ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

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

MINUTES OF MEETING
April 29, 2016
8:00 a.m.

Committee Members Present:
Jeffrey Demain, MD, Chair
Marvin Bergeson, MD (telephonic)
Robert Carlson, MD (telephonic)
Vincent Greear, R.Ph. (telephonic)
Diane Liljegren, MD (telephonic)
Jenny Love, MD
Maggie Rader, CNM (telephonic)
John Riley, PA-C
Chuck Semling, PharmD
Ryan Ruggles, PharmD
Trish White, R.Ph. (telephonic)

Committee Members Absent:
John Pappenheim, MD (telephonic)
Claudia Phillips, MD (telephonic)
Jill Reid, R.Ph

Others Present:
John McCall, R.Ph., Magellan Medicaid Administration
Erin Narus, PharmD, State of Alaska
Rebecca Wall, PharmD
Isabel Howell, Kron Associates

1. Call to Order – Chair

Dr. Demain called the meeting to order at 8:05 a.m.

2. Roll Call

A quorum was present. Dr. Demain reviewed the rules of the meeting.

3. Public Comments - Local Public/Health Practitioners

There were no public comments.

4. Re-review of Androgenic Agents (Red Category)

There were no public comments.

Mr. McCall gave the Magellan presentation on Androgenic Agents. The agents in this class are different forms of topical testosterone for male hypogonadism caused by insufficient production of testosterone. Causes are classified as primary, due to failure of the testes, or secondary, due to failure of the hypothalamus or pituitary gland. Potential risks include osteoporosis, sexual dysfunction and cardiovascular disease. The benefits and safety of these medications have not been clearly established for the treatment of low testosterone levels due to aging. There are no apparent differences in efficacy among the products. Gel formulations of testosterone demonstrate a lower incidence of application site reactions compared to patches. All gel and solution products carry a box warning of virilization of children following secondary exposure. Testosterone patches and nasal gel do not have the box warning, but women and children are cautioned to avoid exposure to the products. Agents in this class carry an updated warning citing reports of venous thromboembolic events, including deep vein thrombosis and pulmonary embolism. New developments were reviewed. The FDA has reported a possible risk of cardiovascular disease in men taking FDA-approved testosterone products. However, the American Association of Clinical Endocrinologists issued a statement saying testosterone could be beneficial in men with cardiovascular risk factors despite recent concerns. AndroGel is now available as a generic. It is indicted for replacement therapy in males with a deficiency or absence of endogenous testosterone. Contraindications, warnings, adverse effects and drug interactions are similar to those for other topical testosterone products with the addition of nasal warnings. Natesto is applied intranasally as one pump actuation per nostril three times daily. It is metered-dose pump with each actuation delivering 5.5 milligrams of testosterone. At the last review, a motion for class effect passed unanimously.

PA-C RILEY MOVED A CLASS EFFECT. SECONDED BY DR. SEMLING. THE MOTION PASSED UNANIMOUSLY.

5. Re-review of Antibiotics, Inhaled (Red Category)

There were no public comments.

Mr. McCall gave the Magellan presentation on Antibiotics, Inhaled. Cystic Fibrosis is an autosomal recessive disorder caused by mutations of the cystic fibrosis transmembrane conductance regulator (CFTR) gene located on chromosome number seven. Loss of functionality of the CFTR protein causes impairment of chloride transport in epithelial cells, which results in different physiologic consequences in different organs. In the lungs, it is associated with impaired mucous clearance, pathogen clearance, and chronic pulmonary infection and inflammation. There are currently two FDA-approved inhaled antibiotics for the management of CF in patients with pseudomonas (P.) aeruginosa, inhaled Aztreonam and inhaled Tobramycin. The 2013 CF Pulmonary Guidelines recommend inhaled Tobramycin (Bethkis, Kitabis Pak, TOBI, TOBI Podhaler) and inhaled Aztreonam (Cayston) at the same rating to reduce exacerbation for patients who are 6 years of age and older. TOBI Podhaler is an alternative device option for self-administration of inhaled Tobramycin. It may also cause increased cough and throat irritation. Aztreonam may have cross-reactivity with other agents. Tobramycin is contraindicated in patients with known hypersensitivity to an Aminoglycoside. In patients with a known or suspected renal, auditory, vestibular or neuromuscular dysfunction, physicians must exercise

caution when prescribing Tobramycin for inhalation. New developments include the first generic for Kitabis Pak is on the marketplace. The FDA listed Kitabis as being therapeutically equivalent with TOBI. At the last review, a motion for therapeutic alternatives passed unanimously.

The committee discussed the utilization from the last three months. Mr. McCall reviewed the non-preferred claims: 60 percent were for generics and 30 percent were for Cayston (inhalation). Erin Narus discussed the tendency to prescribe generic products even when brand-name products were less expensive. After the meeting, staff will review the updates to the PDL in relation to overall utilization.

DR. (UNIDENTIFIED) MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY PA-C RILEY. THE MOTION PASSED UNANIMOUSLY.

6. Re-review of Antifungals, Topical (Red Category)

There were no public comments.

Mr. McCall gave the Magellan presentation on Antifungals, Topical. Agents in this class address varying indications and application forms vary within these specific indications. Some products combine corticosteroids with an anti-fungal for treatment when inflammation is gone. Tinea pedis, cruris and corporis are superficial fungal infections caused by three genera of dermatophytes. Since dermatophhytes require keratin to live, they are restricted to hair, nails and superficial skin. These infections are characterized by pruritus, redness and scaling. Tinea versicolor, a common superficial fungal infection, causes a distinctive change in skin pigmentation. Cutaneous candidiasis, usually caused by candida albicans, may colonize occluded areas or folds of the skin, producing infections in areas such as the groin, axillae, and inter-digital spaces. Onychomycosis is a fungal infection of the nail bed and requires a long duration of therapy. The new agents in the class, Jublia, Kerydin and Luzu, were reviewed. At the last review, a motion for class effect with considerations for several different means of application passed unanimously.

In response to Dr. Demain, Mr. McCall said “several different means of application” meant different formulations such as shampoos, solutions and creams. Erin Narus said there were various modalities and dosage forms within this class because the committee had wanted to ensure a wide variety of options be available to prescribers.

DR. (UNIDENTIFIED) MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE A SOLUTION, A SHAMPOO, AND A TOPICAL CREAM OR OINTMENT. SECONDED BY DR. (UNIDENTIFIED). THE MOTION PASSED UNANIMOUSLY.

7. Re-review of Beta-Blockers (Red Class)

There were no public comments.

Mr. McCall gave the Magellan presentation on Beta-Blockers. Beta-blockers are approved for hypertension, heart failure, angina pectoris, myocardial infarction, and cardiac arrhythmia. Beta-blockers are not recommended as first line treatment for hypertension. Bisoprolol, Metoprolol Succinate ER and Carvedilol all have clinical data to support the reduction of symptoms of heart

failure. Metoprolol Succinate ER and Carvedilol are FDA approved for heart failure. Beta-blockers appear to have similar efficacy, unstable angina and are able to improve exercise capacity and decrease frequency of angina episodes. Beta-blockers prevent recurrent ischemia, life-threatening ventricular arrhythmias, and improve survival in patients with prior MI. Sotylize is a new agent that is an oral suspension formulation. Patients must be in the hospital when they start or change the dosing of Sotylize. It is indicated for life-threatening ventricular arrhythmias and highly symptomatic atrial fibrillations/flutters. At the last review, a motion of class effect to include both Carvedilol and Metoprolol Succinate passed unanimously.

In response to PA-C Riley, Mr. McCall said any Propranolol ER that was prescribed for migraine headaches would be included in the utilization report. Erin Narus said Propranolol ER that was being used for other indications than specifically for blood pressure control might be a selective product. Staff will review and take into consideration the utilization of Propranolol ER. It was suggested that the DUR Committee review the utilization of Propranolol ER in respect to its usage versus its indications.

DR. (UNIDENTIFIED) MOVED A CLASS EFFECT TO INCLUDE BOTH CARVEDILOL AND METOPROLOL SUCCINATE. SECONDED BY DR. (UNIDENTIFIED) THE MOTION PASSED UNANIMOUSLY.

8. Re-review of Bronchodilators, Beta Agonist – Short-Acting (Red Class)

Dr. Contessa Fincher, a representative of Teva, discussed RespiClick, an Albuterol inhaler using dry powder meters. ProAir HFA is currently on the PDL. The mechanisms of action, how the medications work, and the safety and efficacy profiles are very similar in this class. RespiClick is indicated for the treatment and prevention of bronchospasm and acute bronchospasm in patients with Reversible Obstructive Airway Disease who are 12 years of age and older. It is also helpful for exercise induced bronchospasm. A demonstration of the RespiClick device was provided. RespiClick is a dry powder instead of an aerosol, which allows the medication to get into the lungs quicker.

In response to Dr. Semling, Dr. Fincher said the RespiClick device provides a higher pulmonary penetration than aerosol formulations. The device is discarded at the end of its uses. Teva developed RespiClick to decrease patient problems related to poor coordination. In addition, the inhaler is still usable if it accidentally gets wet. There is no priming or shaking required before use. The committee further discussed the dosage and administration of RespiClick.

Mr. McCall gave the Magellan presentation on Bronchodilators, Beta Agonist – Short-Acting. Short-acting $Beta_2$-agonist bronchodilators are the medications of choice for the treatment and prevention of bronchospasm associated with asthma and prophylaxis of exercise-induced bronchospasm in adults and children. They are also used in the treatment of Chronic Obstructive Pulmonary Disease (COPD). Due to its rapid onset of action, relative lack of adverse systemic effects and availability of multiple dosage forms, Albuterol remains the most commonly used short-acting beta-agonist. Levalbuterol is the R-enantiomer form of Albuterol and has similar efficacy to Albuterol inhalation solutions when given in equivalent doses. Metaproterenol has less $beta_2$ selectivity than Albuterol and is not as long acting. It is not considered first line therapy. Terbutaline only comes in an oral formulation. The 2015 Global Initiative for Asthma update states DPIs may be used to deliver SABA as an alternative to pressurized MDI and spacer during worsening asthma or exacerbations; however, the available studies

did not include patients with severe acute asthma. ProAir RespiClick is indicated for patients 12 years and older. It is contraindicated in severe hypersensitivity to milk proteins. At the last review, a motion for class effect to include at least one Albuterol inhaled product and a nebulizer solution passed unanimously.

In response to Dr. Demain, Mr. McCall said he would have to get back to the committee regarding the shelf life of the various products.

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

9. Re-review of COPD Agents (Red Class)

There were no public comments.

Erin Narus read a letter from local provider PA-C Richard Blake of the Cottonwood Creek Clinic in Wasilla, Alaska, to the Medicaid DUR Committee advocating for inclusion of Anoro Ellipta on the PDL for the treatment of COPD.

Dr. Greg Sexton, a representative of GlaxoSmithKline, discussed Incruse Ellipta, which is indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in COPD patients. (Indiscernible – poor telephone connection.) Please see the full prescribing information or visit our website at www.GSKsource.com. The delivery device was described and Dr. Demain passed one around to the committee to see. Several studies and their outcomes were reviewed. We request Incruse Ellipta be included on the PDL for the treatment of COPD.

In response to Dr. Ruggles, Dr. Sexton said if a patient activated the Ellipta, then activated it a second time, they would only receive one dose and the second activation would result in a loss of product. Pharmacists should counsel patients not to open and close the device repeatedly.

Mr. McCall gave the Magellan presentation on COPD Agents. COPD is a disease characterized by the presence of airflow obstruction due to chronic bronchitis or emphysema. COPD assessments in the 2015 and 2016 GOLD Guidelines incorporates spirometry, as well as symptoms, exacerbation/ hospitalization history, and co-morbidities to guide intervention. Inhaled bronchodilator medications continue to be central to symptom management in COPD. Long-acting inhaled bronchodilators are more effective at maintaining symptom relief than short-acting. Combining long-acting agents with anticholinergics may improve efficacy and decrease the risk of side effects compared to increasing the dose of a single bronchodilator. Inhaled steroids are not recommended as monotherapy for COPD but can be added to long-acting beta-agonists for long-acting bronchodilators. The PDE4 inhibitor Roflumilast, an oral agent, reduces inflammatory factors in COPD and is an alternative option in the high-risk patients with C and D in the GOLD Guidelines. Regular use of long-acting beta-agonists or short- or long-acting anticholinergics has been shown to improve health status. At the last review, a motion for therapeutic alternative to includes at least one long-acting, one combination and one oral product passed with one opposed.

Erin Narus reviewed two new products, Seebri Neohaler and Utibron Neohaler. Seebri Neohaler is an anticholinergic inhalation powder approved as monotherapy for the maintenance treatment of COPD. It is dosed twice daily. Utibron Neohaler is a combination product approved for the maintenance treatment of COPD. It is also dosed twice daily. There are black box warnings regarding asthma-related deaths due to its long-acting beta-agonist component, as well as a notice that the product is not indicated for the treatment of asthma. Several studies and their outcomes on both products were reviewed.

In response to Dr. Demain's comment about the wide variety of drugs available in this class, Erin Narus said the current recommendation is to move from specific drug classes to disease-based reviews, which will be developed by staff during the summer and implemented in FY17. Dr. Demain felt a disease-based review would be parallel to the current approach in health care, which is more of a personalize care system.

Dr. Demain said some COPD medications are also used in the management of asthma, but this is not the case here and these medications are specifically for COPD and not recommended for asthma.

PA-C RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE LONG-ACTING, ONE COMBINATION, AND ONE ORAL PRODUCT.

After a question of whether this motion would adhere to each of the alternative GOLD Guidelines, Dr. Demain reminded everyone that non-preferred medications could be prescribed utilizing the medically necessary clause.

SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.

10. Review of Immunomodulators, Asthma (Red Class)

Dr. Nik Seifter discussed Nucala, the first interleukin-5 antagonist monoclonal antibody for adults and adolescents ages 12 years and older. It is indicted for add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype. It is not indicated for treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus. Nucala is dosed as a 100-milligram subcutaneous injection every four weeks and no dosage adjustment is needed in any population. Several studies and their outcomes were reviewed. The most common adverse events are headaches, injection site reactions, back pain and fatigue. Hypersensitivity was reported in 2 percent of placebo patients and 1 percent of Nucala patients.

In response to Dr. Demain, Dr. Seifter said there were ongoing studies looking at the efficacy of Nucala for children ages 4 to 11. The outcomes of those studies will likely take a few years. There is no pregnancy data currently available.

In response to Dr. Contessa Fincher, Erin Narus said Teva's new product, Cinqair, would be included at the next review of Immunomodulators, Asthma, due to the timeframe in which the information was received.

Mr. McCall gave the Magellan presentation on Immunomodulators, Asthma. Xolair is FDA approved for the chronic treatment of minor or severe persistent allergic asthma in patients equal to or greater than 12 years old whose symptoms are inadequately controlled with standard asthma therapy. These patients have specific IgE antibodies to the allergens responsible for their asthma attacks. The major difference between the two drugs in the class is the mode of action. Several trials and their outcomes were reviewed. It has a black box warning regarding the risk of anaphylaxis. Patients should be closely observed for two hours after the first three injections, and 30 minutes for subsequent injections. Caution should be used in patients less than 12 years of age and greater than 65 years of age due to limited outcomes data. Xolair should not be used in the case of an acute asthma exacerbation. Nucala is a new agent for patients 12 years of age and older with severe asthma who have eosinophilic phenotype. Nucala binds to IL-5 receptors and decreases the production and survival of eosinophil and decreases inflammation. The recommended dose is 100 milligrams by subcutaneous injection in the upper arm, thigh or abdomen every four weeks and administered in a physician's office. Several trials and their outcomes were reviewed. In November 2015, there were 43 claims, 100 percent for Xolair.

Dr. Demain further reviewed the drugs in this class. These are very specialized products designed for a select group of patients with asthma, such as those on steroids, hospitalized, ER visits, or really sick patients. Both drugs significantly reduce the cost of health care and improve the quality of life. Although we do not have much experience with Mepolizumab, the literature is sound as far as improving quality of life and decreasing frequency of exacerbations, thereby dramatically decreasing overall health costs. These drugs work in very different ways. As we move into the more personalize care system, five additional drugs will be added to this class. The mechanism of action of both drugs were reviewed. Other indications are being studied at this time. Both of these drugs work and are expensive. They are limited to providers who specialize in asthma care and is not something that will be administered by a family practitioner. Dr. Demain also discussed a new intravenous solution that was recently approved, but not yet in the review materials.

Erin Narus pointed out a published report by the Institute for Clinical and Economic Review (ICER), which focused on the cost of the products compared to the additional qualities. The report can also be seen on ICER's website.

Erin Narus said this was a relatively new class that required prior authorization, although Xolair does not currently have restrictions or prior authorization requirements. Due to the specialty nature of Xolair, there is a broad range of prescribers using it and guidance from the committee would be welcome as to whether there should be restrictions added to Xolair.

The committee discussed a possible motion. It was suggested that this item be tabled to the next meeting as there were several new agents coming online for this class. The committee discussed the criteria for prescribing these drugs, which should be determined by the DUR Committee. Dr. Demain said that there was a form that physicians filled out when prescribing these agents that outlined the criteria for prescribing the drugs in this class.

PA-C RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, WITH CURRENT RESTRICTIONS, AND FORWARDING THIS CLASS TO THE DUR COMMITTEE FOR CLARIFICATION OF PRESCRIBING GUIDELINES. SECONDED BY DR. LOVE. THE MOTION PASSED UNANIMOUSLY.

Break from 9:22 a.m. to 9:32 a.m.

11. Re-review of Immunomodulators, Atopic Dermatitis (Red Class)

There were no public comments.

Mr. McCall gave the Magellan presentation on Immunomodulators, Atopic Dermatitis. Atopic dermatitis, often referred to as eczema, is a chronic, non-contagious, inflammatory disease of the skin resulting from a combination of genetic and environmental factors. Atopic dermatitis is characterized by extremely dry, itchy skin. The 2014 American Academy of Dermatology recommends liberal use of moisturizing agents. In addition, these guidelines consider topical corticosteroids the standard of care to which other treatments are compared and are effective in a majority of patients with atopic dermatitis. Elidel and Protopic are calcineurin inhibitors. They are considered second line treatment in patients who are 2 years of age and older for short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis. They inhibit cytokine production and decrease inflammation. These immunomodulating agents have been shown to reduce the extent, severity, and symptoms of atopic dermatitis. There is a black box warning for these agents for a potential cancer risk. Clinical situations in which topical calcineurin inhibitors may be preferable to topical steroids recalcitrance steroids to sensitive areas such as the face, anogenital, skin folds, and in steroid-induced atrophy. A generic formulation of Tacrolimus is now available on the marketplace. At the last review, a motion for therapeutic alternatives passed unanimously.

Dr. Demain discussed the differences in potency between Tacrolimus and Pimecrolimus. Tacrolimus is the more commonly used drug, but both are immunomodulating agents that down regulate T-cell function with skin. Pimecrolimus does not sting the skin whereas Tacrolimus does, so Tacrolimus should not be prescribed for children. Treatments utilizing these agents were reviewed. These agents, which are good for maintenance therapy, do not replace topical steroids used for acute flare ups. These agents are for patients with moderate to severe atopic dermatitis and not those with mild atopic dermatitis that is managed with emollients.

PA-C RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. SEMLING. THE MOTION PASSED UNANIMOUSLY.

12. Re-review of Intranasal Rhinitis (Red Class)

There were no public comments.

Mr. McCall gave the Magellan presentation on Intranasal Rhinitis. Allergic rhinitis is characterized by sneezing; itching of the eyes, nose, and palate; rhinorrhea; and nasal obstruction. Perennial allergic rhinitis chronic is less severe than seasonal allergic rhinitis. Vasomotor rhinitis, or irritant rhinitis, is aggravated by fumes, odors, temperature, smoke, and other irritants and can be year-round symptoms that include congestion and headache. The agents in this class consist of nasal corticosteroids, intranasal antihistamines, intranasal corticosteroids, antihistamine combinations, and anticholinergic. The choice of an agent is individually based on multiple factors. With the exception of systemic corticosteroids, intranasal corticosteroids are the most effective single agents for controlling the spectrum of allergic rhinitis syndrome according to the 2008 American Academy of Allergy, Asthma

and Immunology and 2015 American Academy of Otolaryngology-Head and Neck Surgery Guidelines. Clinical trials have shown intranasal corticosteroids are similar in efficacy. Local adverse effects such as nasal irritation and bleeding may occur. New developments include several agents are now available in generic or over-the-counter formulations. The new agent is Ticanase, a formulation of Fluticasone, and is indicated for the management of nasal symptoms of perennial non-allergic rhinitis in patients 4 years and older. At the last review, a motion for therapeutic alternatives to include one anticholinergic, one antihistamine and one corticosteroid passed unanimously.

Dr. Demain noted that an update to the American Academy of Allergy, Asthma and Immunology Guidelines state the use of topical antihistamines should be included in the step therapy prior to the utilization of topical steroids. About 20 percent of the population cannot tolerate the taste of Azelastine and its generic is associated with the t2r33 gene mutation. Olopatadine, an alternative to Azelastine, now available as a generic, is well tolerated and does not seem to affect the t2r33 gene.

DR. LOVE MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE ANTICHOLINERGIC, ONE ANTIHISTAMINE AND ONE CORTICOSTEROID. SECONDED BY PA-C RILEY. THE MOTION PASSED UNANIMOUSLY.

13. Re-review of Ophthalmics, Allergic Conjunctivitis (Red Class)

There were no public comments.

Mr. McCall gave the Magellan presentation on Ophthalmics, Allergic Conjunctivitis. Conjunctivitis may occur secondary to infectious or noninfectious stimuli. Seasonal and perennial allergic conjunctivitis are among the most common ophthalmic problems. The range of symptoms varies from itching and redness to swelling, excessive tearing, and mucous discharge. Avoidance of identified allergens is a part of comprehensive therapy for allergic conjunctivitis. The agents in this class are divided into antihistamines, mast cell stabilizers, and anti-inflammatory agents. These agents all work to relieve persistent or frequent symptoms and a mass cell stabilizer may be used. Short courses of ophthalmic corticosteroids may be used to treat disease flares or severe symptoms. Vernal keratoconjunctivitis is an unusually severe chronic condition. It is more common in children and young adults, as well as in hot, dry climates. Patients present with severe eye itching, constant tearing, eye redness, discharge, and photophobia. If left untreated, VKC can lead to permanent vision loss. Common therapies include topical antihistamines and topical mast-cell stabilizers. Topical corticosteroids are usually needed to treat acute exacerbations. Numerous comparative trials using allergic conjunctivitis agents have been conducted. The trials used one-time administration of a single dose in the eye and evaluated the effects based on a conjunctival allergen challenge model. From the results of the trials, it is difficult to declare one agent superior to another. Loteprednol is contraindicated in patients with most viral diseases of the cornea and conjunctiva. The new agent in the class is Pazeo. Several trials and their outcomes that established the efficacy of Pazeo were reviewed. At the last review, a motion for therapeutic alternatives passed unanimously.

PA-C RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RUGGLES.

In response to Dr. Demain's question regarding over-the-counter products, Erin Narus said only the OTC products specifically listed on the PDL were covered by Medicaid. There is a process whereby over-the-counter products can be paid for by Medicaid that requires issuing a statement and a regulation change. Available products have to be prescription unless they are explicitly outlined in the regulations.

THE MOTION PASSED UNANIMOUSLY.

14. Re-review of Otic Antibiotics (Red Class)

There were no public comments.

Mr. McCall gave the Magellan presentation on Otic Antibiotics. The standard treatment for acute otitis media has been the use of systemic antibiotics while topical (otic) therapy antibiotic is generally used for otitis externa. Topical antibiotics, such as Ofloxacin and Ciprofloxacin with Dexamethasone, may decrease resistance for patients that have tympanostomy tubes. Otitis externa is an acute inflammation of the external auditory canal, commonly referred to as swimmer's ear, which can be problematic for everyone. The February 2014 guidelines of The American Academy of Otolaryngology-Head and Neck Surgery Foundation recommend topical agents as initial therapy of diffuse, uncomplicated acute otitis externa. Fluoroquinolones and the combination product of Neomycin, Polymyxin B, and Hydrocortisone are indicated to treat acute otitis externa. However, caution must be used to watch for a hypersensitivity reaction to the Neomycin and ototoxicity from the Aminoglycoside. Fluoroquinolones are not ototoxic. Chronic suppurative otitis media is defined as a perforated tympanic membrane with persistent drainage from the middle ear and initiated by an episode of acute infection. It responds more frequently to topical than to systemic therapy. If the tympanic membrane is perforated, Neomycin should be avoided due to ototoxicity and a sterile product should be chosen. Ciprodex Otic and Floxin Otic are both sterile products. Cipro HC Otic is a non-sterile product. A systematic review of the evidence regarding the development of antibiotic resistance with ototopicals indicates that antibiotic resistance is rare, although in none of the studies was resistance the main study question. Safety and efficacy of otic Quinolones is well documented. These agents are within pregnancy category C. The new agent is Otiprio, a Ciprofloxacin otic suspension, indicated for treatment of pediatric patients with bilateral otitis media within a physician's office. At the last review, a motion for therapeutic alternatives passed unanimously.

Dr. Demain discussed problems with Neomycin and suggested the motion, if class effect or therapeutic alternatives, include at least one preparation that is not Neomycin.

PA-C RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE AGENT IN ADDITION TO A NEOMYCIN PREPARATION. SECONDED BY DR. LOVE. THE MOTION PASSED UNANIMOUSLY.

15. Re-review of Antihistamines, Minimally Sedating (on step edit) (Green Class)

Mr. McCall gave the Magellan presentation on Antihistamines, Minimally Sedating. Although first generation antihistamines are clinically effective, the rationale for using second generation antihistamines is that they control allergic rhinitis symptoms with less sedation and fewer anticholinergic effects. All agents in the category have similar efficacy, although current data suggest

the least likelihood of sedation is with Allegra or Clarinex. At the last review, a motion for class effect to include at least one syrup passed unanimously.

Erin Narus noted that there were over-the-counter products included in the state plan for this particular class of agents.

The committee discussed the availability of a combination with Pseudoephedrine and noted that there were still restrictions on Pseudoephedrine products.

DR. RUGGLES MOVED A CLASS EFFECT TO INCLUDE AT LEAST ONE SYRUP. SECONDED BY PA-C RILEY.

The committee discussed the intent of the motion. For clarification, the intent is to include an oral preparation, a suspension solution or an oral syrup, for pediatric dosing.

THE MOTION PASSED UNANIMOUSLY.

16. Re-review of Antivirals, Influenza (Green Class)

Mr. McCall gave the Magellan presentation on Antivirals, Influenza. Influenza is most often self-limiting; however, very young, older, or immunocompromised patients are predisposed to secondary complications with potential fatalities. Symptoms include abrupt onset of fever, myalgia and headache. Children may also experience otitis media, nausea, and vomiting. Influenza vaccination is the primary method for preventing influenza. The CDC currently does not recommend the use of Amantadine or Rimantadine for the treatment or prophylaxis of influenza A due to viral resistance. The CDC recommends treatment of influenza in hospitalized patients, patients with severe, complicated, or progressive illness, or patients at higher risk to use either Tamiflu or Relenza within 48 hours. There are no double blind controlled studies comparing these products. At the last review, a motion for therapeutic alternatives passed unanimously.

In response to Dr. Demain, Mr. McCall said Rimantadine was for influenza A, Relenza and Tamiflu was for influenza A and B. Dr. Demain said physicians rarely knew what type of influenza they were treating but based prescriptions on the symptoms so it was important to have products that treated both influenza A and B. Patients with asthma are not supposed to use Relenza or inhalation products.

DR. LOVE MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE TAMIFLU. SECONDED BY PA-C RILEY. THE MOTION PASSED UNANIMOUSLY.

17. Re-review of Bronchodilators, Beta Agonists – Long-Acting (Green Class)

In response to Dr. Demain, Erin Narus said this class could be tabled as it should have been a red class since there were new combination agents available. With the current process, there are sometimes fragmented groupings, which is why we will be moving to a disease state model in the future. After discussion, it was decided the committee would review the class as presented and then re-review it when the committee started considering the PDL based on a disease state model.

Mr. McCall gave the Magellan presentation on Bronchodilators, Beta Agonists – Long-Acting. In 2006, the FDA requested that manufacturers of the long-acting beta$_2$-agonists (LABAs), Salmeterol and Formoterol, update their product labeling to alert health care professional about the increased risk of severe asthma episodes and death when those episodes occur. The FDA considered this a class effect. LABA-containing products that entered the market since then all have the same warnings in the labeling. LABAs do not appear to influence airway inflammation in asthma. In 2010, the FDA issued guidelines on the safe use of LABAs. The use of LABAs without the use of an asthma controller medication, such as an inhaled corticosteroid, is contraindicated. They should be used for the shortest duration of time required to achieve control of asthma symptoms and then discontinued once asthma control is achieved. Patients should then be maintained on an asthma controller medication. Adolescent patients who require the addition of LABAs to an ICS should use a combination product containing both to ensure compliance with both medications. They should not be used in patients who are acutely deteriorating with COPD or for acute symptoms. LABA in COPD was discussed. Bronchodilator medications are central to the symptomatic management of COPD. The 2015 GOLD guidelines state that beta$_2$-agonist bronchodilators are among the principal treatments for symptomatic management of COPD. At the last review, a motion for class effect passed unanimously.

Erin Narus said she reviewed the April 17, 2015 meeting minutes and Striverdi had been reviewed so this would be a green class.

Dr. Demain discussed the utilization of long-acting bronchodilators in COPD as opposed to a combination with inhaled steroids. Inhaled steroids have been associated with an increased risk of pulmonary infection and pneumonia in COPD patients. When patients have overlapping asthma and COPD, using a lower dose of inhaled steroids is appropriate. This treatment is not recommended for children and is not preferred in adults. If using a long-acting bronchodilator in asthma, it should be used in combination with other agents. There are studies that suggest using long-acting bronchodilators in patients with asthma may increase the risk of fatalities.

DR. SEMLING MOVED A CLASS EFFECT. SECONDED BY PA-C RILEY. THE MOTION PASSED UNANIMOUSLY.

18. Re-review of Epinephrine, Self-Injected (Green Class)

Mr. McCall gave the Magellan presentation on Epinephrine, Self-Injected. Anaphylaxis is an acute, life-threatening medical emergency with many potential triggers. It has a rapid onset with multiple organ-system involvement and is primarily seen in sensitized individuals after exposure to specific antigens. Reactions typically follow a uniphasic pattern; however, about 20 percent of reactions will be biphasic in nature. The second phase usually occurs after an asymptomatic period of one to eight hours with as much as a 24-hour delay. Auvi-Q, an epinephrine auto injector, approved in 2012 was recalled in October 2015 due to potentially inaccurate dosage delivery. Although epinephrine has a rapid onset of action, it is also quickly metabolized. Therefore, repeat dosing may be necessary if anaphylactic symptoms do not fully resolve in five to 15 minutes. More than two sequential doses of epinephrine should only be administered under direct medical supervision. There are no comparative trials for the self-injector products. At the last review, a motion for class effect to include a grandfathering clause passed unanimously.

Dr. Demain said Adrenaclick was a little more cumbersome to use than the Epi Pen, which is the most recognized product. It is critical that patients be instructed on the use of these devices. A recent study indicates that when used in infants or young children, 60 percent of the time the needle hits the bone if it is administered in the upper portion of the outer thigh. The recommendation is to grab and pull the muscle up before injecting. There is also concern about obese people not reaching the muscle, which is currently being addressed. The grandfathering clause is so patients will not be switched from one product to another so they recognize how to use their injectors.

DR. RUGGLES MOVED A CLASS EFFECT TO INCLUDE THE GRANDFATHERING CLAUSE. SECONDED BY DR. LOVE. THE MOTION PASSED UNANIMOUSLY.

19. Re-review of Fluoroquinolones, Oral (Green Class)

Mr. McCall gave the Magellan presentation on Fluoroquinolones, Oral. Fluoroquinolones effectively treat urinary tract infections and CAP. Their culture and sensitivity information should guide antibiotic selection when available. Little evidence exists suggesting clinical outcomes, safety, and tolerability differ among the Fluoroquinolones when administered for appropriate indications. For pediatric use, in initial studies of Fluoroquinolones, bone and joint abnormalities (osteochondrosis) were seen in young dogs. Permanent damage to cartilage in weight-bearing joints was concerning. Adverse effects in tendons have been reported. The labeling for all oral Fluoroquinolones now includes a box warning regarding the increased risk of tendonitis and tendon rupture in all ages. The risk is further increased in older patients over 60 years of age, in patients taking corticosteroid drugs, and in patients with kidney, heart, or lung transplants. This adverse effect most frequently involves the Achilles tendon, and rupture of the Achilles tendon may require surgical repair. It is renally adjusted. At the last review, a motion for class effect to include at least one second and third generation formulation passed unanimously.

DR. SEMLING MOVED A CLASS EFFECT. SECONDED BY PA-C RILEY. THE MOTION PASSED UNANIMOUSLY.

20. Re-review of Glucocorticoids, Inhaled (Green Class)

Mr. McCall gave the Magellan presentation on Glucocorticoids, Inhaled. Asthma studies have demonstrated the efficacy of inhaled corticosteroids (ICS) in improving lung function, reducing symptoms, reducing frequency and severity of exacerbations, and improving the quality of life (QoL) of patients with asthma. The 2015 Global Initiative for Asthma (GINA) state that inhaled glucocorticoids are currently the most effective anti-inflammatory medications for the treatment of persistent asthma. For COPD, bronchodilator therapy is central to symptom management in COPD and the inhaled route is preferred. The GOLD guidelines recommend the addition of an inhaled steroid to long-acting bronchodilator therapy, if necessary, for patients with severe to very severe COPD. When choosing a product, equivalent dosages and efficacy among all inhaled corticosteroids are similar. There are differences among the agents in dosage frequency and the number of inhalations needed for each dose. Combination products are also available and are used in both COPD and asthma. At the last review, a motion for one high potency, one low to medium potency, and a nebulized Budesonide passed unanimously.

PA-C RILEY MOVED FOR ONE HIGH POTENCY, ONE LOW TO MEDIUM POTENCY, AND A NEBULIZED BUDESONIDE PRODUCT. SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.

21. Re-review of Hypoglycemics, Alpha-Glucosidase Inhibitors (Green Class)

Mr. McCall gave the Magellan presentation of Hypoglycemics, Alpha-Glucosidase Inhibitors. This class has not been reviewed for a while and there is very little usage. These agents prevent the breakdown of sucrose and complex carbohydrates in the small intestine, thereby prolonging the absorption of carbohydrates and glucose. The net effect is a reduction in postprandial glucose concentrations while fasting glucose levels are relatively unchanged. Alpha glucosidase inhibitors only have a modest effect on lowering HbA1c by about 0.4 to 0.7 percent. There is no independent risk of hypoglycemia. Side effects include bloating, flatulence, and diarrhea. At the last review, a motion for class effect passed unanimously.

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

22. Re-review of Hypoglycemics, Meglitinides (Green Class)

Mr. McCall gave the Magellan presentation on Hypoglycemics, Meglitinides. Meglitinides are non-sulfonylurea hypoglycemic agents used in the management of type 2 diabetes mellitus. These agents lower blood glucose levels by stimulating the release of insulin from the pancreas; therefore, they are dependent on functioning beta calls. Nateglinide and Repaglinide are contraindicated in type 1 diabetic patients, patients with diabetic ketoacidosis, and patients with a known hypersensitivity to the drug or its inactive ingredient. Drug reactions are an issue with this class. At the last review, a motion for class effect passed unanimously.

DR. RUGGLES MOVED A CLASS EFFECT. SECONDED BY DR. LOVE.

The committee discussed compliance issues with the drugs in this class. Both agents are approved, but they are being used in reverse. Erin Narus said the brand/generic issues prompted a reevaluation of the class. In a situation like this, there are times when the current status is inconsistent with the actual pricing. We look at what the outcomes pricing would be, look at the prescribers and do a targeted-outreach to those prescribers.

THE MOTION PASSED UNANIMOUSLY.

23. Re-review of Leukotriene Modifiers (Green Class)

Mr. McCall gave the Magellan presentation on Leukotriene Modifiers. The GINA guidelines recommend inhaled corticosteroids as the cornerstone for the treatment of asthma, while leukotriene modifiers are included as potential alternatives or add-on therapy. Leukotriene modifiers are used as add-on therapy in patients receiving inhaled corticosteroids to reduce the dose of the inhaled corticosteroids in patients with moderate to severe asthma, and to potentially improve asthma control in patients whose asthma is not controlled with low or high doses of inhaled corticosteroids. At the last review, a motion for therapeutic alternatives to include all forms of Montelukast passed unanimously.

Dr. Demain said that as a first line therapy, leukotriene modifiers were considered an alternative to inhaled steroids. As an add-on therapy with inhaled steroids, they allow you to use half the amount of steroids. They are also quite effective in exercise-induced and allergic asthma. Zyflo has significant liver toxicity and has to be closely monitored. These are not preferred agents for the general population. Accolate has significant bioavailability issues if it is taken within two hours of a meal, making it somewhat less desirable. Montelukast is widely accepted and well tolerated. However, not everyone tolerates Montelukast and may have symptoms of unusual dreams, mood changes or headaches. An alternative for those patients would be Zafirlukast.

PA-C RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ALL FORMS OF MONTELUKAST. SECONDED BY DR. LOVE. THE MOTION PASSED UNANIMOUSLY.

24. Re-review of Ophthalmic, Antibiotics (Green Class)

Mr. McCall gave the Magellan presentation on Ophthalmic, Antibiotics. While acute bacterial conjunctivitis is often self-limiting, empiric therapy with ophthalmic antibiotics is a common practice. Treatment with antibiotics typically leads to significantly faster rates of clinical and microbiological remission. Corticosteroids provide local anti-inflammatory activity. Loteprednol is an analog of Prednisolone and induces slightly less elevation of intraocular pressure compared to Prednisolone. Antibiotics provide local antibacterial activity in the respective spectrums. There are not enough published comparative trials to distinguish any of the available products from the others. At the last review, a motion for therapeutic alternatives passed unanimously.

PA-C RILEY MOVED A CLASS EFFECT. SECONDED BY DR. LOVE. THE MOTION PASSED UNANIMOUSLY.

25. Re-review of Ophthalmic, Antibiotic-Steroid Combinations (Green Class)

Mr. McCall gave the Magellan presentation on Ophthalmic, Antibiotic-Steroid Combinations. These combination products were reviewed with the Ophthalmic, Antibiotic class. At the last review, a motion for therapeutic alternatives passed unanimously.

PA-C RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. SEMLING. THE MOTION PASSED UNANIMOUSLY.

26. Re-review of Ophthalmic, Anti-Inflammatories (Green Class)

Mr. McCall gave the Magellan presentation on Ophthalmic, Anti-Inflammatories. Ophthalmic anti-inflammatories, including corticosteroids and non-steroidal anti-inflammatory drugs (NSAIDs), are used to treat inflammatory conditions of the eye, including those due to trauma and surgery. Topical corticosteroids are available in drops, gels, and ointments and are the standard of care for treating ophthalmic inflammation. Ophthalmic corticosteroids can, however, lead to side effects such as increased intraocular pressure, cataract development, and increased risk of ocular infection. Ophthalmic NSAIDs are primarily used during and after ophthalmic surgery. These agents reduce

inflammation in the cornea and conjunctiva and help maintain papillary dilatation during surgery. There is no data to suggest a significant advantage for any one product in either subclass in terms of clinical effectiveness or adverse effect profile, nor are there data that show a difference between agents in different subclasses. At the last review, a motion for therapeutic alternatives to include at least one drug from each subclass passed unanimously.

DR. LOVE MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE DRUG FROM EACH SUBCLASS. SECONDED BY PA-C RILEY. THE MOTION PASSED UNANIMOUSLY.

27. Re-review of Ophthalmic, Glaucoma Agents (Green Class)

Mr. McCall gave the Magellan presentation on Ophthalmic, Glaucoma Agents. Glaucoma is the second most common cause of permanent blindness in the United States and the most common cause of blindness among African-Americans. The prevalence of glaucoma in the United States in adults over 40 years old is estimated at 2 percent. Risk factors for the development of glaucoma include elevated IOP, advancing age, family history of glaucoma, and African-American or Hispanic descent. Increased IOP is common in glaucoma and is believed to contribute to the damage to the optic nerve, which can lead to loss of visual sensitivity and field. There are two types: open-angle glaucoma, which is reduced flow through the trabecular meshwork accounts for the majority of cases, and closed-angle glaucoma, where the iris is pushed forward against the trabecular meshwork. Medication classes used in the management of glaucoma include beta-blockers, miotics, sympathomimetics, topical carbonic anhydrase inhibitors, and prostaglandin and analogs. Monotherapy or combination therapy may be used to treat glaucoma and delay the need for surgery and prevent functional vision loss. According to the American Academy of Ophthalmology, prostaglandin analogs and beta blockers are the most frequently used eye drops. Alphagan P, carbonic anhydrase inhibitors, and beta blockers are capable of decreasing IOP by 15 to 25 percent. Prostaglandin analogs may be the most effective drugs, achieving up to 33 percent reductions in IOP. The prostaglandin analogs have also been shown to have an additive effect when used with beta-blocker therapy. Adverse effects include topically applied ophthalmic beta-blockers are systemically absorbed and may produce systemic adverse effects. All prostaglandin analogs can cause permanent changes to ocular tissues by increasing pigmentation of the iris and eyelid and growth of eyelashes. Gradual change in eye color to brown may occur due to the increased number of melanosomes in melanocytes. Therapy may need to be discontinued if the increased pigmentation continues. At the last review, a motion for class effect to include one drug from each subclass passed unanimously.

PA-C RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE DRUG FROM EACH SUBCLASS. SECONDED BY DR. LOVE. THE MOTION PASSED UNANIMOUSLY.

28. Re-review of Ophthalmics, Immunomodulator, Restasis (Green Class)

Mr. McCall gave the Magellan presentation on Immunomodulator, Restasis. Keratoconjunctivitis sicca is defined as dry eye disease related to either decreased tear volume or rapid evaporative loss due to poor tear quality. Both of these conditions may be present in dry eye syndrome. Symptomatic treatment often includes the frequent application of viscous artificial tears and ointments. Cyclosporine ophthalmic 0.05% (Restasis) provides treatment for the cause of the dry eye symptoms rather than the

symptomatic management. However, use of artificial tears remains a part of therapy for symptomatic relief even with Restasis onboard. The immunomodulating activity of cyclosporine is thought to reduce ocular inflammation. At the last review, a motion for class effect passed unanimously.

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

29. Re-review of Smoking Cessation (Green Class)

Erin Narus read a letter from Debbie Chabot, a nurse practitioner advocating for making Chantix available to Medicaid patients without a prior authorization.

Mr. McCall gave the Magellan presentation on Smoking Cessation. Cigarette smoking is the leading preventable cause of death and is responsible for about one in five deaths annually, or about 480,000 deaths per year in the United States. An estimated 41,000 tobacco-related deaths are the result of secondhand smoke exposure. Approximately 70 percent of smokers have a desire to quit completely and nearly 40 percent attempt to quit each year. Discontinuing smoking often requires multiple attempts. Most attempts are unsuccessful because they are unaided. Cessation medications that have demonstrated efficacy include over-the-counter and prescription nicotine replacement therapies in various formulations (nicotine gum, lozenges, transdermal patches, nasal sprays or inhalers) and prescription non-nicotine medications (Zyban and Chantix). The combination of medication and behavioral therapy is more effective for cessation than either as monotherapy. A risk evaluation and communication strategy is required for Zyban and Chantix, which includes a medication guide to inform patients of the risk of neuropsychiatric adverse events associated with the use of these agents. In the utilization, a large portion of the usage was for the non-preferred Chantix and generic/brand name issues. At the last review, a motion for class effect passed unanimously.

The committee discussed the drugs in the class. Chantix requires a prior authorization. An FDA publication that has not been released was discussed. The topic of the publication is the neuropsychiatric effects of Zyban and Chantix versus other agents in 8,000 patients, half of which had neuropsychiatric disorders including depression, bipolar disease, anxiety and psychosis. The study showed no significant differences in the neuropsychiatric adverse effects among the two groups. Dr. Love said Chantix was preferred over Bupropion in primary care settings.

DR. RUGGLES MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES WITH A RECOMMENDATION FOR REEVALUATION BY THE DUR COMMITTEE OF THE PRIOR AUTHORIZATION PROCESS.

The committee discussed the prior authorization process for Chantix. Erin Narus felt the process was cumbersome. In response to the suggestion that adding Chantix to the PDL would remove the prior authorization requirement, it was noted that only the DUR Committee could remove the prior authorization requirement, even on preferred agents. Erin Narus said the DUR Committee would consider the recommendations of the Pharmacy and Therapeutics Committee on such issues. It was suggested that that DUR Committee could review the prior authorization process for Chantix to ensure it was easier, but keep it in place to ensure people were using the drug correctly.

SECONDED BY PA-C RILEY. THE MOTION PASSED UNANIMOUSLY.

Dr. Demain thanked everyone for their attendance and moved the meeting into a closed session.

Break from 11:15 to 11:25 a.m.

Erin Narus said there was an Opioid Task Force being formed on a statewide level. Their first meeting will be in May and they will meet monthly into November with the intent of putting forward policy recommendations and potential recommendations to the Legislature. Additional information and their website can be emailed upon request.

Dr. Demain said Magellan had provided fair and balanced reporting in the past, but he felt the materials provided at this meeting were inadequate. The materials were outdated, appeared to be biased in places, and were incomplete. There were also inappropriate and inflammatory comments about drugs that were misrepresented. In several cases, the information was from 2012 and 2013. According to MedLine, there were 683 additional papers published from the time that the inadequate data was provided to the time of the presentation. He felt Magellan should be asked for an explanation as well as having the cost of Magellan's services renegotiated.

In response to PA-C Riley, Dr. Demain said this was the first time that he felt the information provided by Magellan was inadequate. He said the argument could be made that the committee was not adequately prepared for the meeting due to the quality of the information provided, but the discussions filled in the gaps. He felt the committee took this process very seriously and Magellan should show the same respect. If they cannot show equal respect, the state should look for an alternate source.

Erin Narus said she appreciated Dr. Demain's comments. Staff started a conversation with Magellan on this issue and they were very responsive. Staff did not have adequate time to supplement the information for this meeting, but we will continue to discuss this issue with Magellan to ensure that the quality of the information is sufficient and meets the stature of the work being done by the committee. She encouraged the committee to email her comments on ways to improve the materials.

Dr. Demain said he would like to have all of the materials provided at least a week before the meeting so the committee members had time to review them. He recommended some oversight of the materials, because they were inadequate and/or inappropriate at this meeting.

30. Review Meeting Minutes from January 22, 2016

The committee reviewed the meeting minutes of January 22, 2016.

DR. LOVE MOVED TO APPROVE THE JANUARY 22, 2016 MEETING MINUTES. SECONDED BY PA-C RILEY. THE MOTION PASSED UNANIMOUSLY.

31. Comments from Committee Member or Chair

Erin Narus gave a slide presentation on the Pharmacy Program highlighting the importance of the work of the Pharmacy and Therapeutic Committee. The trends lines run from the third quarter of FY13 through the third quarter of FY15. We were able to stabilize costs up to the third quarter of 2014 and then it started rising again. The cost trajectory for pharmacy reimbursements were reviewed. The cost

continued to increase over the past year. However, with the work of the P&T Committee and the DUR Committee, as well as the supplemental rebates, we were able to blunt that upward trajectory. The committee members were thanked for their work, which allowed the state to build a PDL that captures clinical benefits and manages costs. As we move into the next year, our goal is to incorporate medicals savings costs. We may see a rise in the pharmacy side, but we anticipate decreases on the medical side. The top 10 drug classes were reviewed by pharmacy reimbursement rates. We have shown progress in the area of generic utilization. In 2013, our generic utilization rate was about 79 percent, but several steps have been taken to improve our generic utilization since that time. There are times when it is less expensive to prescribe the branded product rather than the generic product. This presentation will be used to highlight the work of the P&T Committee with other entities. We will also be starting up some pharmacy provider/prescriber town hall meetings. We have also discussed educational opportunities in the DUR Committee and ways to increase the efficiency of the program.

In response to Dr. Demain, Erin Narus said staff was working on being able to show the actual dollars saved through this process. Once the data is assembled, it will be presented to the committee.

Erin Narus explained the PDL process, which is governed under the Alaska Administrative Procedures Act and is a regulatory process. The PDL has to be adopted by reference date. The date on the current PDL is August 2014, but it was not put into place until March 2015. Historically, the PDL has only been updated once a year due to the length of the regulatory process. We are trying to find ways to honor the regulatory process and open public notice process, but be more fluid in our ability to respond to changes in the pharmacy marketplace.

In response to PA-C Riley, Erin Narus discussed the Medicaid legislation that was passed this session. The pharmacy reimburse is run through the regulatory process so the tiered co-pays have not been changed. A dispensing fee survey will be done to ensure that we have appropriate access. Alaska has the highest dispensing fees, but we also have a high operating costs. Co-pays are 50¢ for drugs reimbursed at under $50, and $3.50 for those over $50. An incentive for using the 90-day generic list is that many of those medications are under $50 so the recipient would only pay a 50¢ co-pay.

In response to Dr. Demain, Erin Narus said she did not have any information on the summary judgment against Pfizer for a $750 million due to their bundling practices.

The next meeting will be held in September 2016. Proposed dates for the 2016 meetings will be distributed to the committee for their consideration.

22. Adjourn

DR. RUGGLES MOVED TO ADJOURN THE MEETING. SECONDED BY DR. LOVE. THE MOTION PASSED UNANIMOUSLY.

The meeting adjourned at 11:45 a.m.