key component. AUVI-Q is back on the market, comes in a variety of formulations, and is very expensive.

The committee discussed SYMJEPI and the other Epinephrine agents and their delivery devices. Many of the agents include a “practice” delivery device. Patient education is a key component when prescribing Epinephrine agents. The committee also discussed why a physician would give a patient an Epinephrine agent that had to be self-injected.

In response to Dr. Greear, Dr. Narus said removing SYMJEPI from the review because it is not currently available on the marketplace would move it to next year’s review, initiating a prior authorization requirement until the PDL is updated.

The committee continued discussing Epinephrine agents and their delivery devices. Dr. Demain noted that SYMJEPI could not be used in young children and 8 percent of children have a risk of anaphylaxis. Dr. Greear noted that many of these agents are expensive and expire before the patient uses them. Dr. Demain discussed a recent study that showed EpiPens maintained 80 percent of their potency two years after their expiration date.

DR. GREEAR MOVED A CLASS EFFECT TO INCLUDE A GRANDFATHERING CLAUSE FOR PATIENTS ALREADY TRAINED ON A SPECIFIC DEVICE, AND TO TABLE THE REVIEW OF SYMJEPI UNTIL IT IS AVAILABLE ON THE MARKET. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

In response to Dr. Narus, the committee discussed the motion for Beta Agonists Bronchodilators, Short, and whether they wanted to include an oral Albuterol product as a preferred agent. The committee decided they wanted both a nebulized and an inhaled preparation, to include Albuterol. The motion did not specifically request an oral Albuterol.

Allergy: Intranasal Rhinitis Agents (Red Class)

There were no public testimonies.

Mr. McCall gave the Magellan presentation on Allergy: Intranasal Rhinitis Agents. Allergic rhinitis is the most common chronic disease in children in the United States today. It is an immunoglobin E (IgE)-mediated inflammatory response disease. Symptoms include rhinorrhea, nasal congestion, nasal itching, and sneezing. It can be seasonal or perennial with symptoms being intermittent or persistent. The American Academy of Allergy, Asthma, and Immunology and the American College of Allergy, Asthma, and Immunology Joint Task Force guidelines were reviewed. For initial treatment of patients 12 years of age or older, monotherapy with an intranasal corticosteroid is strongly recommended rather than an intranasal corticosteroid in combination with an oral antihistamine. For patients 15 years of age and older, an intranasal corticosteroid is strongly recommended over a leukotriene receptor antagonist. For treatment of moderate to severe allergic rhinitis in patients 12 years and older, the clinician may recommend the combination of an intranasal corticosteroid and an intranasal antihistamine for initial treatment as a last resort. The new product Xhance, Fluticasone Propionate, is the only corticosteroid nasal spray indicated for the treatment of nasal polyps for patients 18 years of age and older. Xhance utilizes a proprietary exhalation delivery system for Optinoise. It is delivered into the nose by actuating the pump spray into one nostril while simultaneously blowing into the mouthpiece of the device. The utilization report for intranasal rhinitis agents was reviewed. At the last review, the motion was therapeutic alternatives to include one anticholinergic, one antihistamine, and one corticosteroid.

Dr. Demain said Xhance dispensed an existing generic formulation, but through a new device that helps the medication enter the sinus ostia, so it works on intrasinus problems and not just issues with the nasal mucosa. Veramyst has been discontinued.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE ANTICHOLINERGIC, ONE ANTIHISTAMINE, AND ONE CORTICOSTEROID. SECONDED BY WHITE. THE MOTION PASSED UNANIMOUSLY.

Allergy: Leukotriene Modifiers (Green Class)

Mr. McCall gave the Magellan presentation on Allergy: Leukotriene Modifiers. Singular is dosed once daily. With Zileuton there are risks related to liver disease. At the last review, the motion was class effect to exclude Zileuton.

Dr. Demain said the Montelukast product was taken once daily with or without food. Zafirlukast is taken twice daily, 30 minutes before or two hours after a meal. Zileuton was excluded in the last review, because it has unique indications and a risk of liver toxicity. It is appropriate for very limited, specific reasons and should not be included on an open formulary.

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

Allergy: Antihistamines, Minimally-Sedating (Green Class)

Mr. McCall gave the Magellan presentation on Antihistamines, Minimally-Sedating. Utilization of the preferred products is 96 percent. Non-sedating antihistamines are commonly used for nasal rhinitis and hives. Although first-generation antihistamines are effective, second-generation antihistamines can cause less sedation and fewer anticholinergic effects. Cetirizine causes sedation in up to 14 percent of patients. Levocetirizine and Loratadine can be sedating at higher doses. Current data suggests that the least likelihood of sedation is with Fexofenadine or Desloratadine. If one agent does not work, you can switch to another agent within the class. At the last review, the motion was class effect to include an oral syrup for pediatric dosing or suspension.

In response to Dr. Greear, Erin Narus said Medicaid paid for the over-the-counter generics Claritin and Zyrtec.

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

4-C. IMMUNOLOGICAL: Cytokine & CAM Antagonists, Non-GI Indications (Red Class); Immunosuppressants, Oral (Green)

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

Mark Jensen, a representative of Pfizer, discussed Xeljanz. Xeljanz is indicated for the treatment of adult patients with rheumatoid arthritis (RA), who have had an inadequate response or intolerance to Methotrexate. It is dosed once daily as monotherapy or in combination with other nonbiologic disease-modifying antirheumatic drugs (DMARDs). As a tablet, it has no special storage requirements. As of December 14, Xeljanz is additionally indicated for the treatment of adult patients with psoriatic arthritis. The dose for psoriatic arthritis is the same as that for rheumatoid arthritis and in combination with nonbiologic DMARDs. The efficacy of Xeljanz as monotherapy has not been studied in psoriatic arthritis. There is a boxed warning for serious infections and malignancy. Patients treated with Xeljanz are at increased risk for developing serious infections that may lead to hospitalization or death. Lymphoma and other malignancies have been observed in patients treated with Xeljanz. Several studies and their outcomes were reviewed. We request that Xeljanz be included on the Alaska PDL due to its unique mechanism of action, established safety and efficacy, and availability of an oral agent.

In response to Dr. Demain, Mark Jensen said the risk of serious infection or TB with Xeljanz was similar to the other agents in the class. There is a risk of herpes zoster, which can be mitigated through vaccination or decreased when Xeljanz is used in combination with other DMARDs or corticosteroids.

Margaret Olmon, a representative of AbbVie, discussed Humira. Humira is FDA approved for use in rheumatoid arthritis (RA), reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with

moderately- to severely-active RA. It was approved in 2002. In juvenile idiopathic arthritis (JAI), it is approved for reducing the signs and symptoms of moderately- to severely-active polyarticular JAI in patients 2 years of age or older. In psoriatic arthritis (PsA), it's approved for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with active disease. It was approved in 2006 to reduce signs and symptoms of adult patients with active ankylosing spondylitis. It was approved in 2008 for plaque psoriasis in the treatment of adult patients with moderate to severe psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. It was approved two years ago in hidradenitis suppurativa (HS) and the treatment of moderate to severe HS. And in 2016, it was approved for the treatment of non-infectious intermediate, posterior, and panuveitis in adult patients. The majority of Humira utilization is in RA, Crohn's Disease and psoriasis. With longstanding safety data, 71 global clinical trials, 14 years of on-market experience, and over one million patients exposed, Humira has a well-defined, published benefit-risk database. All TNF antagonists carry similar boxed warnings regarding serious infections, TB, and malignancies. Patients starting any anti-TNF, including Humira, should be screened for TB and carefully monitored for serious events. Please see the full prescribing information at www.rxabbvie.com. We request Humira be included on the PDL due to its proven efficacy, well-established safety profile, and maintenance dosing across a wide range of indications.

Mary Kemhus, a representative of Novartis, discussed Secukonumab (Cosentyx), the only fully human IL17A antagonist approved for moderate to severe plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis. Data also supports the use of Cosentyx for the most hard-to-treat psoriatic populations. The CLARITY trial and its outcomes were reviewed. For all indications, Cosentyx has demonstrated long-term safety, efficacy and a well-tolerated safety profile with over 125,000 patients treated to date. The most common adverse events include nasopharyngitis, diarrhea, and upper respiratory tract infections. Considering comparative data, and long-term safety and efficacy across multiple indications, we request that you consider adding Cosentyx to the Alaska Medicaid PDL.

In response to Dr. Demain, Mary Kemhus said agents that act on the IL17 pathway have a slightly increased risk of candida, because IL17 is the primary mechanism that helps protect against fungal infections. Otherwise, there is not a significant difference between Cosentyx and other biologics as far as infection risk.

Chioma Ezenduka, a representative of UCB Pharma, discussed Cimzia, a recombinant, humanized anti-TNF biologic that is FDA approved for the treatment of moderately- to severely-active rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. It is also effective for extra intesticular manifestations that many with rheumatological conditions experience such as irritable bowel disease. Rheumatoid arthritis is a life-long, systemic autoimmune disease that affects women three times more frequently than men, and often in their reproductive years. Several studies and their outcomes were reviewed. Cimzia should be added as a preferred agent on the Alaska PDL, especially for women in their reproductive years or women who would like to start a family. Cimzia has a black boxed warning for increased risk of infection such as CB. For a complete list of the warnings and precautions, please refer to the Cimzia package insert.

Dan Allen, a representative of Sanofi-Aventis, discussed Kevzara. Please refer to the full prescribing information for complete prescribing guidelines. Kevzara is an interleukin-6 receptor antagonist indicated for either monotherapy or in combination with Methotrexate or other conventional DMARDs for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have

inadequate response or intolerance to one or more disease-modifying medication. Kevzara was new to the marketplace in 2017. The recommended dose is 200 milligrams once every two weeks, which can be reduced to 150 milligrams once every two weeks to help manage certain laboratory abnormalities. Common adverse and serious adverse reactions include infections, as is common with this class. Most seriously observed serious infections were pneumonia and cellulitis. Several trials and their outcomes were reviewed. Kevzara has a boxed warning for serious infections to include fungal infections such as candidiasis, bacterial, viral and other infections due to opportunistic pathogens. Other warnings and precautions include lab abnormalities. GI perforation may be increased in patients with concurrent diverticulitis or concomitant use of NSAIDs and corticosteroids. Kevzara should be avoided in patients with active hepatic disease. Avoid live vaccines during treatment with Kevzara. We would request that Kevzara be made available on the Alaska PDL for the management of moderately- to severely-active rheumatoid arthritis that has been intolerant to previously administered DMARDs.

In response to Dr. Demain, Dan Allen said the instance of neutropenia, which was an anticipated adverse event, was 9.3 to 14.4 percent across two clinical trials depending on the dosage groups, compared to 1 percent in the placebo group. Further analysis of that data did not indicate a correlation between neutropenia and severe infection. Additional information on neutropenia can be forwarded to the committee if requested.

Anthony Hagar, a representative of Bristol-Myers Squibb, discussed Orencia, which is indicated for the reduction of signs and symptoms, inducing major clinical response, inhibiting the production of structural damage, and improving physical function of moderate to severe rheumatoid arthritis as mono or combination therapy in adults. For children 6 years of age and older, Orencia is indicated for the reduction of signs and symptoms of moderate to severe polyarticular juvenile idiopathic arthritis. It should not be administered concomitantly with TNF antagonists. Its use is not recommended concurrently with other biologic RA treatments. In the last year, Orencia has added two new indications including moderately- to severely-active polyarticular juvenile idiopathic arthritis for patients 2 years of age and older, and the treatment of adult patients with active psoriatic arthritis. It may be administered as an IV or infusion or subcutaneous injection with or without nonbiologic DMARDs. It is the only T-cell co-stimulation modulator among biologic therapies for RA, which gives it a unique mechanism of action. Orencia has been shown to reduce serum levels of TNF alpha, IL-6, soluble IL-2 receptors, rheumatoid factor, and C-reactive protein. The most commonly reported adverse events included headache, upper respiratory tract infection, nasopharyngitis, and nausea. The most serious adverse events in clinical trials were serious infections and malignancies. Several trials and their outcomes were reviewed. We request that Orencia be included on the Alaska PDL.

In response to Dr. Demain, Anthony Hagar said Orencia should not be used in combination with TNF alpha antagonists. A publication from 2013 on the risk of hospitalized infection in RA patients receiving biologics was reviewed. While it is not statistically significant, Orencia trends toward less risk of severe infections.

Mr. McCall gave the Magellan presentation on Immunological: Cytokine & CAM Antagonists, Non-GI Indications. Treatment guidelines for rheumatology arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, plaque psoriasis, and psoriatic arthritis were reviewed.

The committee discussed how a physician would decide between using IV or subcutaneous formulations when both were available. Some physicians prefer weight-based agents because they allow more control over the dosing, but the outcomes of both formulations are similar.

Mr. McCall continued his presentation by reviewing treatment guidelines, new drugs in the class, utilization tables, and indications for the drugs in the class. Renflexis, a second biosimilar to Remicade, has been approved by the FDA for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, Crohn's disease, and ulcerative colitis. Golimumab for IV use has been approved for the treatment of adults with AS and PsA. Orencia has been approved for moderate to severe active polyarticular JIA in patients 2 years of age and older, and for adult psoriatic arthritis. Stelara is now approved for moderate to severe plaque psoriasis, including patients 12 to 17 years of age. Actemra is now approved for giant cell arthritis in adults. Actemra IV is now approved for patients 2 years of age and older for T cell-induced severe to life-threatening CRS. Kevzara, an IL-6 receptor antagonist, is approved for moderately- to severely-active RA. Tremfya, an IL-23 blocker, is approved for moderate to severe plaque psoriasis. Xeljanz and Xeljanz XR are now indicated for the treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to Methotrexate or other DMARDs. These drugs are related to Periodic Fever Syndrome and the IL-1 receptor. Kineret is also for rheumatoid arthritis. At the last review, the motion was therapeutic alternatives to include one formulation for pediatrics, one for arthritis, one for psoriasis, and one for inflammatory bowel disease.

In response to Dr. Greear, Mr. McCall reviewed the notes from the last review, which did not indicate that the committee had preferentially included Humira in the motion.

Dr. Claire Tan noted that Xeljanz was a good medication for patients who lived in bush Alaska. As an oral formulation, it is more stable, easier for them to take, and has better compliance.

In response to Dr. Demain, Dr. Claire Tan said she had patients who have kept their rheumatoid arthritis disease activity controlled with Xeljanz after TNF failure. Otezla, which is approved for psoriasis and not rheumatoid arthritis, has a long lifespan, but it can take four to five months before the treatment is effective.

Dr. John Boston discussed the oral formulation of Xeljanz. He felt it had been under-utilized and under-represented in how effective it is compared to TNF. Since we cannot use it as a first-line agent, we can only capture the CNF failures. Private insurance companies are starting to approve it as a first-line oral option after Methotrexate, deeming it equivalent to TNF inhibitors. In most cases, there is close to equal response in Methotrexate DMARD failures. He supported Xeljanz being a first-line agent, equivalent with the TNF inhibitor, after Methotrexate in cases where it was appropriate.

The committee discussed the Cytokine & CAM Antagonists, Non-GI Indications class. Dr. Carlson said this class encompassed a very complex matrix of diseases and medications. To have any order, we should simplify the motion and then rely on the medically necessary clause for the remainder of the cases. Dr. Demain said the biggest categories were rheumatoid arthritis, psoriasis, psoriatic arthritis, and inflammatory bowel disease. The remainder of the disease states could be handled on a patient-by-patient basis. He felt the motion should include a pediatric formulation and an oral therapy like Xeljanz. Dr. Carlson felt the oral medication could be handled through the medically necessary clause.

The committee continued discussed a possible motion. It was noted that inflammatory bowel disease would be reviewed in a different drug class.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE FORMULATION FOR PEDIATRICS, ONE FOR ARTHRITIS, ONE FOR PSORIASIS, AND AN ORAL AGENT FOR RHEUMATOID ARTHRITIS. SECONDED BY DR. GREEAR. THE MOTION PASSED UNANIMOUSLY.

Break from 10:25 a.m. to 10:40 p.m.

4-C. IMMUNOLOGICAL: Cytokine & CAM Antagonists, Non-GI Indications (Red Class); Immunosuppressants, Oral (Green) (Continued)

Immunological: Immunosuppressants, Oral (Green Class)

Mr. McCall gave the Magellan presentation on Immunological: Immunosuppressants, Oral. These drugs are also used as disease-modifying agents as well. The ultimate goal of immunosuppressant therapy after organ transplantation is to prevent rejection and prolong graft survival. The drugs in the class were reviewed. The dosage forms of brand name agents are not interchangeable. Often these drugs are used in combination. Levels vary depending on the organ transplant. At the last review, the motion was class effect.

DR. RUGGLES MOVED A CLASS EFFECT. SECONDED BY UNIDENTIFIED FEMALE. THE MOTION PASSED UNANIMOUSLY.

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

Dermatological: Antipsoriatics Topical (Green Class)

Mr. McCall gave the Magellan presentation of Dermatological: Antipsoriatics Topical. Eighty percent of patient with psoriasis have mild to moderate disease. Topical agents are indicated as a treatment of choice. Steroids are first-line therapy. Vitamin D can be monotherapy, but more often it is used as a steroid-sparing adjunctive therapy. It also enhances efficacy of the steroid. Side effects include transient skin irritation and photosensitivity. Calcitriol is less irritating and better tolerated on sensitive skin. Per the guidelines, these agents can be used with phototherapy if it is monitored. These agents can cause hypercalcemia. Avoid patients at risk. The utilization report was reviewed. At the last review, the motion was class effect.

In response to Dr. Demain, Erin Narus explained that the tendency is to prescribe generics, because the acquisition cost is less. However, branded Dovenex was less expensive due to negotiated rates. We have addressed this issue for the updated PDL.

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

Dermatological: Immunomodulators, Atopic Dermatitis (Green Class)

Mr. McCall gave the Magellan presentation of Dermatological: Immunomodulators, Atopic Dermatitis. Atopic dermatitis is a chronic inflammatory disease of the skin. It is characterized by extremely dry, itchy skin on the inside of the elbows, behind the knees, and on the face, hands, and feet. Ninety percent of patients develop atopic dermatitis before 5.5 years of age. First-line options are hydration, moisturizers, topical corticosteroids, and then calcineurin inhibitors. New agents in the class include Eucrisa and Dupixent. At the last review, the motion was therapeutic alternatives.

Dr. Demain discussed the two new drugs in the class. Dupilumab (Dupixent) is an interleukin-4 receptor alpha antagonist that diminishes IL-4 and IL-13 signaling. Its benefits are profound. Studies indicated that 50 percent of patients had complete resolution after a few doses and 85 percent had significant improvements. Atopic dermatitis can be very severe and impacts quality of life. Twenty percent of children and 10 percent of adults have atopic dermatitis. There is a spectrum of severity, just like with any other disease. Biologic agents are used for moderate to severe cases that is recalcitrant to therapy. Dupilumab would be prescribed to patients well beyond just topical therapy. Atopic dermatitis is treated much the way rheumatoid arthritis is treated. Cyclosporine is very effective, but patients only tolerate it for a time before they can develop renal and hypertension issues. Dupilumab has an incredible safety profile. Studies indicated minimal risks and side effects associated with Dupixent. It is self-administered in various dosages. It is not approved in children, but studies are ongoing for that indication. Crisaborole (Eucrisa), is a phosphodiesterase 4 (PDE4) inhibitor. It works by turning off the inflammatory response. It is a steroid-free ointment. It seems to irritate the skin a little when treatment is first initiated, but it is effective. Physicians use Eucrisa if steroids are ineffective.

In response to Dr. Hiestand, Dr. Demain said Tacrolimus was used for children, but it can sting the skin when administered. Physicians generally start with Elidel for younger children, and then transition from Elidel once the skin inflammation has calmed down.

The committee reviewed the utilization report, which indicated that two-thirds of the prescriptions were for Tacrolimus. Erin Narus noted that the generic formulation had not been available at the last review. Dr. Demain said Dupixent was a life-changing drug that should not be a first-line therapy and should have prior authorization restrictions.

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

Dermatological: Topical Steroids Low Potency (Green Class)
Dermatological: Topical Steroids Medium Potency (Green Class)
Dermatological: Topical Steroids High Potency (Green Class)
Dermatological: Topical Steroids Very High Potency (Green Class)

Mr. McCall gave the Magellan presentation on all the Dermatological: Topical Steroids. Topical steroids are used for a variety of inflammatory skin conditions. They are first-line therapy in atopic dermatitis and psoriasis. They are also used in seborrheic dermatitis. Local cutaneous side effects are more frequent than the systemic side effects. They include skin thinning, stretch marks in the armpits or groin, easy bruising, tearing of the skin, and large blood vessels. Only low-potency corticosteroids should be used in the most vulnerable areas such as the face, places where the skin is thin, or places where skin is touching other skin. The utilization reports were reviewed. At the last review, the motion was class effect within each potency group, and to include at least one ointment and one cream from each potency group.

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

Dermatological: Acne, Topical (Green Class)

Mr. McCall gave the Magellan presentation of Dermatological: Acne, Topical. According to the American Academy of Dermatology, acne is a chronic inflammatory disease with open comedones and inflammatory lesions including cysts. It is one of the most common disorders treated by dermatologists and other healthcare providers. While it most often affects adolescents, it is not uncommon for it to affect adults as well. Topical antibiotics are effective acne treatment, but they are not recommended as monotherapy because of their risk of bacterial resistance. Adding Benzoyl Peroxide helps prevent bacterial resistance. Benzoyl Peroxide or combinations with Erythromycin or Clindamycin are effective acne treatments and are recommended as monotherapy for mild acne, or in conjunction with a topical retinoid or systemic antibiotic therapy. Topical Dapsone gel is recommended for inflammatory acne, particularly in adult females with acne. Retinoids are recommended as first-line therapy, particularly for comedonal acne. Tretinoin and Adapalene are pregnancy category C, while Tazarotene is category X, and patients should be counseled on the risks associated with the use of these products. At the last review, the motion was therapeutic alternatives to include at least one drug from each subclass and at least one combination Benzoyl Peroxide and antibiotic.

In response to Dr. Demain, Erin Narus explained that BenzaClin was the branded combination product of Benzoyl Peroxide and Clindamycin. BenzaClin, the branded product, is less expensive than the generic by a significant margin. However, physicians and/or pharmacists are dispensing the generic formulation. We could do some education on this class to encourage physicians and pharmacies to dispense the preferred agent.

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

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

Ophthalmics: Ophthalmic, Allergic Conjunctivitis (Green Class)

Mr. McCall gave the Magellan presentation of Dermatological: Ophthalmic, Allergic Conjunctivitis. This class includes ophthalmic antihistamines, ophthalmic mast cell stabilizers, and ophthalmic anti-inflammatory agents. At the last review, the motion was therapeutic alternatives.

In response to Dr. Phillips, Erin Narus said the generic Patanol came out after the last review. The general trend is toward generic products. Patanol should be included on the PDL coming out shortly.

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

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

Mr. McCall gave the Magellan presentation of Dermatological: Ophthalmic, Antibiotics-Steroid Combination and Ophthalmic, Antibiotic-Steroid Combinations. Fluoroquinolones are used for variety of gram-negative/gram-positives. They are particularly useful for corneal ulcers related to contact lenses when pseudomonas is suspected. Utilization was 95 percent for the fluoroquinolones. At the last review, the motion for ophthalmic, antibiotics was class effect for each subclass. The motion for ophthalmic, antibiotics-steroid combination was therapeutic alternatives.

DR. RYAN MOVED A CLASS EFFECT FOR EACH SUBCLASS FOR THE OPHTHALMIC, ANTIBIOTICS; AND THERAPEUTIC ALTERNATIVES FOR THE OPHTHALMIC, ANTIBIOTICS-STEROID COMBINATIONS. SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.

Ophthalmics: Ophthalmic, Anti-inflammatory (Green Class)

Mr. McCall gave the Magellan presentation of Dermatological: Ophthalmic, Anti-inflammatory. The anti-inflammatories include the ophthalmic NSAIDs and the Ophthalmic anti-inflammatory steroids. The utilization report was reviewed. At the last review, the motion was therapeutic alternatives to include one drug from each subgroup.

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

Ophthalmics: Ophthalmic, Glaucoma Agents (Green Class)

Mr. McCall gave the Magellan presentation of Dermatological: Ophthalmic, Glaucoma Agents. Glaucoma is an optic (indiscernible) primarily attributed to elevated intraocular pressure. Chronic open angle is the most common. Treatment with ophthalmic agents was designed to decrease intraocular pressure by decreasing aqueous humor. There are four major subclasses in this class: prostaglandin analogs, sympathomimetics, non-selective beta-blockers, and carbonic anhydrase inhibitors. The

utilization report was reviewed. At the last review, the motion was therapeutic alternatives to include at least one drug from each subclass.

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

Ophthalmics: Ophthalmic, Immunomodulators (Green Class)

Mr. McCall gave the Magellan presentation of Dermatological: Ophthalmic, Immunomodulators. Immunomodulators are used for diseases with chronic dry eyes. The drugs in the class include Restasis and Xiidra. At the last review, the motion was therapeutic alternatives.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES.

In response to Dr. Demain, Erin Narus explained that with a motion of therapeutic alternatives there could be the possibility of getting one medication over the other. If the committee wants both medications on the PDL, then that should be reflected in the motion.

SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.

5. Review Minutes from November 2017 November Meeting

This item was not addressed.

6. Comments from Committee Members or Chair

This item was not addressed.

7. Adjourn

The meeting moved into executive session at 11:23 a.m.