

**ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE**

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

FINAL MINUTES OF MEETING

April 17, 2009

8:00 a.m.

Committee Members Present:

Dharma V. Begich, Pharm.D
Marvin Bergeson, MD
Heidi Brainerd, MS R.Ph.
Amber L. Briggs, Pharm.D.
Richard E. Brodsky, MD
Robert H. Carlson, MD
Jeffrey G. Demain, MD
Traci Gale, PharmD. (telephonic)
Vincent Greear, R.Ph.
Daniel P. Kiley, DDS, MPH
Diane Liljegren, MD (telephonic)
Andrzej Maciejewski, MD
(telephonic for a portion of the meeting)
Claudia Phillips, MD
Sherrie D. Richey, MD
Janice L. Stables, MSN, ANP (telephonic)
Trish D. White, R.Ph. (telephonic)

Committee Members Absent:

Lucy Curtiss, MD

Others Present:

David Campana, R.Ph.
Melinda Sater, Pharm.D., First Health
Jan Culver, Staff
Sheila Westfall, Staff

1. Call to Order – Chair

The meeting was called to order at 8:01 a.m.

2. Roll Call

A quorum was present.

3. Public Comment – Local Public / Health Practitioners

There were no public comments.

4. Topical Antivirals (Red Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Topical Anti-virals. This is a new classification. There are three available chemical entities and four available products. Abreva is an over the counter product and will not be considered for this discussion. Zovirax cream and Denavir are indicated for the management of cold sores and fever blisters. Zovirax ointment is indicated for initial genital herpes and non-life-threatening mucocutaneous herpes outbreaks. The adverse event profiles and efficacies are similar for all drugs in the class. All agents provide modest benefits if started very early in the prodrome period of herpes outbreak. In March, there were 27 claims: 67% for Zovirax ointment, 26% for Zovirax cream, and 7% for Denavir.

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

5. Re-review of Anti-emetics (Red Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Anti-emetics. There are five agents in this class, available in a variety of dosage forms. The indications vary by agent and all agents are used for all indications in clinical settings. All agents, except Emend (Aprepitant), selectively block 5-HT₃ receptors and have similar efficacy and adverse drug reaction profiles. Emend is an NK₁ receptor antagonist and has a different mechanism than the others in the class. Head to head trials are limited and usually fairly small. In March, there were 170 claims: 50% for Ondansetron tablets; 35% for the Ondansetron rapid dissolving tablets, 4.7% for Ondansetron solution, 4.7% for Zofran ODT, 2.4% for Anzemet, 1.8% for Granistron, and 1.2% for Zofran tablets. In the previous review, there was a significant discussion on the availability of Ondansetron for pregnant patients, as well as a discussion on generic versus branded products. The motion for a class effect passed with three opposed. Since the last review, Aloxi capsules and Sancuso patches were added to the marketplace. A letter was received from a pharmacist at Providence Hospital asking that we consider adding Emend (Aprepitant) to the PDL, because it has a unique mechanism of action.

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

6. Re-review of Inhaled Steroids (Red Category)

RANDY LEGG: A representative of AstraZeneca discussed three inhaled steroids. Pulmicort Respules is available in a .25, .5 and a 1-milligram per 2cc strength. It is the only inhaled steroid available for nebulizer. It is indicated for the treatment of persistent asthma from ages 1 to 8. It is a category B FDA pregnancy rated inhaled steroid. Pulmicort Flexhaler is the only inhaled dry powder steroid with a category B FDA pregnancy rating. It is indicated for asthma for ages 6 and above. Symbicort is a combination of Budesonide and Formoterol. Symbicort is available in two strengths and is two puffs BID. It is indicated for asthma for ages 12 and above. It recently received a new approval for treatment of COPD for the 160 micrograms/4.5 strength, which is indicated for the treatment of long-term chronic obstructive pulmonary disease, chronic bronchitis, and emphysema.

BARBARA FELT: A representative of GlaxoSmithKline discussed Advair. Advair is currently on the preferred drug list and there are four reasons why it should remain there. First, it has been on the market for over eight years so physicians and patients have a lot of experience with it. Second, it is one of two combination agents in this class and contains both an inhaled steroid and a long-acting beta agonist. Third, there have been many studies that show Advair is clinically effective. For asthma, it has been shown to be more effective than doubling the dose of an inhaled steroid alone. For COPD patients that have history of exacerbations, it has been shown to decrease the rate of exacerbations. The Asthma Guidelines, NIH Guidelines, ATS and Gold Guidelines for COPD all support the use of combination therapy. Fourth, it is a very versatile product. It is available in a dry powder device and a meter dose inhaler, both of which have a dose counter. It is available in three strengths. It is indicated for use in both asthma and COPD. Advair Diskus is indicated all the way down to age 4. Advair contains some Salmeterol and carries the class warning that Salmeterol may increase the risk of asthma related death. Advair should remain on the PDL due to its place in asthma therapy, COPD therapy, and the versatility that it gives both patients and physicians.

DAN MANNING: A representative of Schering-Plough discussed Asmanex (Mometasone Furoate). It is a dry powder inhaler. Inhaled corticosteroids are the foundation for asthma management. The Asmanex Twisthaler is the only inhaled corticosteroid that is FDA approved for once daily dosing. It comes in two strengths, 110 and 220, and has a dose counter. It is indicated down to 4 years of age. Asmanex offers a proven safety and tolerability profile. We request that the Asmanex be retained on the PDL.

Dr. Sater gave the First Health presentation on Inhaled Steroids. There are seven available agents in this class. Fluticasone is available in combination with Salmeterol. Budesonide is available in combination with Formoterol, and has a suspension for nebulization. All agents are approved for maintenance and prophylactic treatment of asthma. There are two major delivery devices, the dry powder inhaler and the MDI. Only Budesonide and Mometasone are available in the DPI. All agents have similar efficacy and tolerability when used in equipotent doses. Asmanex and Advair contain lactose. Other warnings, adverse drug reactions and drug interactions are similar for the agents. In March there were 796 claims; 437 for the combination products, 86% for Advair Diskus, 10.5% for Symbicort, and 3.7% for Advair HFA; 323 of these claims were for the single entity products, 65% for Flovent HFA, 21% for QVAR, 8% for Pulmicort, 3.7% for Azmacort; .93% for Asmanex; and less than 2% for everything else. There were also 36 claims for Pulmicort Respules. At the last review, there was limited discussion on the advantages of one agent over the other. A motion to include a low to medium potency and a high potency agent, and prefer Budesonide in all forms, passed with two opposed. Since the last review, Alvesco (Ciclesonide) has been added to the marketplace. In addition, generic Pulmicort Respules have been approved, although they may not be widely commercially available. Aerobid, Aerobid-M and Azmacort are still CFC products. The discontinuation or reformulation of those products must be complete by December 31, 2009. Advair and Symbicort received additional COPD indications. Since the last review, the GOLD Guidelines recommend an inhaled corticosteroid and a long-acting beta agonist for the treatment of severe or very severe COPD.

Dr. Demain felt the new product, Alvesco, might have some advantages. It is a pro-drug and does not become activated until it hits the respiratory tract. In theory, there is a decreased risk of systemic absorption when you are going to use high doses of inhaled steroids.

DR. DEMAIN MOVED A LOW TO MEDIUM POTENCY, A HIGH POTENCY, AND INCLUDE PULMICORT ON THE PDL. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

Dr. Brodsky noted that the re-review of the Oral Beta-blockers would be delayed until later in the meeting when Dr. Maciejewski was available telephonically.

7. Review of Ophthalmic NSAIDS (Red Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Ophthalmic NSAIDS. This is a new classification. There are five available chemical entities and seven available products. All the agents are indicated for pain and inflammation associated with ocular surgery. Acular is also indicated for seasonal allergic conjunctivitis. Systemic absorption is low for all agents. Xibrom contains sodium sulfite, which is a problem for patients that are allergic or sensitive to sulfite. Efficacy and adverse drug reaction profiles are similar among the agents. In March, there were 10 claims: 30% for Flurbiprofen, 20% for Acular LS, 20% for Acular PF, 10% for Acular, 10% for Diclofenac, and 10% for Nepafenac.

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

8. Re-review of Anti-migraine (Red Category)

JENNIFER BRZANA: A representative of GlaxoSmithKline discussed Treximet. Treximet treats the multiple mechanisms of migraine, which sets it apart from all the other medications in this class. It has proven superiority to Imitrex. Last, I will address the question of why not give this as two separate prescriptions. The current understanding of the migraine suggests that there are multiple mechanisms. Single entities can address some of these components, but not all of them. Treximet, which is a single tablet, addresses all of these mechanisms. Treximet provides superior results across a variety of outcomes. In addition, the use of rescue medication was significantly reduced in patients using Treximet. Headache specialists have been combining NSAIDs and triptans for years. A survey showed that 71% of patients use other medications with their triptans to treat migraines utilized step-care. We know that step-care offers less than optimal outcomes and increases the use of rescue medication. In most clinical trials, Treximet was generally well tolerated with the most common adverse events were dizziness, somnolence, nausea, chest and neck discomfort, and paresthesia. Due to Treximet's ability to address these multiple mechanisms of migraines, the superior efficacy over Imitrex, and the decreased need for rescue medication, it is recommended that Treximet be added to the PDL.

Dr. Sater gave the First Health presentation on Anti-migraine. There are seven available chemical entities. Imitrex, Maxalt and Zomig are available in a variety of dosage forms and are considered short acting; Axert and Relpax are considered intermediate acting; and Amerge and Frova are considered long acting. All agents are indicated for the treatment of migraines with or without aura. Imitrex is also indicated for cluster headaches. Efficacy and adverse drug reaction profiles are similar among the agents. There are slight differences in 5-HT receptor subtype activity between the agents, but the clinical significance of that is unknown. In March there were 180 claims: 31% for Maxalt MLT, 18% for

Sumatriptan tablets; 15% for Maxalt tablets; 5.6% for Relpax; 5.6% for Sumatriptan injectible, 5% for Imitrex tablets, 5% for Treximet, 3.3% for Sumatriptan nasal spray, 2.8% for Imitrex cartridge, 1.7% for Axert, 1.1% for Imitrex nasal spray, 1.1% for Sumatriptan injectible, and less than 3% for all the rest. At the last review, there was a brief discussion on the necessity of adding one injectible agent to the PDL. The motion for a class effect passed with one opposed. Since the last review, generic Imitrex has been approved and Treximet has been added to the marketplace.

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

Dr. Liljegren felt all three dosage forms – injectibles, nasal sprays and rapidly dissolving oral formulations should be available on the PDL. The efficacy of injectibles is 80% and 60% for nasal sprays. Because the stomach does not always work as well during migraines, oral medications may be less effective for those patients, as well as patients that suffer from nausea.

Dr. Sater said the currently preferred agents were Maxalt, in all its forms; Imitrex, in all its forms, and Relpax oral tablets.

THE MOTION PASSED WITH ONE OPPOSED.

9. Re-Review Nasal Steroids (Red Category)

JOHN SEDONA: A representative of Sanofi-Aventis discussed Nasacort AQ, which is currently on the PDL. Nasacort AQ is approved for children ages 2 to 5 and is the only inhaled steroid that has an efficacy trial with that age group with regard to perennial allergic rhinitis. The trial was discussed. Published studies show that Nasacort AQ is effective in relieving ocular symptoms. Two safety data trials have shown that Nasacort AQ, 110 micrograms once a day, did not show any significant adrenal suppression in children ages 2 to 5. It also had no effect on growth, bone velocity growth after 3 years, or bone density after 3 years.

BARBARA FELT: A representative of GlaxoSmithKline discussed Veramyst, which is currently on the PDL. Veramyst is available for a wide variety of patients to treat symptoms of seasonal allergic rhinitis and perennial allergic rhinitis. It is also available for patients down to age 2. Veramyst is very effective in treating the total nasal symptom scores, but like some of the other agents in this class, it has FDA recognition for decreasing the ocular symptoms related to seasonal allergic rhinitis in patients 12 and older. It is available in a unique and innovative device based on feedback from patients and physicians. The nozzle is very small, which works well for pediatrics, and it is side actuated. The mist comes out at a very low volume and has no smell. It also has a viewing window so patients know when to get their medication refilled. Veramyst is a different molecule than Fluticasone Propionate, which was described in further detail. The adverse reactions are very similar to placebo in the randomized controlled trials with the most common side effects being headaches and epistaxis. Veramyst is a potent molecule delivered from a unique device that can be used down to age 2. It also has an effect on ocular symptoms in patients 12 and older with seasonal allergic rhinitis. Due to these reasons, we request that Veramyst be retained on the PDL.

DAN MANNING: A representative of Schering-Plough discussed Nasonex. It is scent and alcohol free. It has a broad range of indications and is indicated down to 2 years of age. It is the only nasal steroid

with a prophylaxis of seasonal allergic rhinitis. It is also the only nasal steroid approved for the treatment of nasal polyps. Clinical studies have shown Nasonex to have a total systemic bioavailability of less than 0.1%. We would ask that Nasonex be maintained on the PDL.

Dr. Sater gave the First Health presentation on Nasal Steroids. There are seven available chemical entities and nine available products. All agents are FDA approved for the treatment of seasonal allergic rhinitis and perennial allergic rhinitis. Beclomethasone is indicated for the prevention of recurrence of nasal polyps following surgical removal. Mometasone is indicated for the treatment of nasal polyps. All are available as sprays. Contraindications, warnings, adverse drug reactions, and drug interactions are similar for all the products. All agents have similar efficacy and tolerability. In March there were 547 claims: 52% for Nasonex, 15% for generic Flonase, 11.5% for Veramyst, 8.2% for Nasacort, 7.5% for Flunisolide, 3% for Rhinocort Aqua, 1.2% for Omnaris, .7% for Beconase AQ, and .35% for Flonase. At the last review, there was limited discussion. The agents were deemed equivalent for efficacy. A motion for a class effect with an aqueous, non-alcohol containing preparation passed unanimously. Since the last review, Omnaris has been added to the marketplace. The new American Academy of Allergy, Asthma & Immunology rhinitis management guidelines were published last year.

Dr. Liljegren felt at least one medication approved for children under 5 or 6 years of age should be included on the PDL. Dr. Demain said the new product Omnaris works, but probably does not bring anything new to the table. Dr. Sater noted that all the products were indicated for children ages 6 and under.

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

Dr. Demain recommended maintaining an aqueous preparation on the PDL. The alcohol preparation is not tolerated by a significant number of patients. It would also be reasonable to have one product, approved for patients down to 2 years of age, on the PDL.

Dr. Sater said the motion, as it exists, would probably include an agent approved for children above 6 years of age. You can specifically state that you want an aqueous preparation and a product for patients down to 2 years of age, but you probably do not need to.

DR. LILJEGREN MOVED TO AMEND THE MOTION TO DECLARE A CLASS EFFECT AND INCLUDE AN AQUEOUS PREPARATION AND A PRODUCT APPROVED FOR PATIENTS DOWN TO 2 YEARS OF AGE. SECONDED BY DR. DEMAIN.

THE MOTION, AS AMENDED, PASSED WITH ONE OPPOSED.

10. Re-Review of Hepatitis C Agents (Blue Category)

VANDANA SLATTER: A representative of Roche Pharmaceuticals discussed PEGASYS. Cirrhosis is chronic hepatitis C virus. It is a leading specific indication for liver transplant in the United States. IN 2009, PEGASYS remains the most commonly prescribed interferon for hepatitis C in the United States. Due to its pharmacokinetics, PEGASYS does not need to be dosed by weight and has one standard dose for all patients. Safety is detailed in the PEGASYS package inserts. Additional information has also

been published and/or presented at major liver meetings in 2008, which was reviewed. Several studies were reviewed. We requested that PEGASYS remains available on the PDL.

ISAAC LLOYD: A representative of Schering-Plough discussed PEG-Intron, which is currently on the PDL. It has two new and unique indications. PEG-Intron is the first and only approved pegylated interferon in combination with Ribavirin for previously untreated children ages 3 and older with chronic hepatitis C. It is dosed by body surface area at 60 micrograms per meter square per week, and 15 milligrams per kilogram per day of Ribavirin, in two divided doses. Last month, PEG-Intron received the indication for retreatment of patients that were previously interferon or pegylated interferon treatment failures, patients who relapsed, or non-responders based on the EPIC 3 Trial. There are currently no head-to-head published studies comparing pegylated interferons, but it is important for the committee to know the results of the IDEAL Study, which were reviewed. PEG-Intron is the only pegylated interferon that has the ability to weight-base dose. Since 1960, the average weight for U.S. men and women has increased by almost 25 pounds. According to the Alaska State Behavioral Risk Factor Surveillance System figures from 2007, 37% of Alaskan adults are overweight by greater than 25 BMI and approximately 20% greater than 30 BMI. Patients weighing more than 165 pounds have lower SVR rates when flat dose interferon therapy is administered. We requested that PEG-Intron remain on the PDL.

Dr. Sater gave the First Health presentation on Hepatitis C Agents. There are two available agents. They have similar adverse drug reaction profiles, drug interactions, warnings, and contraindications. Head to head trials are small and usually open labeled, but sustained virological response rates appear to be similar with both agents. In March, there were 5 claims: 4 for PEG-Intron pens, and 1 for the PEGASYS convenience pack. At the last review, after a very brief discussion of the high cost of treating hepatitis C, a class effect was declared and passed unanimously. Since the last review, PEG-Intron had a few changes in their indications.

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

Dr. Maciejewski arrived at the meeting telephonically. The committee returned to the Red Category.

11. Re-review of Oral Beta-blockers (Red Category)

LONG NGUYEN: A representative of GlaxoSmithKline discussed Coreg CR. There is no new information on Coreg CR at this time, but I am here to provide support should the committee members have any questions or comments.

Dr. Sater gave the First Health presentation on Oral Beta-blockers. There are 13 available entities. Indications vary between agents. Carvedilol and Labetalol have alpha1 receptor activity. Carvedilol and Toprol XL are indicated for heart failure, but other beta1 selective agents have been used. There has been recent concern about increased mortality with beta-blockers. In March, there were 1,994 claims: 38% for Atenolol, 12.3% for generic Lopressor, 10% for Propranolol, 9.9% for generic Coreg, 8.5% for Toprol XL, 6.9% for generic Toprol XL, 4.4% for Propranolol LA, 2.9% for Coreg CR, 2.1% for Nadolol, 1.2% for Bystolic, and less than 3% for all the rest. At the last review, there was a brief discussion on the therapeutic benefits of Carvedilol over the other agents. The motion to include

Carvedilol and Coreg CR, and include a mix of beta1 selective and non-selective agents, passed with two opposed. We have received a lot of support for Carvedilol, both Coreg and Coreg CR, from the Alaska Heart Institute.

Dr. Maciejewski (telephonic and difficult to hear) attended a meeting in Chicago on hypertension drugs, but beta-blockers were not addressed. The literature on beta-blockers in the last decade was discussed. There were negatives about beta-blockers noted in clinical outcome studies that include elevation of triglycerides, reduction of HDL, vaso constriction, increasing insulin resistance leading to diabetes type II, and creating erectile dysfunction, fatigue and depression. Recent studies on Atenolol show negative outcomes. Several classifications of beta-blockers, both their positives and negatives, were discussed. Atenolol is the most utilized beta-blocker, but numerous studies have shown it to have a higher mortality and morbidity rate than the other beta-blockers. Several studies were reviewed. Problems being reported with beta-blockers, Atenolol in particular, include increased mortality, cardiovascular mortality, increased strokes, and decreased value in the treatment of hypertension. In the local Anchorage market, cardiologists do not use Atenolol for the reasons mentioned. I do not believe this issue can be revisited in a clinical trial, because of ethical issues associated with the many issues with Atenolol.

DR. MACIEJEWSKI MOVED TO REMOVE ATENOLOL FROM THE PDL, AND RETAIN CARVEDILOL AND NEBIVOLOL ON THE PDL.

The motion failed due to lack of a second.

Dr. Brainerd suggested the following: Until JNC-8 comes out, include a note on the PDL that for uncomplicated hypertension with no co-morbidities, the committee does not consider beta-blockers to be used as a first line agent.

Dr. Demain noted that beta-blockers, and probably much of the Atenolol use, is being used outside of the FDA recommendations for the management of migraines.

Dr. Carlson asked if it would be better to promote physician education than to change the PDL, because Dr. Maciejewski's discussion was very important and valid, but the mention of the other uses might make our actions complicating for many people.

Dr. Liljgren noted that other beta-blockers could be used for the other indications mentioned.

Dr. Maciejewski said Atenolol appears to have problems that the other beta-blockers do not have. The problem with the other beta-blockers is their metabolic effect, but we still use them with awareness. The new class of beta-blockers, Carvedilol and Nebivolol, are free from the metabolic issues. Carvedilol has excellent outcomes in heart failure. My intention is just to limit the Atenolol use, which seems to be a problematic agent.

Dr. Demain asked if Atenolol would be available for patients on a grandfather type basis.

Dr. Maciejewski said the usage of Atenolol cannot be stopped without considering an appropriate replacement and physicians probably need some guidance on that issue.

In response to Dr. Carlson, Dr. Sater said generic Atenolol would not be included if Atenolol was specifically excluded from the PDL.

Ms. White suggested a grandfather clause for Atenolol due to the volume currently being prescribed. She also requested a written document on the issue that could be distributed to physicians.

Mr. Campana said most of the information provided by Dr. Maciejewski was in the December medical letter on the beta-blockers, which could be used to create an educational piece on beta-blockers. It might be best to prefer it, put a note on it that the literature and clinical evidence has shown it might not be the best choice for patients, and then watch it over the next year to see if the prescription volume decreases. If mortality and morbidity is increasing, it is not necessarily a drug that we want to prefer. The other option would be the grandfather clause and an educational piece.

DR. BERGESON MOVED TO NON-PREFER ATENOLOL, BUT GRANDFATHER IT TO ALLOW PATIENTS CURRENTLY USING IT TO CONTINUE USING IT. SEND OUT AN EDUCATIONAL LETTER TO PRESCRIBERS OUTLINING CONCERNS ON THE USE OF ATENOLOL IN HYPERTENSION. RETAIN CARVEDILOL AND ADD NEBIVOLOL ON THE PDL. IN ADDITION, DECLARE A CLASS EFFECT FOR THE REMAINDER OF THE AGENTS. SECONDED BY DR. DEMAIN. THE MOTION PASSED WITH THREE OPPOSED.

Break from 9:21 a.m. to 9:44 p.m.

12. Re-review Low Sedating Antihistamines (Green Category)

Dr. Sater gave the First Health presentation on Low Sedating Antihistamines. At the last review, the motion for a class effect, including one single entity product, passed unanimously. In March, there were 433 claims: 35% for Fexofenadine, 26% for Xyzal (ph), 24% for Clarinex tablets, and less than 10% for the rest.

Dr. Demain noted that there had been a previous discussion about making over the counter products available by prescription, which could yield a significant savings.

Mr. Campana said there was a regulation going slowly through the system that would cover various over the counter products. The regulation could be adopted any time in the next six months.

DR. DEMAIN MOVED A CLASS EFFECT, INCLUDING AT LEAST ONE SINGLE ENTITY PRODUCT ON THE PDL. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

13. Re-Review of Short Acting Beta Agonists (Green Category)

Dr. Sater gave the First Health presentation on Short Acting Beta Agonists. In March, there were 1,098 claims. For the NDI products there were 1,404 claims: 35% for Ventolin HFA, 27% for Xopenex, 21% for Proventil HFA, and 16% for ProAir. For the nebulized products, 74% for Albuterol, 16% for Xopenex, and 9% for the generic Accuneb. At the last review, the motion was for a class effect,

including at least one Albuterol HFA product and excluding Metaproterenol and Pirbuterol, and including only unit dose nebulizer products, passed unanimously.

Dr. Demain said there had been no significant changes in these products, except there are two that have been extended from the Montreal Proposal for removal of CFCs. Pirbuterol may get a continuation, because of the uniqueness of its auto inhaler.

DR. DEMAIN MOVED A CLASS EFFECT, WITH AT LEAST ONE ALBUTEROL HFA PRODUCT, AT LEAST ONE ALBUTEROL SOLUTION. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

14. Re-Review of Long-Acting Beta Agonists (Green Category)

Dr. Sater gave the First Health presentation on Long-Acting Beta Agonists. In March, there were 9 claims: 6 for Serevent and 3 for Foradil. At the last review, the motion for class effect, with preauthorization required, passed with one opposed.

The committee discussed whether the preauthorization requirement had changed the prescribing habits. Dr. Sater said the use had decreased. It is now on an electronic step-edit and if there is an inhaled corticosteroid on board or it is inferred from the other drugs that the patient has COPD, the claim will be paid without anyone having to call. Dr. Demain said long-acting beta agonists were still an important step in the management of COPD. A long-acting bronchodilator, used alone, is recommended prior to the addition of an inhaled steroid.

DR. DEMAIN MOVED A CLASS EFFECT. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

15. Re-Review of COPD Inhalants (Green Category)

Dr. Sater gave the First Health presentation on COPD Inhalants. In March, there were 371 claims: 46% for Combivent, 30% for Spiriva, 14% for generic Duoneb, 5% for Atrovent HFA, 5% for generic Ipratropium nebulization, and .5% for branded Duoneb. At the last review, the motion for a class effect, preferentially including Spiriva and one combination product, passed unanimously.

Dr. Demain noted that there is a recent FDA watch looking at the increased risk of strokes in patients using these drugs, in particular Ipratropium and Tiotropium. However, that has not changed the recommendations for the management of COPD and no specific box warning has been issued yet. The use of these drugs in the management of COPD is essential and has had a large impact in the last decade. Spiriva is very well tolerated and shows clinical benefits over using an Ipratropium four times daily. However, it is also important to have a combination product, because COPD patients with exacerbations may not respond well to Albuterol alone. Mild COPD patients also can use the combined product alone as an ongoing, four times a day therapy. There is not enough information at this time to change our recommendation from the last review.

DR. DEMAIN MOVED A CLASS EFFECT, TO INCLUDE A LONG-ACTING ANTICHOLINERGIC AGENT SUCH AS A TIOTROPIUM AND TO INCLUDE A COMBINED AGENT OF ALBUTEROL AND IPRATROPIUM. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.

16. Re-Review of Leukotriene Inhibitors (Green Category)

Dr. Sater gave the First Health presentation on Leukotriene Inhibitors. In March, there were 866 claims: 861 for Singulair. At the last review, the motion for a class effect, with Singulair being preferentially preferred, passed unanimously.

Dr. Demain said both Montelukast and Zafirlukast were equivalent in effectiveness. Montelukast was preferred, because of ease of administration. It is an oral drug that is usually taken at bedtime. Zafirlukast is taken twice daily, 30 minutes before a meal or 2 hours after a meal with a significant impact on bioavailability if it is not taken in that manner.

Dr. Liljegren said another advantage of Singulair is the age indication for children.

Dr. Demain noted that Montelukast granules were now available for infants. There was a concern about increased risk of suicide in children related to Montelukast. A study was conducted by the FDA and found there was no correlation in the risk of suicide in children and Montelukast.

DR. DEMAIN MOVED A CLASS EFFECT WITH SINGULAIR BEING PREFERENTIALLY PREFERRED. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

17. Re-Review of 2nd & 3rd Generation Cephalosporins (Green Category)

Dr. Sater gave the First Health presentation on 2nd Generation Cephalosporins. In March, there were 74 claims: 28 for Cefprozil suspension, 31% for Cefuroxime tablets, 15% for Cefuroxime Axetil suspension, 11% for Cefprozil tablets, 2.7% for Cefaclor suspension, 1.4% for Cefaclor capsules, and 1.4% for Cefzil suspension. At the last review, the motion for a class effect, preferentially excluding Cefaclor and including Cefzil suspension, passed unanimously.

The committee discussed why Cefaclor had been excluded. There is a relationship between Cefaclor and a significant adverse effect.

DR. BERGESON MOVED A CLASS EFFECT, EXCLUDING CEFACTOR, AND INCLUDING ONE PLEASANT TASTING ORAL PREPARATION. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

Dr. Sater gave the First Health presentation on 3rd Generation Cephalosporins. In March, there were 378 claims: 65% for Cefdinir suspension, 17.5% for Omnicef suspension, and 13% for Cefdinir capsules. At the last review, the motion for a class effect, preferentially including a Cefdinir suspension product, passed with one opposed and one abstaining.

DR. BERGESON MOVED A CLASS EFFECT, PREFERENTIALLY INCLUDING A CEFDINIR SUSPENSION PRODUCT. SECONDED BY DR. DEMAIN. THE MOTION PASSED UNANIMOUSLY.

18. Re-review of Macrolides (Green Category)

Dr. Sater gave the First Health presentation on Macrolides. In March, there were 743 claims for the adult Macrolides (tablets): 92% for Azithromycin tablets and 6.3% for Clarithromycin tablets. In the suspension category, there were 599 claims: 82% for Azithromycin suspension, 14% for Zithromax suspension, and 3.5% for Clarithromycin suspension. At the last review, the motion for a class effect, preferentially including Azithromycin, passed unanimously.

DR. GREEAR MOVED A CLASS EFFECT, PREFERENTIALLY INCLUDING AZITHROMYCIN. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

19. Re-review of 2nd & 3rd Generation Quinolones (Green Category)

Dr. Sater gave the First Health presentation on 2nd Generation Quinolones. In March, there were 158 claims: 151 for Ciprofloxacin. At the last review, the motion for a class effect, preferentially excluding Noroxin, passed with one abstaining. The preferred agents are Ciprofloxacin and Ofloxacin.

DR. BERGESON MOVED A CLASS EFFECT, PREFERENTIALLY EXCLUDING NOROXIN. SECONDED BY DR. DEMAIN. THE MOTION PASSED UNANIMOUSLY.

Dr. Sater gave the First Health presentation on 3rd Generation Quinolones. In March, there were 181 claims: 176 for Levaquin. At the last review, the motion for a class effect, preferentially including Levaquin, passed with three opposed.

DR. DEMAIN MOVED A CLASS EFFECT, PREFERENTIALLY INCLUDING LEVAQUIN. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

20. Re-Review of Oral Anti-fungal Onychomycosis (Green Category)

Dr. Sater gave the First Health presentation on Oral Anti-fungal Onychomycosis. In March, there were 53 claims: 62% for generic Lamisil, 14% for Griseofulvin oral suspension, 10% for Itraconazole, 2% for Grifulvin V suspension, 4% for Grifulvin V tablets, 4% for branded Lamisil, and 2% for Gris-PEG. In addition, there were 3 claims for the topical anti-fungals, 2 for Penlax and 1 for generic Penlax. At the last review, the motion for a class effect, with Griseofulvin not being the only agent on the PDL, passed with one opposed.

DR. BERGESON MOVED A CLASS EFFECT, WITH GRISEOFULVIN NOT BEING THE ONLY AGENT ON THE PDL. SECONDED BY DR. CARLSON.

Dr. Liljegren asked if Utilization Review had reviewed these drugs. Subsets of people need them for medical reasons, but many people use them for cosmetic reasons.

Dr. Demain said there was literature on Onychomycosis being associated with and linked to fully controlled, severe asthma. If you treat the Onychomycosis, the asthma improves. There are other indications besides cosmetic ones, such as diabetic patients and those with respiratory disease. Mr. Campana noted that the price of these drugs had decreased substantially, so it might be better to cover it as we have in the past rather than requiring a prior authorization.

THE MOTION PASSED UNANIMOUSLY.

21. Re-Review of Anti-Herpes Oral Medication (Green Category)

Dr. Sater gave the First Health presentation on Anti-Herpes Oral Medication. In March, there were 249 claims: 59% for Valtrex, 28% for Acyclovir tablets and capsules, 7.2% for Acyclovir suspension, 3.6% for Famciclovir, and 2.5% for Famvir. At the last review, there was a brief discussion of use of agents in pregnancy. The motion for a class effect passed unanimously.

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

Dr. Liljegren asked if any of the medications, except for Acyclovir, were indicated for children under the age of 12. If not, we need to consider including one for pediatric use. Dr. Sater said the only agent indicated for patients down to 12 was Valtrex and that was only for Herpes Labialis.

DR. LILJEGREN MOVED TO AMEND THE MOTION TO DECLARE A CLASS EFFECT, PREFERENTIALLY INCLUDING ACYCLOVIR ON THE PDL. SECONDED BY MS. STABLES. THE MOTION FAILED WITH 9 OPPOSED.

THE MOTION FOR A CLASS EFFECT PASSED WITH 1 OPPOSED.

22. Re-Review of Ophthalmic Anti-Allergy Agents (Green Category)

Dr. Sater gave the First Health presentation of Ophthalmic Anti-Allergy Agents. In March, there were 79 claims: 76 for some form of Olopatadine, Patanol or Pataday. At the last review, the superiority of Patanol was briefly discussed. At the last review, the motion for a class effect, with an Olopatadine product preferentially included for all ages, passed unanimously.

DR. DEMAIN MOVED A CLASS EFFECT, WITH AN OLOPATADINE PRODUCT PREFERENTIALLY INCLUDE FOR ALL AGES. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

23. Re-Review of Ophthalmic Mast Cell Stabilizers (Green Category)

Dr. Sater gave the First Health presentation on Ophthalmic Mast Cell Stabilizers. There were no claims in March. At the last review, the motion for a class effect passed unanimously.

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

24. Re-Review of Ophthalmic Quinolones (Green Category)

Dr. Sater gave the First Health presentation on Ophthalmic Quinolones. In March, there were 82 claims: 38% for Vigamox, 34% for Ofloxacin drops, 22% for Ciprofloxacin drops, and 6% for Zymar. At the last review, the motion for a class effect passed unanimously.

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

25. Re-Review of Ophthalmic Immunomodulators (Green Category)

Dr. Sater gave the First Health presentation on Ophthalmic Immunomodulators. There is one drug in this class. In March, there were 21 claims for Restasis. At the last review, the motion to prefer Restasis passed unanimously.

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

26. Re-Review of Otic Quinolones (Green Category)

Dr. Sater gave the First Health presentation on Otic Quinolones. In March, there were 235 claims: 50% for Ciprodex, 45% for Ofloxacin Otic drops, 3.4% for Cipro HC, and 1.7% for Floxin drops. At the last review, the motion for a class effect passed unanimously.

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

DR. LILJEGREN MOVED TO AMEND THE MOTION TO DECLARE A CLASS EFFECT, AND INCLUDE ONE TOPICAL AGENT WITH A STEROID AND ONE WITHOUT A STEROID. SECONDED BY DR. DEMAIN. THE MOTION, AS AMENDED, PASSED UNANIMOUSLY.

27. Re-Review of Ribavirins

Dr. Sater gave the First Health presentation on Ribavirins. In March there, were 11 claims for generic Ribavirin. All of the agents are preferred. At the last review, the motion for a class effect passed unanimously.

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

28. Review Minutes from January 2009 Meeting

Mr. Campana reviewed the corrections to the meeting minutes.

THE MEETING MINUTES OF JANUARY 2009 WERE APPROVED, AS CORRECT.

29. Comments from Committee Members or Chair

Mr. Campana said the DUR Committee was now being provided their packets electronically. The Pharmacy and Therapeutics Committee was asked if they would like to receive their packets electronically, with the meeting minutes and the clinical submissions still being on paper. Power strips could be arranged for committee members who wanted to bring their laptop computers to the meeting.

The committee further discussed the issue. It was decided that the green classifications would be sent electronically only. For the rest of the material, the committee members will be polled individually this summer to see what each prefers.

Mr. Campana asked for feedback on the new format utilizing the red classes, blue classes, and green classes. The committee members indicated they liked the new format.

Mr. Campana thanked everyone for his or her work on the committee. This has been a great way to keep the costs down and is a great partnership between the Department and the drug manufacturers. The committee was formed 6 years ago and has gone from reviewing the easy classes to the more difficult classes, which has saved \$14 million. Most of the major manufacturers are involved in the National Medicaid Pooling Initiative. More than 50 classes are addressed in the PDL. This summer, we will be sending out letters to see if the committee members would like to continue serving on the committee for another 3 years.

The next scheduled meetings will be September 11 and November 20, 2009. The 2010 meetings will be held in January and April, but the exact date has not been set.

Dr. Sater reviewed the list of preferred drugs on the PDL to date. The list will be updated, to include the drugs added at this meeting, and e-mailed to the committee by Friday. The updated PDL will be implemented in late July or early August.

30. Adjourn

The meeting adjourned at 10:53 a.m.