

**ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE**

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

MINUTES OF MEETING

April 20, 2012

8:00 a.m.

Committee Members Present:

Marvin Bergeson, MD
Richard Brodsky, MD
Robert H. Carlson, MD
Mary Elizabeth Gardner, ANP
Vincent Greear, R.Ph.
Daniel P. Kiley, DDS MPH
Diane Liljegren, MD (telephonic)
William McCormick, Pharm.D.
Paul Michaud, Pharm.D.
John Pappenheim, MD
Claudia Phillips, MD
Jill Reid, R.Ph. (telephonic)
John Riley, PA
Trish White, R.Ph. (telephonic)

Committee Members Absent:

Dharma Begich, Pharm.D.
Amber L. Briggs, Pharm.D.
Jeffrey G. Demain, MD

Others Present:

Chad Hope, Pharm.D.
Julie A. Pritchard, Pharm.D.
Erin Narus

1. Call to Order – Chair

Dr. Demain called the meeting to order at 7:57 a.m.

2. Roll Call

A quorum was present.

3. Public Comments - Local Public/Health Practitioners

There were no public comments.

4. Re-review of Long-Acting Beta Agonists (Red Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Long-Acting Beta Agonists. These drugs are used in the treatment and prevention of asthma, exercise-induced bronchospasm, and COPD. They exhibit activity by increasing cyclic A and P levels, which relax bronchial smooth muscles. The onset of action is under 60 minutes and the duration of action is 12 hours, except for the new agent, Arcapta, whose longer half-life allows for once daily dosing. These agents are for controlling purposes and are not meant to replace short-acting inhalers for rescue. The 2011 GINA Guidelines advise against using these agents as monotherapy in asthma. As of May 2011, the FDA requires a REMS program for these agents. In the month of March, there were eight claims: four claims for Foradil and two claims for Serevent Diskus. For the nebulizers, there was one claim each for Brovana and Perforomist. At the last review, a motion for class effect to include at least one hand-held device passed unanimously. Significant changes include Arcapta Neohaler is new to the class. It is approved for use in COPD. All drugs in this class now require a medication guide be dispensed with the drug.

INDISCERNIBLE: A representative of Novartis discussed Arcapta, which is approved for the maintenance treatment of COPD patients. Several studies and their outcomes were reviewed. Arcapta is the first drug in the class to include SGRQ data in its product labeling. Arcapta is contraindicated in patients with asthma, without the use of long-term asthma control medications and is not indicated for the treatment of asthma. The dosing mechanism, which ensures proper use, was reviewed. Arcapta is the first once daily drug in the class approved for the treatment of COPD. It provides rapid onset of bronchodilation and sustains bronchodilation over a 24-hour dosing interval. The delivery device provides reliable feedback to ensure the proper delivery.

DR. KILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. GARDNER. THE MOTION PASSED UNANIMOUSLY.

5. Review of Ophthalmic Antibiotic-Steroid Combinations (Red Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Ophthalmic Antibiotic-Steroid Combinations, which are indicated for corticosteroid responsive inflammatory ocular conditions for which corticosteroids are indicated and where bacterial infection, or a risk of bacterial infection, exists. These combinations are contraindicated in viral diseases of the cornea and conjunctiva, in mycobacterium infection of the eye, and fungal diseases of ocular structures. They should be used with caution in patients with glaucoma. Prolonged use may warrant evaluation of intraocular pressure. Safety and effectiveness of these agents in pediatrics has not been established, with the exception of the Tobramycin Dexamethasone and Maxitrol, which has been established in patients 2 years and older. Data is available for patients older than 2 months for various agents. In March, there were 50 claims: The top three had nine claims each: Tobradex Suspension, Tobradex Ointment, and Neomycin/Polymyxin Ointment and Pred-G Suspension. There was no previous discussion as this is a new class.

In response to Dr. Bergeson, Dr. Hope discussed why the committee was reviewing combination products. There are therapeutic differences between single agents and combination agents. Regarding the Affordable Care Act, there has been discussion about the line item extension rebate differences between single agents and combination agents. CMS released the proposed regulations in February, the comment period closed in April, but we do not yet know if there will be any changes.

In response to Dr. Carlson, Dr. Hope pointed out that generic drugs were usually less expensive, but not always. The medically necessary clause could be utilized for generic drugs that were not included on the PDL.

DR. BERGESON MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC EQUIVALENTS.

Dr. Carlson discussed how the drugs in the class could be separated. Dr. Pritchard said the committee could include specific items in its motion to ensure a specific item was included on the PDL.

SECONDED BY DR. KILEY. THE MOTION PASSED WITH ONE OPPOSED.

6. Re-Review of Hepatitis C Agents (Red Category)

JAMIE TOBITT: A representative of Vertex discussed Telaprevir (Incivek). Telaprevir is indicated only in combination with Peginterferon and Ribavirin for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, which includes cirrhosis. It is indicated for treatment in naive patients and those who were previously treated with Interferon-based treatments, including prior null responders, partial responders, and relapsers. The dosing regimen for Telaprevir therapy, for all patients, was reviewed. The contraindications were reviewed. Prescribing information should be reviewed for all three drugs for complete safety, warnings, and precautions. Several trials and their outcomes were reviewed. Telaprevir is the only direct-acting antiviral agent that has been shown to have substantially higher SVR rates in the treatment naïve cirrhotic patients, as well as in null responders, compared to Peginterferon and Ribavirin alone. The recently updated and published AASLD Guidelines for hepatitis C specifically lists Telaprevir as the agent to use when considering treatment for any prior null responders of Peginterferon and Ribavirin.

In response to Dr. Gardner, Mr. Tobitt said patients were retested six months after therapy, and if they tested negative then they were considered cured.

Dr. Pritchard gave the Magellen presentation on Hepatitis C agents. Hepatitis C is the most common chronic blood-borne infection in the U.S., affecting more than 4 million individuals and disproportionately affecting African-Americans. Co-infection with HIV is believed to affect approximately 14 percent of chronic HCV individuals. Transmission occurs primarily through exposure to infected blood. Disease progression may result in cirrhosis and end-stage liver disease. Peginterferons act to inhibit virus replication inside infected cells via a complex cascade. The pegylation of the Interferons alter the clearance of the molecule, increasing the steady state half-life and allowing these agents to be administered once weekly. In March and for the Peginterferons, there were eight claims for the PEGASYS syringe and four claims for PegIntron. Ribavirin is a nucleoside analog, which disrupts cellular metabolic processes and acts as a potent RNA virus mutagens. Ribavirin should never be used as monotherapy. In March for the Ribavirins, there were 12 claims, all

of which were for Ribavirin. Oral Protease Inhibitors are indicated for chronic hepatitis C genotype 1 infections. They are used in combination with Peginterferon Alpha and Ribavirin as triple therapy in adult patients, and should not be used as monotherapy. In March and for the Oral Protease Inhibitors, there were seven claims: six for Incivek and one for Victrelis. At the last review, a motion for therapeutic alternatives to include one Interferon and one Ribavirin passed unanimously. Significant changes include pediatric patients have been shown to experience delays in height and weight after 48 weeks of treatment with Peginterferon and Ribavirin. Some of these patients catch-up within two years following treatment, while others do not.

Dr. Brodsky referenced the two letters from Anchorage practitioners. Both request that Telaprevir be added to the PDL.

In response to Dr. Brodsky, Dr. Pritchard said there were 12 claims for Ribavirin, but the specific reasons they were prescribed was unknown.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, WITH AT LEAST ONE AGENT FROM THE INTERFERONS, THE RIBAVIRINS, AND THE ORAL PROTEASE INHIBITORS BEING INCLUDED ON THE PDL. SECONDED BY DR. McCORMICK. WITHOUT OBJECTION, THE MOTION PASSED UNANIMOUSLY.

7. Re-review Ophthalmic NSAIDs (Red Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Ophthalmic NSAIDs. The main use of these products is to relieve inflammation and pain associated with ophthalmic surgery. Use for longer than 14 days increases risk of adverse corneal events. Transient burning, irritation and corneal edema are the most commonly reported adverse events. These products have no significant effect on intraocular pressure. However, after cataract surgery, Diclofenac and Nepafenac have been associated with an elevation of pressure. Frequency and number of drops vary between agents. All products show similar efficacy. In March, there were 36 claims: 42% for Lotemax, 14% for Ketorolac, and 11% each for Durezol and Ketorolac 0.5. At the last review, a motion for class effect passed unanimously. Significant changes include Bromfenac, Ketorolac, and Nepafenac should not be used while wearing contact lenses. Ketorolac PF, also known as Acular PF, is no longer available.

DR. KILEY MOVED A CLASS EFFECT. SECONDED BY DR. PHILLIPS.

In response to the committee's discussion of patient who wears contact lenses, Dr. Pritchard said only 13 of the 36 claims were for NSAID-only products.

THE MOTION PASSED UNANIMOUSLY.

8. Re-Review of COPD Inhalant Drugs (Red Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on COPD Inhalant Drugs. Bronchodilators are central to the management of COPD symptoms. For mild disease, a short-acting agent is advised. For moderate to severe disease, scheduled use of one or more bronchodilators is recommended. The anticholinergic agents exert activity by blocking cholinergic neurotransmission, thereby causing bronchodilation. The most common adverse event is dry mouth, which tends to resolve with continued use. In March, there were 455 claims: 40% for Spiriva, 38% for Combivent, and 11.5% for the combination Ipratropium/Albuterol. At the last review, a motion for class effect to include one long-acting and one combination product passed unanimously. Significant changes include Daliresp became FDA approved in February 2011. It is taken orally, 500 milligrams, once daily. It works differently than other agents in this class by inhibiting PDE-4. The exact mechanism leading to Daliresp's therapeutic effect is unknown. It is not a bronchodilator and should not be used for the relief of acute bronchospasm. Daliresp has been shown to increase FEV-1 and decrease the rate of COPD exacerbations by 17 percent. Some psychiatric events, including suicide, have been reported.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE ONE LONG-ACTING, ONE COMBINATION, AND ONE ORAL AGENT. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.

9. Re-review of Ophthalmic Anti-Allergy Agents (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Ophthalmic Anti-Allergy Agents. These agents are used to treat symptoms of perennial and seasonal allergies. All but three products have some systemic absorption. These products should not be used to treat contact lens irritation, as the Benzalkonium Chloride may be absorbed by contacts. Lenses may be reinserted 10 minutes after administration of the drops. All products are in solution form and are dosed as one drop, but the frequency of dosing varies among agents. In March, there were 88 claims: 49% for Patanol and 42% to Pataday. At the last review, a motion for class effect passed unanimously. Significant changes include Lastacraft was added to the class and is approved for patients 2 years and older.

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

10. Re-Review of Ophthalmic Mast Cell Stabilizers (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Ophthalmic Mast Cell Stabilizers. There are four products available in this class. They are used for persistent or frequent symptoms of conjunctivitis. Very low or undetectable levels of systemic absorption have been recorded. All agents are available in solution form. The dosing is one to two drops, BID or up to six times a day depending on the drug. In March, there were four claims: three for Cromolyn Sodium and one for Alomide. At the last review, a motion for class effect passed unanimously. There were no significant changes.

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

11. Re-review of Otic Quinolones - Otic Antibiotics (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Otic Quinolones - Otic Antibiotics. Topical treatment by Fluoroquinolones is used in cases of otitis externa and chronic suppurative otitis media. These agents act by inhibiting the DNA gyrase enzyme needed for replication. Drops are generally administered twice daily for seven days. Cipro HC is a non-sterile product and should not be used if the tympanic membrane is perforated. The other products are sterile. In March, there were 268 claims: 61% for Ciprodex and 35% to Ofloxacin otic drops. At the last review, a motion for class effect passed unanimously.

In response to Dr. McCormick, Dr. Pritchard said only the Otic Quinolones were being reviewed.

DR. McCORMICK MOVED A CLASS EFFECT. SECONDED BY DR. CARLSON.

Dr. Liljegren suggested including both a sterile and non-sterile product.

DR. LILJEGREN MOVED TO AMEND THE MOTION TO INCLUDE AT LEAST ONE STERILE PRODUCT. SECONDED BY DR. GARDNER. THE AMENDMENT PASSED WITH TWO OPPOSED.

THE MOTION, AS AMENDED, PASSED UNANIMOUSLY.

12. Re-review of Inhaled Steroids - Glucocorticoid Inhaled (Blue Category)

ELENA PIZZI: A representative of Astra-Zeneca provided new information on Symbicort relating to new clinical studies and recent FDA requirements. Several recent studies have provided information that is not within the approved prescribing information for Symbicort. Astra-Zeneca does not recommend the use of Symbicort in any other manner than that prescribed in the full package insert. Symbicort is indicated for the twice-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and emphysema. It is also indicated for the treatment of asthma in patients 12 years and older. Several studies and their outcomes were reviewed. Symbicort does have a boxed warning stating that long-acting beta agonists increase the risk of asthma related deaths. We ask that Symbicort be maintained on the PDL.

Dr. Hope noted that with the current rebate process, line extension drugs were currently limited to oral products, but that could change. Due to the high utilization, he suggested splitting the group into inhaled corticosteroids and beta-adrenergic corticosteroids.

Dr. Pritchard gave the Magellen presentation on Inhaled Steroids - Glucocorticoid Inhaled. Many patients will still require adjunctive therapy with agents from another class. Most of these are dosed twice daily, but Mometasone can be dosed once daily and Triamcinolone can be used up to four times daily. Products containing Salmeterol or Formoterol should be used with caution in those patients on MAOIs, tricyclic antidepressants, or other QTc prolonging drugs. The combination products should be reserved for those patient not adequately controlled on a long-term inhaled corticosteroid or whose

disease severity clearly warrant initiation of treatment with both an inhaled corticosteroid and LABA. Patients should be assessed at regular intervals to determine if a step-down in therapy is possible while continuing to maintain control. In March and for the Beta Agenergics/Corticosteroids, there were 490 claims: 70% for Advair Diskus and 15% for Symbicort. The other two products are Dulera and Advair HFA. In March and for the Inhaled Corticosteroids, there were 565 claims: 50% for Flovent HFA, 22% for QVAR, and 12% for Asmanex. At the last review, a motion to include one high potency product, one low to medium potency product, a combination product, and nebulized Budesconide passed unanimously. Significant changes were reviewed. As of April 2011, the FDA is requiring the manufacturers of long-acting beta agonists to conduct five randomized double-blind controlled clinical trials to further evaluate the safety of LABAs when used in combination, in comparison to inhaled corticosteroids alone. These clinical trials were set to begin in 2011, with the results expected to be delivered in 2017.

Dr. Brodsky referenced the letters from local practitioners in the packet. Dr. Woodard supports the inclusion of Symbicort on the PDL.

DR. BERGESON MOVED TO INCLUDE ONE HIGH POTENCY PRODUCT, ONE LOW TO MEDIUM POTENCY PRODUCT, ONE COMBINATION PRODUCT, AND NEBULIZED BUDESCONIDE ON THE PDL. SECONDED BY DR. KILEY.

In response to Dr. Gardner, Dr. Carlson said the long-acting drugs clearly increased mortality. However, there are those who believe that adding the steroid negates the excessive mortality, but that is not proven. FDA-required studies will either prove or disprove that hypothesis. Dr. Brodsky pointed out that there was a black box warning regarding increased rates of death, particularly for those with prolonged QT intervals.

DR. McCORMICK MOVED TO AMEND THE MOTION TO INCLUDE ONE LOW POTENCY AND ONE MEDIUM POTENCY PRODUCT TO THE PDL. THE AMENDMENT FAILED DUE TO LACK OF A SECOND.

THE MOTION PASSED WITH ONE OPPOSED.

13. Re-review of Topical Antivirals (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Topical Antivirals. These products are used for cold sores occurring from either an HSV-1 or -2 infections. Recurrences resulting from HSV-2 are rare. About 80 percent of the adult population in the U.S. is infected. Abreva offers the advantage of being the only FDA-approved over-the-counter medication. There were no significant differences noted between the available products. In March, there were 33 claims: 61% for Zovirax ointment and 33% for Zovirax cream. At the last review, a motion for class effect passed unanimously. Xerese is a combination product of Acyclovir and Hydrocortisone. It is for use for patients 12 years and older.

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

14. Re-review of Hepatitis B - Oral (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Hepatitis B - Oral. All four products are indicated for use in patients with chronic hepatitis B viral infection. Prolonged antiviral therapy is needed for suppression of chronic hepatitis B infection. Epivir HBV can be used in those older than 2 years of age. In March, there were 18 claims: 50% for Viriad and 44% for Baraclude Tablet. At the last review, a motion for therapeutic alternatives passed unanimously. Significant changes include due to high rates of resistance in treated patients, initiation of Epivir should only be considered when the use of an alternative antiviral agent with lower resistant rates is not available or appropriate. The FDA recently determined that the REMS and medication guide previously required for Tyzeka was no longer required. Due to the risk of peripheral neuropathy, co-administration of Tyzeka and Interferons is contraindicated.

In response to Dr. Greear, Dr. Hope said there was an error on the handout and there were preferred agents in this class.

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

15. Re-review of Topical Antifungals (Blue Category)

There were no public testimonies.

Dr. Pritchard gave the Magellen presentation on Topical Antifungals. Ciclopirox is active against many of the fungi, including dermatitis and yeast. Its mechanism of action is through inhibition of metal dependent enzymes needed for the organism to degrade Peroxides. It should not be used in patients with a history of seizures or immunosuppression. It is applied once daily to affected nails at bedtime for 48 weeks. The shampoo is applied twice a week for four weeks. In March, there were 11 claims: eight for the solution, two for the shampoo, and one for the cream. At the last review, a motion for class effect passed unanimously.

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

16. Re-review of Self Injectable Epinephrine (Green Category)

Dr. Hope asked the committee to skip this class, because every product except Epi Pen has recently been discontinued by the manufacturers.

17. Re-review of Intranasal Antihistamines (Green Category)

Dr. Pritchard gave the Magellen presentation on Intranasal Antihistamines. Intranasal Antihistamines have proven effective or superior to oral 2nd generation products for relief of seasonal allergic rhinitis symptoms. All of the products are dosed at one to two sprays in each nostril, twice daily. In March,

there were 11 claims: 64% for Patanase and 36% for Azelastine 0.1 percent spray. At the last review, a motion for class effect passed unanimously.

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

18. Re-review of Nasal Steroids (Green Category)

Dr. Pritchard gave the Magellen presentation on Nasal Steroids. The 2008 guidelines list nasal corticosteroids as the most effective product for treating allergic rhinitis. They are also used to treat symptoms of non-allergic rhinitis. Clinical trials show similar efficacy, although there may be patient preference for spray or mist formulations. The differences between the products are the number of sprays and frequency of dosing. In March, there were 686 claims: 50% for Nasonex, 27% for Fluticasone Propionate, and 8% for Flunisolide. At the last review, a motion for class effect to include one aqueous preparation and one product indicated for ages 2 and older passed unanimously. Significant changes were reviewed. In recent trials, Mometasone showed statistical improvements in total nasal symptom scores and total symptom scores as compared to placebo in both adults and children, while being well tolerated.

In response to Dr. Brodsky, Dr. Pritchard said the total symptom scores were compared to placebo, but not one another.

DR. GARDNER MOVED A CLASS EFFECT TO INCLUDE ONE PRODUCT ACCEPTABLE FOR PATIENTS DOWN TO 2 YEARS OLD. SECONDED BY DR. BERGESON.

In response to Dr. McCormick, Dr. Hope said Nasonex had been preferred until the last update. The 345 claims for Nasonex used the medically necessary clause.

DR. PAPPENHEIM MOVED TO AMEND THE MOTION TO INCLUDE ONE AQUEOUS PRODUCT. SECONDED BY DR. LILJEGREN. THE AMENDMENT PASSED UNANIMOUSLY.

THE MOTION, AS AMENDED, PASSED UNANIMOUSLY.

19. Re-review of Low-Sedating Antihistamines (Green Category)

Dr. Pritchard gave the Magellen presentation on Low-Sedating Antihistamines. Minimally sedating antihistamines are selective, competitive, peripherally acting histamine H1-receptor antagonists with little or no central autonomic nervous system activity. Zyrtec, Allegra, Loratadine, Desloratadine, and Xyzal are all similar in efficacy. Sedation was reported in up to 14 percent of patients using Cetirizine. Levocetirizine has a lower incidence of sedation at lower doses, but an increased risk at higher doses. Fexofenadine tends to cause the fewest CNS effects. In March, there were 514 claims: 30% for Loratadine over-the-counter tablets, 28% for Levocetirizine tablets, and 15% for Clarinex tablets. Significant changes were reviewed. As of March 2011, all Fexofenadine products became available as over-the-counter medications. Use of Cetirizine in children less than 6 years of age with impaired renal or hepatic function is not recommended. Zyrtec ODT is now available as a 10-milligram tablet. There

was no previous discussion, because this class was put on step edits and had been removed from the PDL.

In response to Dr. Bergeson, Dr. Hope said Medicaid had CMS authority to cover over-the-counter Loratadine. Staff is working on a new state plan to initiate coverage of other over-the-counter medications.

DR. LILJEGREN MOVED A CLASS EFFECT WITH AT LEAST ONE PEDIATRIC PREPARATION BEING INCLUDED ON THE PDL. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

20. Re-review of Ophthalmic Quinolones - Ophthalmic Antibiotics (Green Category)

Dr. Pritchard gave the Magellen presentation on Ophthalmic Quinolones - Ophthalmic Antibiotics. All available products, except Levofloxacin 1.5%, are indicated for the treatment of bacterial conjunctivitis. Levofloxacin 1.5% only has an indication for corneal ulcers. Ofloxacin and Ciprofloxacin solution may also be used on corneal ulcers. Fluoroquinolones exert activity by inhibiting DNA gyrase. All products are available in solution form. Ciprofloxacin also comes as an ointment. In March, there were 151 claims: 34% for Ofloxacin drops, 31% for Vigamox, and 26% for Ciprofloxacin HCL drops. At the last review, a motion for class effect passed unanimously.

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

21. Re-review of Ophthalmic Macrolides - Ophthalmic Antibiotics (Green Category)

Dr. Pritchard gave the Magellen presentation on Ophthalmic Macrolides - Ophthalmic Antibiotics. These agents are also used for bacterial conjunctivitis or superficial ocular infections of the conjunctiva or cornea. The mechanism of action is to inhibit the protein synthesis. Both have very low side effect profiles with itching, discomfort, and transient burning being reported at low rates. Azithromycin appears to be more favorable than the Erythromycin, as far as side effect profiles, and has the advantage of less frequent administration. Azithromycin is available in solution form and is dosed as one drop, twice a day, for two days, followed by one drop, every day, for five days. Erythromycin is available as an ointment and is dosed one-half inch to the affected eye, up to six times daily. In March, there were 115 claims: 91% for Erythromycin and 9% to AzaSite. At the last review, a motion for class effect to include the Erythromycin ointment passed unanimously.

DR. BERGESON MOVED A CLASS EFFECT TO INCLUDE THE ERYTHROMYCIN OINTMENT. SECONDED BY DR. GARDNER. THE MOTION PASSED UNANIMOUSLY.

22. Re-review of 2nd and 3rd Generation Cephalosporins (Green Category)

Dr. Pritchard gave the Magellen presentation on 2nd and 3rd Generation Cephalosporins. The 2nd generation Cephalosporins are active against primarily the gram-positive, as well as some gram-negative, organisms with indications ranging from pharyngitis to uncomplicated skin infections. Cefuroxime has an additional indication for gonorrhea. Primarily, these are renally excreted. These agents do require renal dose adjustments. In March and for the 2nd generation products, there were 106

claims: 38% for Cefprozil suspension and 32% for Cefuroxime. At the last review and for the 2nd generation products, a motion for class effect to include at least one good-tasting product and exclude Ceclor passed with one opposed. The 3rd generation Cephalosporins have more gram-positive coverage, as well as penicillin-susceptible *S. pneumonia* coverage. Therefore, most of the agents in this class have an indication for community-acquired pneumonia. Cephalosporins lack activity against the Enterococcus and atypical pathogens as a group. The adverse drug reaction profiles include similar renal dosing needs, drug interactions, warnings, and contraindications across the oral agents. Cefixime suspension has higher bioavailability than tablets, preventing interchange between those two products. In March and for the 3rd generation products, there were 520 claims: 81% for the Cefdinir suspension and 14% for the Cefdinir capsule. At the last review, a motion for class effect passed unanimously.

Dr. Hope noted that Cefprozil suspension and Cefdinir suspension were recognized as the good-tasting products.

DR. BERGESON MOVED, FOR THE 2ND GENERATION PRODUCTS, A CLASS EFFECT TO INCLUDE AT LEAST ONE GOOD-TASTING PRODUCT AND EXCLUDE CECLOR; AND FOR THE 3RD GENERATION PRODUCTS, A CLASS EFFECT. SECONDED BY DR. RILEY. THE MOTION PASSED UNANIMOUSLY.

23. Re-review of 2nd and 3rd Generation Quinolones (Green Category)

Dr. Pritchard gave the Magellen presentation on 2nd and 3rd Generation Quinolones. The 2nd generation agents have stronger action against the gram-negative organisms. They are primarily used to treat UTIs and abdominal infections. The 3rd generation agents exhibit a broader spectrum of activity and have an indication for community-acquired pneumonia. Select Quinolones also play a role in certain genital urinary and STD infections. Fluoroquinolones have good bioavailability and are frequently candidates for IV to oral therapy conversion. Safety concerns for this class include tendon rupture, especially in elderly or malnourished individuals, exacerbated muscle weakness in individuals with myasthenia gravis, QT prolongation, pseudo membranous colitis, photosensitivity, and glucose tolerance issues. In March, there were 390 claims: 61% for Ciprofloxacin tablets and 36% for Levofloxacin tablets. At the last review, a motion for class effect to include Ciprofloxacin passed unanimously.

DR. KILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. THE MOTION FAILED DUE TO LACK OF A SECOND.

DR. GREEAR MOVED A CLASS EFFECT. THE MOTION FAILED DUE TO LACK OF A SECOND.

DR. RILEY MOVED A CLASS EFFECT TO INCLUDE A 2ND AND A 3RD GENERATION PRODUCT. SECONDED BY DR. GARDNER. THE MOTION PASSED UNANIMOUSLY.

24. Re-review of Macrolides (Green Category)

Dr. Pritchard gave the Magellen presentation on Macrolides. Erythromycin was the first Macrolide introduced back in 1952 with activity against gram-positive cocci and atypical pathogens. Azithromycin and Clarithromycin are newer agents that are better tolerated and have more convenient

dosing regimens. The newer agents have enhanced activity against hemophilus influenza. The mechanism of action was reviewed. Drug interactions, cautions, dosing, etcetera, vary among agents. In March, there were 1,611 claims: 54% for Azithromycin tablets and 31% for Azithromycin suspension. At the last review, a motion for therapeutic alternatives to include Azithromycin passed unanimously.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AZITHROMYCIN AND ONE PEDIATRIC FORMULATION. SECONDED BY DR. PAPPENHEIM. THE MOTION PASSED UNANIMOUSLY.

25. Re-review of Anti-Migraine Agents (Green Category)

Dr. Pritchard gave the Magellen presentation on Anti-Migraine Agents. These agents come in a variety of forms. Triptan products include a warning regarding the possibility of serotonin syndrome when used in conjunction with SSRIs. Diclofenac and the combination product of Sumatriptan/Naproxen contain a boxed warning for the possibility of gastric ulceration perforation and inflammation. Each drug has a defined maximum 24-hour dose that should not be exceeded. Overuse of these agents may result in medication overuse headaches in susceptible patients characterized by migraine-like daily headaches or an increase in migraines. In March, there were 234 claims: 29.5% for Maxalt MLT and 29% for Sumatriptan Succinate tablet. At the last review, a motion for class effect passed unanimously. Significant changes were reviewed. A recent study suggests that Rizatriptan has some benefit in Sumatriptan non-responders.

Dr. Carlson and Dr. Brodsky discussed the differences in the treatment of migraines in the emergency room versus neurology offices.

DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. GREER.

The committee discussed having several different dosage forms available on the PDL.

DR. GARDNER MOVED TO AMEND THE MOTION TO INCLUDE SEVERAL DIFFERENT DOSAGE FORMS ON THE PDL. SECONDED BY DR. LILJEGREN.

Dr. Carlson noted that the medically necessary clause could be utilized.

THE AMENDMENT FAILED WITH SEVEN OPPOSED.

THE MOTION PASSED UNANIMOUSLY.

26. Re-review of Anti-Emetics (Green Category)

Dr. Pritchard gave the Magellen presentation on Anti-Emetics. There are three main classes of Anti-Emetics used to treat or prevent nausea and vomiting associated with cancer chemotherapy or radiation. The 5-HT3 antagonists are the first line drugs for these indications. When nausea and vomiting is associated with motion sickness, agents such as antihistamines, H1 antagonist anticholinergics, phenothiazines, and antidopaminergics should be considered. In March, there were

546 claims: 50% for Ondansetron rapid tablets and 47% for Ondansetron tablets. The NK-1 receptor antagonist, or Emend, had 14 claims. At the last review, a motion for therapeutic alternatives passed unanimously. Significant changes include the updated 2011 and version one of the 2012 Guidelines, which now suggest that Palonosetron (Aloxi) demonstrates superiority in preventing emesis due to high or moderate risk chemotherapy agents, compared to the other five HT-3 medications. However, the guidelines concluded that due to the shortcomings of the studies comparing Palonosetron to the other, agents, they could not recommend Aloxi as having a preferred status at this time and more studies are warranted. Since January 2012, there have only been two claims for Aloxi in Alaska.

DR. PAPPENHEIM MOVED THAT ALL THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. GARDNER. THE MOTION PASSED UNANIMOUSLY.

27. Re-review of Leukotriene Inhibitors (Green Category)

Dr. Pritchard gave the Magellen presentation on Leukotriene Inhibitors. This class of asthma medication is used as add-on therapy in patients with mild persistent symptoms or aspirin sensitive asthma. They are also used in patients utilizing inhaled Glucocorticoid to reduce the steroid dose. Leukotriene-mediated effects include airway edema, smooth muscle contraction, mucus secretion, and micro vascular permeability. In March, there were 963 claims: 51% for Singulair tablets and 46% for Singulair chew tabs. At the last review, a motion for therapeutic alternatives to include all forms of Singulair passed unanimously. Significant changes include Singulair is the only agent in the group approved for use in allergic rhinitis. Patients on asthma therapy with Singulair may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome. Patients with known aspirin sensitivity should continue to avoid aspirin and NSAIDs while taking Singulair.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ALL FORMS OF SINGULAIR. SECONDED BY DR. PAPPENHEIM. THE MOTION PASSED UNANIMOUSLY.

28. Re-review of Short-Acting Beta Agonists (Green Category)

Dr. Pritchard gave the Magellen presentation on Short-Acting Beta Agonists. Agents in this class are available in typical inhaler form or nebulizer solution form. These drugs are categorized as reliever medications and are used to treat acute exacerbation of asthma symptoms due to their quick onset of action. They are not to be used as controller medications. All can be dosed every four to six hours as needed, with a duration of action between two to eight hours depending on product. In March, there were 1,984 claims. For the short-acting inhalation agents: 37% for ProAir HFA, 32% for Ventolin HFA, and 26% for Preventil HFA. For the beta-adrenergic nebulizers: 85% for Albuterol sulfate and 10% for Albuterol generic. At the last review, a motion for class effect to include Albuterol HFA preparations passed unanimously. Significant changes include Primatene Mist was removed from the marketplace on December 31, 2011.

Dr. Hope noted that ProAir was adding a dose counter, which tells a patient how many puffs they have left on their inhaler.

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

In response to Dr. Riley, Dr. Hope said this class has changed from year to year and has not remained consistent.

THE MOTION PASSED UNANIMOUSLY.

29. Re-review of Ophthalmic Immunomodulators (Green Category)

Dr. Pritchard gave the Magellen presentation on Ophthalmic Immunomodulators. Restasis is the only product in this class. It is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis, which may decrease tear volume or cause poor tear quality. In March, there were 29 claims for Restasis. At the last review, a motion for class effect passed unanimously.

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

30. Re-review of Anti-Herpes Oral Medication - Antivirals HSV (Green Category)

Dr. Pritchard gave the Magellen presentation on Anti-Herpes Oral Medication - Antivirals HSV. CDC recommendations for initial or recurrent episodes of genital herpes or chronic suppressive therapy indicate no preference for any of the three oral agents. Valacyclovir is rapidly converted to Acyclovir. Famciclovir is metabolized to its active metabolite, which is Penciclovir. Renal failure is a risk. Probenecid has been shown to interact with Acyclovir and Penciclovir. In March, there were 295 claims: 47.5% for Valacyclovir and 36% for Acyclovir. At the last review, a motion for class effect to include an oral suspension and a capsule or tablet passed unanimously. There were two studies suggesting Valacyclovir to be somewhat more efficacious in suppressing genital herpes and associated shedding.

DR. BERGESON MOVED A CLASS EFFECT TO INCLUDE AN ORAL SUSPENSION AND A CAPSULE OR TABLET. SECONDED BY DR. GARDNER.

In response to Dr. Carlson, none of the committee members knew what happened when patients took these medications for many years for suppression reasons.

THE MOTION PASSED UNANIMOUSLY.

31. Re-review of Anti-Fungal - Oral (Green Category)

Dr. Pritchard gave the Magellen presentation on Anti-Fungal - Oral. Dermatophytes, yeasts, and molds are the primary pathogens of infections of the nail bed, occurring more often in toenails versus fingernails. The onychomycosis is generally hard to treat. Chronic infections occur more frequently in the elderly. In March, there were 53 claims: 57% for Terbinafine and 25% for Griseofulvin suspension. At the last review, a motion for therapeutic alternatives with Griseofulvin for patients less than 17 years of age passed unanimously. Significant changes include Itraconazole has been approved for use

in patients with pulmonary and extra pulmonary blastomycosis, histoplasmosis, or refractory aspergillosis.

The committee discussed why Griseofulvin was included in last year's motion for patients less than 17 years of age. Dr. Riley noted that Terbinafine could be used in patients 4 years and older. Dr. Bergeson said he used Vicks Vapor Rub for toenail infections in children. Dr. Gardner questioned if these medications should be used for children at all due to potential damage to the liver. Dr. Hope said these medications could require prior authorization and only be approved for certain indications, but that would cause an access issue from the claims processing side. Dr. Carlson felt this was an issue of physician education.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. McCORMICK. THE MOTION PASSED UNANIMOUSLY.

32. Re-review of Anti-viral - Influenza (Green Category)

Dr. Pritchard gave the Magellen presentation on Anti-viral - Influenza. All available products should be administered no later than 48 hours after onset of symptoms. Amantadine and Rimantadine frequently have high rates of resistance. Local susceptibility patterns should be taken into account during the current season when deciding on the use and selection of an anti-viral agent. Vaccination should remain the primary form of prophylaxis. Relenza and Tamiflu are indicated for types A and B. Amantadine and Rimantadine are only indicated for type A. In March, there were 101 claims: 81% for Tamiflu and 19% for Amantadine. It is unknown whether the Amantadine claims were for flu or Parkinson's disease. At the last review, a motion for therapeutic alternative, to prefer Tamiflu, passed unanimously. The emergency use authorization for children less than 1 year of age expired in June 2010.

Dr. Carlson said there was a lot of controversy regarding Tamiflu, and related agents. Further studies have been done on safety and efficacy, but that information has not been released. Dr. Brodsky noted that none of these drugs has been shown to be good. They have marginal effects and have to be administered very quickly after symptoms are exhibited. Dr. Bergeson noted that Amantadine was being used for autism, which was an off-label use.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.

33. Re-review of Topical Antibiotics (Green Category)

Dr. Pritchard gave the Magellen presentation on Topical Antibiotics. Mupirocin irreversibly and specifically binds to a bacterial enzyme resulting in inhibition of protein synthesis. Altabax is the first in a unique class. It shows a clinical advantage over Mupirocin for *S. pyogenes*, including multi drug resistant strains. In March, there were 426 claims: 96% for Mupirocin, 2.35% for Bactroban nasal, and 1.88% for Altabax. At the last review, a motion for therapeutic alternatives to include Mupirocin passed unanimously.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE MUPIROCIN. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

34. Review Minutes from January 20, 2012, Meeting

There were no changes to the January 20, 2012, meeting minutes.

DR. BRODSKY MOVED FOR APPROVAL OF THE January 20, 2012, MEETING MINUTES BY UNANIMOUS CONSENT. THERE WERE NO OBJECTIONS.

35. Comments from Committee Members or Chair

Dr. Hope said future meetings would be held on the third Friday of the months of September, November, January, and April. Dr. Pritchard will be replaced by Erin Narus, from Magellen. Other staffing changes were discussed. The committee was thanked for their participation.

36. Adjourn

Without objection, the meeting adjourned at 9:57 a.m.