ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

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

MINUTES OF MEETING
April 18, 2014
8:00 a.m.

Committee Members Present:
Marvin Bergeson, MD
Robert Carlson, MD
Robin Cooke, Pharm.D.
Jeffrey Demain, MD
Vincent Greear, R.Ph.
Jenny Love, MD
Claudia Phillips, MD
Maggie Rader, CNM
John Riley, PA-C
Greg Salard, MD
Chuck Semling, R.Ph.
Trish White, R.Ph. (telephonic)

Committee Members Absent:
Diane Liljegren, MD
John Pappenheim, MD
Jill Reid, R.Ph.

Others Present:
Julie Pritchard, Magellen Medicaid Administration
Erin Narus, State of Alaska
Chad Hope, Pharm.D.

1. Call to Order – Chair

Dr. Demain called the meeting to order at 8:02 a.m.

2. Roll Call

A quorum was present. Julie Pritchard of Magellen was welcomed back to the meeting as Erin Narus was now with the State of Alaska. Dr. Demain reviewed the rules of the meeting.

3. Public Comments - Local Public/Health Practitioners

DR. ROBERTS: The committee should consider the variability of patient needs and not just the cost of the agents for pancreatic enzymes and inhaled antibiotics. Despite the standardization, pancreatic

enzyme products differ in composition, bead size and dissolution characteristics. For example, Creon has extremely tiny beads, can be used in newborns and small infants without the risk of choking, but it does not dissolve well in formula. Zenpep dissolves well, but has bigger beads and is more challenging to use in infants. The PDL should include at least three pancreatic enzyme agents including Zenpep, Pancreaze and Creon. Inhaled antibiotics have become the cornerstone of treatment for cystic fibrosis. Tobramycin inhaled solution has been around for 15 years and is appropriate for young children, infants, and elderly patients. Older patients with cystic fibrosis, who are the primary consumers of these products, spend two to three hours a day on pulmonary therapy, which equates to one-and-a-half 40-hour weeks of missed work or school. Cost considerations should include not only the antibiotic, but also the cost of those who drop out of school, never get a good job, and remain on Medicaid forever. Due to the different characteristics, all of the currently available inhaled antibiotics should be included on the PDL.

Dr. Demain noted that the Pharmacy and Therapeutics Committee does not consider the cost of the drugs, but strives to ensure there are appropriate products available in each class. Physicians can utilize the medically necessary clause to prescribe drugs that are not included on the PDL.

Dr. Roberts said the medically necessary clause worked in the past, but since Medicaid went to the new contractor, he has been unsuccessful in getting approvals. After writing a letter, it can take one to three months to get approval for a non-preferred drug, which is an unreasonable period for a patient to wait. Therefore, the current system really does not allow physicians to prescribe whatever agents they feel are necessary for their patients.

Dr. Hope explained that the preferred and non-preferred status of an agent is an automatic point of sale edit. The DUR Committee addresses agents that require a hard prior authorization, which are much tighter and often result in a denied prior authorization request.

The committee further discussed the PDL, the medically necessary clause, and the pricing structure of the drugs on the PDL. Considering the cost of the drugs and the limited funds available, the committee has to make the best clinical and financial decision as to what to include on the PDL.

In response to Dr. Demain, Dr. Roberts felt that, as a minimum, the PDL should include Creon and Zenpep for the pancreatic enzyme agents. Although a few of the agents within the inhaled antibiotic class are equivalent, the inhaled antibiotics are not equivalent.

4. Review of Irritable Bowel Agents (Red Category)

There were no public testimonies.

Ms. Pritchard gave the Magellen presentation on Irritable Bowel Agents. Irritable bowel syndrome is a functional bowel disorder that can be chronic, relapsing, and lifelong. It is characterized by abdominal pain associated with abnormal stool frequency, abnormal stool form and passage, and bloating. It can be classified as constipation predominant, diarrhea predominant, or alternating mixed. Causes are not fully known. There are three drugs in the class. Lotronex (Alosetron) is indicated for the treatment of severe diarrhea predominant irritable bowel syndrome in women who have failed conventional therapy. Lotronex is a selective serotonin 5-HT_3 receptor antagonist and a pregnancy category B drug. Lotronex is contraindicated in severe hepatic dysfunction. No dose adjustment for renal impairment is

required. It is available as a 0.5-milligram and a 1-milligram tablet that is taken once daily, but is to be discontinued after four weeks if there is no adequate symptom control. Linzess (Linaclotide) is indicated for the treatment of chronic idiopathic constipation and irritable bowel syndrome with constipation. It is a guanylate cyclase-C agonist and a pregnancy category C drug. Linzess is available as a 145- and a 290-microgram capsule that is taken once daily. Amitiza (Lubiprostone) is indicated for the treatment of chronic idiopathic constipation, irritable bowel syndrome with constipation in females, and opioid-induced constipation in adults with chronic non-cancer pain. It activates CIC-2 chloride channels and is a pregnancy category C drug. A dose adjustment is required with hepatic impairment. No dosage adjustment is needed for renal impairment. Amitiza is available as an 8- and 24-microgram capsule that is taken twice daily. In February, there were 59 claims for irritable bowel agents. Significant changes were reviewed. In April 2013, Amitiza was granted an indication for the treatment of opioid-induced constipation in adults with chronic non-cancer pain. There was no previous discussion as this is a new class.

In response to Dr. Carlson, Ms. Pritchard said she did not know why these drugs were grouped together in a single class. However, the drugs are not classified by their mechanism of action, but for the indication of irritable bowel syndrome.

DR. CARLSON MOVED THE DRUGS IN THE CLASS WERE THERAUPEUTIC ALTERNATIVES, TO INCLUDE ONE AGENT FOR DIARRHEA AND ONE FOR CONSTIPATION. SECONDED BY DR. SALARD. THE MOTION PASSED UNANIMOUSLY.

5. Re-Review of Bladder Relaxants (Red Category)

There were no public testimonies.

Ms. Pritchard gave the Magellen presentation on Bladder Relaxants. Overactive bladder is a chronic and debilitating syndrome that is characterized by urinary urgency with or without urge incontinence, usually in combination with urinary frequency of eight or more voids per 24 hours. It occurs in 16 percent of males and 16.9 percent of females, but more females have an overactive bladder with incontinence. The drugs work predominantly on the detrusor muscle with the mechanism of action either increasing bladder capacity or depressing both voluntary and involuntary bladder contractions. The new drug in the class is Myrbetriq (Mirabegron), which is an extended release tablet approved by the FDA in late June of 2012. Myrbetriq is a urinary tract anti-spasmodic, anti-incontinence agent. It is available as a 25-milligram extended release tablet. There are no contraindications reported for Myrbetriq. Drug interactions include drugs metabolized by the CPY2D6 system. The most common adverse effects are hypertension, nasopharyngitis, urinary tract infection, and headaches. Myrbetriq is for use in adults only. In February, there were 334 claims for bladder relaxants: 121 for the preferred agents, 159 for the non-preferred agents, and 22 for Myrbetriq. Significant changes were reviewed. In September 2013, the Oxytrol transdermal patch moved from prescription to over-the-counter for the treatment of overactive bladder in women ages 18 and older. For men, the Oxytrol patch remains available only by prescription. In January 2014, Detrol LA became available as a generic. At the last review, a motion for class effect passed unanimously.

Dr. Demain noted that Detrol LA, which had the highest utilization, was now available as a generic. The pricing and availability of generic drugs, which did not always initially lower the cost of the drugs, were discussed.

Dr. Riley noted that almost half of the utilization was for long-acting agents, which required providers to use the medically necessary clause.

Dr. Hope reported that the new PDL was adopted into regulation and deployed in March. Prior to the last update, Detrol LA was a preferred agent, but is now non-preferred. The company wants utilization to shift to Toviaz for various reasons include the rebate. The medically necessary clause continues to operate as it has in the past. From a pharmacist point of view, we have done a better job managing our utilization, prior authorization, step edits, and quantity limits. A new product on the marketplace has an automatic prior authorization until it can be reviewed, which is standard in the Medicaid world, but new to Alaska.

DR. RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC EQUIVALENTS. SECONDED BY DR. GREEAR. THE MOTION PASSED UNANIMOUSLY.

6. Re-Review of Cytokine and CAM Antagonists and Related Agents (Red Category)

DR. BEPPU: A representative of Abbott discussed Humira. Please refer to the package insert for full safety and efficacy data. Humira is approved for rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, Crohn's disease, and ulcerative colitis, but is predominantly used for rheumatoid arthritis, Crohn's disease, and psoriasis. Humira is indicated in the American College of Rheumatology's treatment goals for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving the physical function of moderate to severe active rheumatoid arthritis patients. Newly published data on Humira with Methotrexate versus Methotrexate alone in early rheumatoid arthritis was reviewed. Several trials and their outcomes were reviewed. Humira has a broad benefit/risk database. The majority of the safety data came from the rheumatoid arthritis patient population. All these agents carry similar boxed warnings regarding serious infections, tuberculosis, and malignancies. As Humira has proven efficacy and a well-established safety profile as a maintenance agent across a wide range of indications, we request that it be maintained as a preferred agent on the PDL.

In response to Dr. Carlson, Dr. Beppu said open-label extensions were key for these products. Patients have these chronic diseases for many years, especially younger patients in the dermatology and gastroenterology arena. Information is continually tracked and extended data will be available in the future. Humira has been on the market since 2002. Twelve years of post-marketing data shows that the majority of patients continue to have efficacy. Antibody formation depends on a number of variables, but out data indicates that the majority of patients on combination therapy have lower percentages of antibody formation. However, the formation of antibodies differs across disease states.

DR. GROSS: A representative of Pfizer discussed Xeljanz (Tofacitinib), which was approved in November 2013. Xeljanz is a novel orally administered, small molecule approved for the treatment of moderate to severe rheumatoid arthritis in adults who have an inadequate response or intolerance to Methotrexate. Xeljanz can be administered as monotherapy or in combination with Methotrexate or other non-biologic DMARDs. It should not be used in combination with biologic DMARDs or potent immunosuppressive drugs such as Cyclosporine or Azathioprine. The recommended dose of Xeljanz is 5 milligrams, twice daily; or 5 milligrams, once, daily, for select indications. Several trials, studies and package insert updates were reviewed. The most common serious adverse events are serious infections,

lymphomas, and malignancies. Even though this is the newest drug in the category, there is five years of efficacy and safety long-term extension studies.

In response to Dr. Demain, Dr. Gross said Xeljanz was approved for moderate to severe cases of rheumatoid arthritis in adults who have an inadequate response or intolerance to Methotrexate. The risk of liver damage is comparable to the other agents in the class, long-term extension studies indicate there is no increased risk, and there are strict guidelines in the dosing recommendations for monitoring.

Ms. Pritchard gave the Magellen presentation on Cytokine and CAM Antagonists and Related Agents. Cytokines and cell adhesion molecules are chemical mediators involved in inflammatory processes throughout the body. They contribute to tissue degeneration in fibrosis associated with chronic inflammation. Drugs in this class inhibit this process. Xeljanz is on a REMS program, which includes a medication guide and communications plan to inform healthcare providers and patients about the serious risks associated with the drug. In February, there were 94 claims: 87 for the preferred agents, 7 for the non-preferred agents, and no claims for Xeljanz, the new product. Significant changes were reviewed. In January 2013, Kineret was approved for the treatment of neonatal onset multisystem inflammatory disease. In May 2013, Actemra was approved for the treatment of polyarticular juvenile idiopathic arthritis in children 2 years and older. The 2013 American Gastroenterology Association Position Statement on the treatment of Crohn's disease recommends Remicade or Humira to induce remission in patients with moderately severe Crohn's disease. In August 2013, Simponi Aria, an IV formulation of Simponi, was approved for the treatment of the rheumatoid arthritis. In September 2013, Stelara was approved, alone or in combination with Methotrexate, for the treatment of active psoriatic arthritis in adults. In October 2013, Actemra subcutaneous was approved for the treatment of rheumatoid arthritis. In October 2013, Cimzia was approved for the treatment of active psoriatic arthritis and active ankylosing spondylitis in adults. In November 2013, Simponi was approved for the treatment of moderate to severe ulcerative colitis in adults. In March 2014, an advisory was issued indicating that Xeljanz, in combination with biologic DMARDs or potent immunosuppressants, was not recommended. At the last review, a motion for therapeutic alternatives passed unanimously.

The committee discussed the grouping of this class. It was noted that there were seven different diseases and multiple medicines that were related, but very different. Ms. Pritchard explained that this class would be continually changing to provide better groupings as new drugs became available, but is currently grouped for the main indication of arthritis.

Dr. Hope discussed the differences between medical claims and pharmacy claims. A medical claim includes a diagnosis, but a pharmacy claim does not, which makes it difficult to link the pharmacy claims to the diagnoses. We could require medical diagnoses on a pharmacy claims, but that would require physicians to put a diagnosis on each prescription, pharmacists to transmit the diagnosis code, and we would have to validate each diagnosis code. Although this process is making its way into the profession, it probably will not take effect in Alaska for about five years.

In response to Dr. Semling, Dr. Hope said none of these medications required prior authorizations.

Ms. Pritchard said there were no recommended PDL changes for this class other than looking at the new product Xeljanz.

DR. CARLSON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES (INCLUDING XELJANZ). SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

7. Re-Review of COPD Agents (Red Class)

MS. BRONSON: A representative of AstraZeneca discussed Symbicort, a combination of Budesonide and Formoterol, for both the COPD Agents and Glucocorticoids, Inhaled classifications. Symbicort is indicated for the treatment of asthma in patients 12 years of age and older. AstraZeneca does not recommend the use of Symbicort in any other manner except as described in the full prescribing information. Several studies and their outcomes were reviewed in relation to asthma. Symbicort 164.5 is also approved for the twice-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and emphysema. Several studies and their outcomes were reviewed in relation to COPD. The Symbicort prescribing information contains a boxed warning stating long-acting $beta_2$ agonists such as Formoterol, one of the active ingredients in Symbicort, increased the risk of asthma-related death. The most common adverse reactions for asthma include nasopharyngitis, headache, upper respiratory tract infection, and sinusitis. The most common adverse reasons for COPD include nasopharyngitis, oral candidiasis, bronchitis, sinusitis, and upper respiratory tract infection viral. Please refer to the Symbicort PI for complete product information. We request that Symbicort be maintained on the PDL.

In response to Dr. Demain, Ms. Bronson said Symbicort was indicated for GOLD stage three and higher.

DR. FELT: A representative of GlaxoSmithKline discussed Anoro. Anoro is a combination agent with LAMA, a long-acting muscarinic agent, and LABA, a long-acting beta agonist. It contains 62.5 micrograms of Umeclidinium and 25 micrograms of Vilanterol. It comes in a new inhaler called the Ellipta. It is indicated for the long-term, once-daily maintenance treatment of airflow obstruction in patients with COPD. It is not indicated for asthma. Several clinical trials and their outcomes were reviewed. Three head-to-head comparisons that included a comparison of Anoro versus Tiotropium and their outcomes were reviewed. Anoro bears a boxed warning related to the deaths associated with long-acting beta agonist use in asthma patients. The most common adverse events were pharyngitis, sinusitis, lower respiratory tract infection, constipation, and diarrhea. Adverse events of special interest show no evidence of increased cardiac arrhythmias or any other on-treatment cardiovascular adverse events, and no evidence of increased anticholinergic effects.

Ms. Pritchard gave the Magellen presentation on COPD agents. Chronic obstructive pulmonary disease is characterized by airflow obstruction due to chronic bronchitis or emphysema. It is progressive, may be accompanied by airway hyperactivity, and may be partially reversible. Drugs in this class work to improve emptying of the lungs, reduced dynamic hyperinflation at rest and during exercise, and improved exercise performance. The drugs are used either as needed for symptom relief or scheduled to prevent symptoms. In February, there were 384 claims: 252 for the preferred agents and 151 for the non-preferred agents. The two new agents in the class are Tudorza Pressair and Anora Ellipta, with Tudorza Pressair having 4 claims. Significant changes were reviewed. Tudorza is indicated for the maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema. The breath actuated dry powder inhaler is dosed as one inhalation, twice daily, with 60 doses included in each inhaler. There is no comparative data available. As for February 2013, the

update to the GOLD Guidelines did not contain any significant changes to recommendations for drug therapy. Anora Ellipta is given as one inhalation daily. As of December 2013, there was no comparative clinical data available. At the last review, a motion for therapeutic alternatives, to include at least one long-acting, one combination, and one oral agent passed unanimously.

In response to Dr. Demain, Dr. Felt said there have been no published comparative studies between Anora Ellipta and other agents from December 2013 to January 2014.

In response to Dr. Greear, Ms. Pritchard said Daliresp (Roflumilast) had 17 claims in February and is included in the class being reviewed.

DR. GREEAR MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE AT LEAST ONE LONG-ACTING, ONE COMBINATION, AND ONE ORAL AGENT. THE MOTION WAS WITHDRAWN TO ALLOW ANOTHER TESTIMONY.

MR. WARNOCK: A representative of Boehringer-Ingelheim discussed Spiriva Handihaler and Combivent Respimat. We have previously testified about the safety and efficacy of Spiriva Handihaler. As a number of new agents are being introduced, I want to reinforce that Spiriva is still the only once-daily, long-term maintenance treatment approved by the FDA for reducing COPD exacerbation. We have also previously testified about Combivent Respimat inhalation spray is indicated for patients with COPD on a regular aerosol bronchodilator who continue to have evidence of bronchospasm and require a second bronchodilator. As the Combivent inhalation aerosol is no longer available, the new inhalation delivery system was reviewed. This device provides a substantial improvement in disposition of active drugs so that less drug is required. Adverse reactions were reviewed.

DR. GREEAR MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE AT LEAST ONE LONG-ACTING, ONE COMBINATION, AND ONE ORAL AGENT. THE MOTION PASSED UNANIMOUSLY.

8. Re-Review of Glucocorticoids, Inhaled (Red Class)

DR. FELT: A representative of GlaxoSmithKline discussed Breo Ellipta, a combination of Fluticasone Furoate and Vilanterol, an ICS LABA combination. It is indicated for the long-term, once-daily maintenance treatment of airflow obstruction in COPD and to reduce exacerbations in patients with a history of exacerbation. It is not indicated for asthma. Several exacerbation studies and their outcomes were reviewed. Several studies comparing Breo Ellipta to Advair 250/50 and their outcomes were reviewed. This product bears a similar boxed warning to that of Anoro. The most common adverse events were nasopharyngitis, upper respiratory tract infection, headache, and oral candidiasis. Two adverse events of special interest in which Brea Ellipta had a higher incident rate were pneumonia and non-traumatic fractures.

In response to questions from the committee, Dr. Felt said exacerbations were defined by any non-treatment medications such as oral steroids or similar agents, ED visits, and hospitalization. Both Breo Ellipta and Advair are GSK products. The results of all human studies are available on GSK's website. GSK attempts to submit all studies for publication, although not all are accepted by the journals.

Ms. Pritchard gave the Magellen presentation of Glucocorticoids, Inhaled. The agents in this class are used to treat asthma symptoms and have demonstrated efficacy in improving lung function, reducing symptoms, reducing frequency and severity of exacerbations, and improving quality of life. However, there is significant variability of response with inhaled corticosteroids. Add-on therapy with another class of agents is preferred over increasing the dose of these drugs. There is a relationship between the dose and prevention of severe acute exacerbation so some patients may benefit from long-term treatment with higher doses of drugs in this class. These agents can also be used as add-on therapy for those patients with COPD. In February, there 965 claims: 910 for the preferred agents and 122 for the non-preferred agents. The two additions to this class are Aerospan and Breo Ellipta. Significant changes were reviewed. The 2012 Update to the Global Initiative for Asthma and the 2013 GOLD Guidelines did not contain any significant changes to recommendations for therapy. Breo Ellipta is given as one inhalation daily. The inhaler has a dose counter and two 30-blister strips. As of July 2013, there was no comparative data available for Breo Ellipta. Aerospan is indicated for maintenance treatment of asthma in patients 6 years of age and older, and in asthma patients where adding Aerospan may reduce or eliminate the need for oral steroids. Contraindications, warnings, adverse effects, and drug interactions are similar to those for other inhaled Flunisolide formulations. Aerospan includes a built-in spacer in their delivery device. The starting dose is 160 micrograms, twice daily, in patients 12 years of age and older; and 80 micrograms, twice daily, in patients 6 to 11 years of age. As of December 2013, there was no comparative data available for Aerospan. At the last review, a motion to include one high-potency product, one low- to medium-potency product, one combination product, and nebulized Budesonide passed unanimously.

Dr. Demain noted that Budesonide was the only inhaled steroid that was category B in pregnancy.

The committee discussed Breo Ellipta's lack of indication for asthma or pediatrics. Dr. Hope said the drug classes were based on how the drugs were bid and managed. Dr. Demain said the class could be considered therapeutic alternatives, because they were used for different indications. Dr. Carlson noted that cortisone has been around since the 1950s in a variety of different forms and delivery systems, and the drugs were not significantly different.

DR. BERGESON MOVED TO INCLUDE ONE HIGH-POTENCY PRODUCT, ONE LOW- TO MEDIUM-POTENCY PRODUCT, ONE COMBINATION PRODUCT, AND NEBULIZED BUDESONIDE. SECONDED BY DR. RADER. THE MOTION PASSED UNANIMOUSLY.

9. Re-review of Antibiotics - Inhaled (Blue Class)

DR. KEMHUS: A representative of Novartis discussed TOBI Padhaler, a dry powder formulation of Tobramycin that preserves the GOLD standard efficacy of TOBI solution while decreasing treatment burden for patients. It is indicated for the management of pulmonary pseudomonas infection in patients with cystic fibrosis. It is well documented that high treatment can lead to a low adherence rate. More specifically in cystic fibrosis, these low adherence rates can be associated with an increase in loss of lung function and increased hospitalizations. Dr. Kemis demonstrated the difference between using a nebulizer versus the padhaler. In 1985, the medium predicted age that a patient would live with cystic fibrosis was 25 years of age and that has increased to 40 years of age. The patient population is now 50 percent adults who are in the workforce and trying to participate in daily activities, which can be difficult when they are dependent on nebulizers. The padhaler is more than just a convenience for

patients, but a means to allow them to more successfully participate in society and lower their treatment burden, which can increase adherence rates.

In response to several questions from the committee, Dr. Kemhus said Tobramycin is indicated for use in the TOBI Padhaler and not lightweight ultrasonic nebulizers. After discussing the cost differences between nebulizer solutions and the padhaler, Dr. Hope said the nebulizer solution, which is now off patent, was quite a bit less expensive than the padhaler. The committee discussed the availability of the padhaler, which was currently available through the specialty pharmacy network.

Ms. Pritchard gave the Magellen presentation on Antibiotics, Inhaled. Cystic fibrosis is a lethal genetic disease usually diagnosed by 6 months of age, with at least 74 percent being diagnosed by 2 years of age. It is an autosomal recessive disorder caused by mutations of the cystic fibrosis transmembrane conductace regulator gene located on chromosome number seven. Loss of functionality results in different consequences in different organs. In the lungs, it is associated with impaired mucous clearance, pathogen clearance, and chronic pulmonary infection and inflammation. The goal of these agents is to treat and prevent infections. In February, there were 2 claims: 1 for the preferred agent and 1 for the non-preferred agent. The new drugs in the class are TOBI Padhaler, generic Tobramycin solution, and Bethkis. Significant changes were reviewed. There were shortages of Cayston at the beginning of 2013, but those have been resolved. TOBI Padhaler, the new formulation of TOBI, is administered as four inhalation capsules, twice daily, via the handheld padhaler device. Bethkis, which is Tobramycin, is indicated for the management of cystic fibrosis patients with pseudomonas aeruginosa infection. Contraindications, warnings, adverse effects, and drug interactions are similar to those for other Tobramycin products. Bethkis is administered in 300 milligrams, twice daily, via a nebulizer and over a 15-minute period. It comes as a 300-milligram ampule. As of September 2013, there was no comparative data available. In November 2013, TOBI solution became available as a generic. In June 2013, the 2013 American Thoracic Society Cystic Fibrosis Pulmonary Guidelines have given Cayston the same level of recommendation as TOBI in cystic fibrosis treatments. The information on the last review could not be located.

In response to Dr. Demain, Ms. Narus said prior authorization was required for Bethkis and the TOBI Padhaler. Dr. Hope said the prior authorization requirement would not be removed after the class was reviewed as the DUR Committee dealt with prior authorization requirements. Ms. Narus reviewed the prior authorization criteria. The TOBI Padhaler is currently listed as a class one drug, which would require an individual to have failed a previous therapy prior to being approved. The interim suspend list criteria is listed on the DUR website.

Dr. Demain continued to discuss the prior authorization criteria, which differs from state to state. In Alaska, it is more appropriate to have these drugs on a prior authorization. The purpose of our process is to ensure that there is an appropriate therapeutic choice available. Although convenience is not a criterion, it should be acknowledged.

Dr. Greear said this was an expensive disease state and patient life expectancy has increased tremendously. The price of the padhaler should not be a consideration. Regardless of what is on the PDL, prior authorization is required. These patients are probably some of the most compliant patients in the medical field, which should be a consideration. Not considering the price or convenience, this class is probably therapeutic alternatives.

In response to Dr. Phillips, Dr. Roberts said this was not an agenda item on the DUR Committee's next meeting as the data is not readily available with some research being done first. The DUR Committee always looks at the cost of the drugs reviewed, as healthcare costs in the United States are a huge problem.

In response to several questions by the committee, Dr. Roberts said his clinic had about 50 cystic fibrosis patients, but there were 65 to 75 in the state of Alaska. Some patients, particularly in the southeast, go to Seattle for treatment. The cost to Medicaid includes the cost of transporting patients to Anchorage or Seattle. The requirement for in-patient care can change dramatically depending on the preferred drugs on the PDL. If patients are more compliant with their outpatient treatments, they are hospitalized less frequently. The face of the disease has changed a lot since the advent of newborn screenings. There are now patients under 12 years of age who has pseudomonas and rarely require hospitalization, but begin to be hospitalized in their teenage years. However, older patients are colonized with pseudomonas or something worse and have high rates of hospitalization.

Dr. Salard said he has not prescribed drugs for cystic fibrosis, but does prescribe medications to other Medicaid patients. The P&T Committee does not make their decisions based on cost, but the DUR Committee does. Patients have to take some responsibility for their own care and realize that Medicaid funds are limited. The drug companies that make medications that cost 10 times more than an alternative drug needs to realize that they are not going to sell much of that drug in Alaska.

Dr. Carlson thanked Dr. Roberts for his input and for being such a strong patient advocate.

Dr. Phillips agreed that the P&T Committee needed to ensure that there were appropriate drugs available. However, the issues of convenience, compliance, and cost need to be addressed by a different committee.

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

Break from 9:45 a.m. to 9:59 a.m.

10A. Re-Review of Ophthalmic Anti-Inflammatories (Blue Class)

There were no public testimonies.

Ms. Pritchard gave the Magellen presentation on Ophthalmic Anti-Inflammatories. Products in this class reduce ocular inflammation resulting from a number of events such as trauma, surgery, and infection. The drugs used include corticosteroids and NSAIDs. The topical corticosteroids exert anti-inflammatory effects by depressing edema, fibrin deposition, capillary dilation and proliferation, leukocyte migration, collagen deposition, scar formation, and fibroblastic proliferation. The effects are on the conjunctiva, sclera, cornea, lids, iris, and anterior segment of the globe. Ophthalmic NSAIDs have analgesic and anti-inflammatory activity via inhibition of cyclooxygenase enzymes. They constrict the iris sphincter without affecting intraocular pressure. In February, there were 10 claims: 9 for the preferred agents and 1 for the non-preferred agents. The new product to the class is Prolensa (Bromfenac) is indicated for the treatment of post-operative inflammation and reduction of ocular pain in patients who have undergone cataract surgery. Contraindications, warnings, adverse effects, and

drug interactions are similar to those for other ophthalmic NSAIDs. Prolensa is installed as one drop in the effected eye, once daily, beginning the day before surgery and continuing through post-op day 14. As of the spring of 2013, there were no comparative data available. At the last review, a motion for therapeutic alternatives, to include one agent from each class, passed unanimously.

In response to Dr. Demain, Ms. Pritchard said she was unsure whether Prolensa was a COX-1 or a COX-2 agent.

Dr. Hope noted that all of the ophthalmic drugs were grouped together last year, which is why the motion called for one agent from each class. For this grouping, last year's motion would be equivalent to therapeutic alternative or class effect.

DR. LOVE MOVED A CLASS EFFECT. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

In response to Dr. Demain, Ms. Pritchard said Restasis was in a separate class. The committee decided to re-review Restasis, although it was the only agent in its class.

10B. Re-Review of Anti-Inflammatory-Immunomodulators

Ms. Pritchard gave the Magellen presentation on Anti-Inflammatory-Immunomodulators. The only drug in this class is Restasis, which is used to treat keratoconjunctivitis sicca, a dry eye disease related to either decreased tear volume or rapid evaporative loss due to poor tear quality. Restasis is a cyclosporine ophthalmic emulsion. It should not be administered if patients are wearing contact lenses, and patients should wait at least 15 minutes following administration before inserting contact lenses. The drops are administered as one drop to each eye, twice daily, 12 hours apart. In February, there were 18 claims. There is no new clinically significant data. At the last review, a motion for class effect passed unanimously.

DR. RILEY MOVED A CLASS EFFECT. SECONDED BY DR. SALARD. THE MOTION PASSED UNANIMOUSLY.

11. Re-Review of Intranasal Rhinitis Agents (Blue Class)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Intranasal Rhinitis Agents. Allergic rhinitis is a constellation of symptoms characterized by sneezing; itchy eyes, nose, and palate; rhinorrhea, and nasal obstruction. It is also associated with post-nasal drip, cough, fatigue, and irritability. Drugs in this class consist of nasal corticosteroids, intranasal antihistamines, intranasal corticosteroid/antihistamine combinations, and anticholinergic. In February, there were 623 claims: 269 for the preferred agents and 299 for the non-preferred agents. Significant changes were reviewed. As of July 2013, the 2013 Diagnosis and Treatment of Respiratory Illness in Children and Adults guidelines do not distinguish between the use of corticosteroids or antihistamines or amongst products within those two designations. In the fall of 2013, Astepro received the indication for use in patients 6 years of age and older. As of March 2014, Nasacort is available as an over-the-counter product. At the last review, a motion for therapeutic alternatives, to include one from each subclass, passed unanimously.

In response to the committee, Dr. Hope explained that therapeutic alternatives and class effect have essentially the same result in relation to the bidding process and product placement. Dr. Demain explained the differences therapeutically and gave several examples. Dr. Hope said a motion of therapeutic alternatives does not guarantee there will be an agent from each subclass unless it is specifically stated in the motion.

In the future, Dr. Demain recommended reviewing the August or September utilization in this class and the ophthalmic class due to seasonal increases in allergies.

Dr. Bergeson felt the difference between therapeutic alternatives and class effect were the mechanism of action of the drugs. Class effect assumes the same mechanism of action. Therapeutic alternatives would have different mechanisms of action, but the same end result.

Dr. Demain noted that a 20 to 30 percent of the patients could not tolerate Astelin and Astepro (Azelastine) due to the bitter taste, which he further explained.

DR. CARLSON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE ONE AGENT FROM THE ANTIHISTAMINE, ANTICOLENERGIC, AND CORTICOSTEROID SUBCLASSES. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

12. Re-Review of Smoking Cessation Agents (Blue Class)

There were no public testimonies.

Ms. Pritchard gave the Magellen presentation on Smoking Cessation Agents. There are two types of pharmacologic therapies available: the nicotine replacement products and non-nicotine replacement products including agents such as Chantix and Bupropion SR tablets. In February, there were 166 claims: 100 for the preferred agents and 66 for the non-preferred agents. Significant changes were reviewed. There is no recent information of significance in this class. In the spring of 2013, it was released that there is an increased risk of certain cardiovascular adverse events in patients with existing cardiovascular disease who use Chantix or Varenicline, which was reviewed. At the last review, a motion for therapeutic alternatives passed unanimously.

Dr. Hope highlighted the utilization pattern and noted that more people tried to quit smoking around the New Year. Dr. Demain noted that some of these products were available through the Tobacco Quit Line, which has different funding. Dr. Hope said products available through the Tobacco Quit Line did not impact the utilization very much, but he did not receive data on their call volume.

Dr. Demain discussed the side effects of Prop ion such as the development of severe angioedema. Dr. Carlson said a recent paper on cardiovascular effects stated just the opposite, which shows that if you have enough small studies that are done retrospectively, you can come to any conclusions.

In response to Dr. Salard, Dr. Hope said the remaining categories have bids submitted or there are financial reasons to review the class. For example, there are no bidders for ACE inhibitors so those were not reviewed.

Dr. Bergeson said these agents have vastly different mechanisms of action. There may be patients who have strong contraindications for one agent, but not for another. Given the health effects of tobacco use versus the cost of helping someone stop using tobacco, we would be well served by having all of these agents available.

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

In response to Dr. Bergeson, Dr. Demain said there was a chance that some of the agents would not be available on the PDL with the therapeutic alternatives motion. The medically necessary clause could be utilized to prescribe any of these drugs. Dr. Hope explained that there was a six-month accumulation edit, which allows a patient to receive a six-month supply of these drugs. At the end of the six months, a prior authorization would be required for any of these products.

SECONDED BY (NOT STATED ON THE RECORD). THE MOTION PASSED UNANIMOUSLY.

13. Re-Review of Topical Androgenic Agents (Green Class)

Ms. Pritchard gave the Magellen presentation on Topical Androgenic Agents. Testosterone replacement therapy for males is used in cases of deficiency or absence of indigenous testosterone such as occurs in hypogonadism, primary or secondary, and either congenital or acquired. The drug is available topically in gel, transdermal patch, and solution formulations. In February, there were 11 claims, all for the preferred agents. Significant changes were reviewed. Effective February 2014, Abbie is discontinuing production of the Androgel 1 percent pump due to decreased utilization, but the 1 percent gel packets and 1.62 percent formulations will remain. At the last review, a motion for class effect passed unanimously.

In response to Dr. Salard, Ms. Pritchard said this class was topical formulations only and Alaska does not review the injectable formulations.

DR. SEMLING MOVED A CLASS EFFECT. SECONDED BY DR. PAPPENHEIM. THE MOTION PASSED UNANIMOUSLY.

14. Re-Review of Pancreatic Enzymes (Green Class)

Ms. Pritchard gave the Magellen presentation on Pancreatic Enzymes. The pancreas secretes enzymes necessary for digestion and neutralizes gastric acid in the duodenum to achieve the appropriate pH to maintain activity of the enzymes. These products supplement pancreatic enzymes when indigenous function is lost. This occurs in situations of cystic fibrosis, chronic pancreatitis, pancreatic tumors, and absence of all or parts of the pancreas. In February, there were 58 claims: 56 for the preferred agents and 2 for the non-preferred. The new drugs in the class are Pertzye, Ultresa, and Viokace. There is no clinically significant information for this class, other than just to note that the Pertzye capsules can be opened and it contains bicarbonate-buffered enteric-coasted microspheres. Ultresa capsules can also be opened. Viokace tablets should be swallowed whole and not crushed. Viokace is for adults only and

used in combination with a PPI. At the last review, a motion for therapeutic alternatives passed with one opposed.

In response to Dr. Demain, Dr. Hope said he was not sure why this was a green class when there were three new agents. Ms. Pritchard explained that these drugs were not new to the review packet, but they were new to Alaska since the last review of this class was in September 2012. Dr. Demain recommended postponing this item to the next meeting so information on the three new agents could be reviewed. It was noted that Dr. Roberts' comments on this class was probably based on the old PDL and not the new PDL, which includes one of these new products. Dr. Semling noted that all of these drugs had been reformulated in the last five years as well.

DR. BERGESON MOVED TO TABLE THE REVIEW OF PANCREATIC ENZYMES TO THE SEPTEMBER MEETING. SECONDED BY.

Dr. Demain requested that Dr. Roberts' review of this class be attached as a separate document in September's informational packet.

THE MOTION PASSED UNANIMOUSLY.

15. Re-Review of Ophthalmic Allergic Conjunctivitis - Antihistamines (Green Class)

Ms. Pritchard gave the Magellen presentation on Ophthalmic Allergic Conjunctivitis - Antihistamines. The drugs in this class are divided into antihistamines, mast cell stabilizers, or others. All work to relieve symptoms of conjunctivitis such as itching and redness, swelling, excessive lacrimation, and mucous discharge. The ophthalmic antihistamines may be used for allergic conjunctivitis. For persistent or frequent systems, a mast cell stabilizer may be used. Short courses of ophthalmic corticosteroids may be used to treat disease flares or severe symptoms. In February, there were 84 claims: 70 for the preferred agents and 14 for the non-preferred agents. There were no significant changes to this class. At the last review, a motion for class effect passed unanimously.

Dr. Demain said all of these agents were effective, although some are more desirable than others based on dosing and comfort levels.

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

16. Re-Review of Bronchodilators - Long-Acting Beta Agonists (Green Class)

Ms. Pritchard gave the Magellen presentation on Bronchodilators - Long-Acting Beta Agonists. Medications in this class are used to treat COPD. Some have indications for the prevention and treatment of reversible bronchospasm associated with asthma, and some have the indication of prevention of exercise-induced bronchoconstriction. REMS requirements have been discontinued. In February, there were 3 claims: 2 for the preferred agents and 1 for the non-preferred agents. There were no significant changes other than the 2012 Guidelines for Global Initiative for Asthma and the 2013 Update to the GOLD Guidelines, neither of which contain any significant changes to

recommendations for drug therapy. At the last review, a motion for class effect passed with two opposed.

The committee discussed whether Serevent should remain on the list. Dr. Demain said Serevent was used for COPD, but could be used in adults who use a separate inhaled steroid. Dr. Hope said there could be a financial advantage to keeping Serevent on the list, but there were only three claims for the long-acting agents. Clinically, good arguments could be made for not preferring any of these agents.

Dr. Demain noted that none of these agents was indicated for children, who have to use combined agents.

Dr. Greear thought the committee had placed the long-acting beta agonists on the non-preferred list in the past. Dr. Demain said prior authorization was required when the long-acting beta agonists first received a black boxed warning. At that time, people were using them as monotherapy and we wanted to block that use. Dr. Hope said these medications still required a prior authorization.

DR. PHILLIPS MOVED A CLASS EFFECT. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

17. Re-Review of Bronchodilators - Short-Acting Beta Agonists (Green Class)

Ms. Pritchard gave the Magellen presentation on Bronchodilators - Short-Acting Beta Agonists. These agents have indications for prevention and treatment, as well as relief of reversible bronchospasm. One also has the indication for use to prevent exercise-induced bronchospasm. The short-acting agents are referred to as relievers, whereas the long-acting agents are called controllers. In February, there were 2,444 claims with most of the usage being in the preferred agents. There were no new clinical significant changes. At the last review, a motion for class effect, to include at least one Albuterol agent, passed unanimously.

Dr. Demain noted that in the past when there was a motion just for class effect, Albuterol did not make the list and physicians had to rewrite all their prescriptions.

DR. GREEAR MOVED A CLASS EFFECT, TO INCLUDE AT LEAST ONE ALBUTEROL AGENT. SECONDED BY DR. BERGESON.

Dr. Demain felt the PDL should also include a solution as an inhaler. For some of these products, an opened inhaler has to be thrown away in six months or less, whereas ProAir can be used for 18 months, and some of the inhalers do not freeze.

DR. GREEAR AMENDED THE MOTION TO A CLASS EFFECT, TO INCLUDE AT LEAST ONE ALBUTEROL INHALER PRODUCT AND A NEBULIZER SOLUTION. SECONDED BY DR. BERSESON. THE MOTION PASSED UNANIMOUSLY.

18A. Re-Review of Ophthalmic Antibiotics - Quinolones (Green Class)

Ms. Pritchard gave the Magellen presentation on Ophthalmic Antibiotics - Quinolones. These agents are used to treat bacterial conjunctivitis and/or corneal ulcers in children and adults. In February, there

were 177 claims: 176 for the preferred products and 1 for the non-preferred products. Significant changes were reviewed. In October 2013, Zymaxid became available as generic Gatifloxacin. At the last review, a motion for therapeutic alternatives, to include one from each class and Erythromycin ointment, passed unanimously. However, the agents are now divided into separate classes.

In response to Dr. Demain, Dr. Hope said Medicaid had not received any letters of recommendation on any of the classes being reviewed.

In response to Dr. Riley, Ms. Pritchard said the only change was that Zymaxid became available as generic Gatifloxacin. Dr. Hope disagreed with the categorization of those being new drugs to the class.

DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

18B. Re-Review of Ophthalmic Antibiotics - Ointments (Green Class)

Ms. Pritchard gave the Magellen presentation on Ophthalmic Antibiotics - Ointment. These drugs are used to treat superficial ocular infections involving the conjunctiva or cornea, or treatment of external infections of the eye and its adnexa in patients 2 months of age and older. In February, there were 152 claims for Erythromycin ointment. There is no new clinically significant information for this class. Ilotycin is a brand-name product of Erythromycin. At the last review, a motion for therapeutic alternatives, to include one from each class and Erythromycin ointment, passed unanimously. However, the agents are now divided into separate classes.

In response to Dr. Demain, Dr. Hope said he was not aware of any past problems with Erythromycin ointment availability. Dr. Demain said there was a shortage in the hospital, and they had to go to the CDC to determine a viable alternative.

DR. RADER MOVED A CLASS EFFECT. THE MOTION PASSED UNANIMOUSLY.

18C. Re-Review of Ophthalmic Antibiotics - Macrolides (Green Class)

Ms. Pritchard gave the Magellen presentation on Ophthalmic Antibiotics - Macrolides. There are two agents in this subclass. AzaSite (Azithromycin) treats bacterial conjunctivitis in patients 1 years of age and older. Erythromycin is used to treat superficial ocular infections involving the conjunctiva or cornea, as well as ophthalmia neonatorum due to Chlamydia trachomatis and prophylaxis of ophthalmia neonatorum due to Neisseira gonorrhoeae in newborns. In February, there were 2 claims. There is no new clinically significant information for this class. At the last review, a motion for therapeutic alternatives, to include one from each class and Erythromycin ointment, passed unanimously. However, the agents are now divided into separate classes.

DR. SALARD MOVED A CLASS EFFECT. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

19. Review minutes from January 17, 2014, meeting

This item was not addressed.

20. Comments from Committee Member or Chair

This item was not addressed.

21. Adjourn

Without objection, the meeting adjourned at 10:44 a.m.