

**ALASKA MEDICAID  
PHARMACY AND THERAPEUTICS COMMITTEE**

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

**FINAL MINUTES OF MEETING  
September 11, 2009  
8:00 a.m.**

**Committee Members Present:**

Dharna V. Begich, Pharm.D  
Marvin Bergeson, MD  
Richard E. Brodsky, MD  
Robert H. Carlson, MD  
Traci Gale, PharmD. (telephonic)  
Vincent Greear, R.Ph.  
Daniel P. Kiley, DDS, MPH  
Diane Liljegren, MD (telephonic)  
Claudia Phillips, MD  
Sherrie D. Richey, MD  
Janice L. Stables, MSN, ANP  
Trish D. White, R.Ph. (telephonic)

**Committee Members Absent:**

Heidi Brainerd, MS R.Ph.  
Amber L. Briggs, Pharm.D.  
Lucy Curtiss, MD  
Jeffrey G. Demain, MD  
Andrzej Maciejewski, MD

**Others Present:**

David Campana, R.Ph.  
Melinda Sater, Pharm.D., First Health  
Alex Malter, MD, MPH  
Chad Hope, Pharm D.

**1. Call to Order – Chair**

The meeting was called to order at 8:02 a.m.

**2. Roll Call**

A quorum was present.

**3. Public Comment – Local Public / Health Practitioners**

**PAT NOLAN:** It would be untrue if I were to say that 95% of my patients with diabetic dyslipidemia are extremely compliant with enormous amounts of weight loss, proper meal planning, complete avoidance of alcohol, and complete lifestyle changes, which results in the lack of my use of these drugs. Lipotropic drugs are necessary for almost everybody with diabetic dyslipidemia at some point. The Fenofibric acid controversy was discussed. Fenofibric acid has been very effective and safe for my patients and should be on the formulary. The Rosuvastatin controversies in treatment were discussed. Rosuvastatin has been a real breakthrough for me. I've been able to use much lower doses of statins with Rosuvastatin in comparison to others. Rosuvastatin should remain on the formulary.

**DR. DIRK CRAFT:** An internist from Wasilla discussed statins. When you look at preventative treatment, cholesterol ranks high in importance. These classes of drugs might limit the number of statins available, but I do not believe eliminating an entire class of drugs is a good idea. When tailoring a cholesterol regiment, your success is hampered if you do not have all of the arms of treatment available. Statins are very similar in their effect, but the drugs within the class are not the same. I would support limiting regiments, but not an entire class of drugs.

#### **4. Review of Bile Acid Salts (Red Category)**

There were no public testimonies.

Dr. Sater gave the First Health presentation on Bile Acid Salts. This is a new class. There is one chemical entity, Ursodil. There are three distinct products, all of which have generic equivalents. Ursodil is a naturally occurring bile acid, which is formulated for therapeutic use. The indications differ between the agents. The Urso products are indicated for primary biliary cirrhosis. Actigall is indicated for the treatment of radiolucent, non-calcified gallbladder stones and for the prevention of gallstone formation in obese patients experiencing rapid weight loss after bariatric surgery. In July there were 26 claims: 20 for generic Actigall, 4 for generic Urso, and 2 for the brand name Urso. There was no previous discussion as this is a new class. No physicians wanted to talk about bile acid salts.

In response to Dr. Brodsky, Dr. Sater said bile acid salts were not considered generically interchangeable. However, within a practice, they are generally considered therapeutically interchangeable, although the dosing regiments are different for different indications.

**DR. KILEY MOVED THAT THE CLASS REPRESENTED A THERAPEUTIC ALTERNATIVE AND THERE IS NO PREFERENCE. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.**

#### **5. Review Pancreatic Enzymes (Red Category)**

There were no public testimonies.

Dr. Sater gave the First Health presentation on Pancreatic Enzymes. There are dozens of combinations and products in this category, all of which contain Amylase, Lipase, and Protease in various combinations of strengths. None of these products are considered interchangeable. All manufacturers in this class were required to submit a new drug application to the FDA by April 2009 and receive approval by April 2010 to continue marketing their drug. In July there were 67 claims: 30% for Viokase, 15% for Pancrelipase EC, 7.5% for Creon 10, 7.5% for Pancrease MT10, 7.5% for Pancrease MT16, 6% for Creon 20, 6% for Ultrase MT20, 4.5% for Pancrease MT4, 4.5% for Pangestyme EC, and less than 10% for the rest of the products. There was no previous discussion as this is a new class. No physicians wanted to talk about pancreatic enzymes.

**DR. LILJEGREN MOVED THAT THE CLASS REPRESENTED A THERAPEUTIC ALTERNATIVE AND THERE IS NO PREFERENCE. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.**

## 6. Re-review of Statins (Red Category)

**DAVID GROSS:** A representative of Pfizer discussed Lipitor. Pfizer has a robust amount of data that demonstrates the safety and efficacy of Lipitor. There are specific evidence-based reasons why prescribers choose Lipitor. We have conducted more than 400 clinical trial with 80,000 patients in long-term outcome studies. And we have studied most types of patient that commonly receive statins in clinical practice. There are several high-risk patient populations in which the only statin data available is with Lipitor. The results and evaluations of these studies have been instrumental in the development of recommended treatment guidelines being utilized by practitioners. Lipitor has five primary prevention indications and five secondary prevention indications, many of which came about due to the positive outcome studies in the high-risk populations. Since current treatment guidelines are much more aggressive in treating to lower goals, higher dosages are required and utilized, which leads to safety concerns. Lipitor has long-term safety data at all dosages and similar outcomes. The highest dose of 80 milligrams has been studied in more than 14,000 patients in long-term trials with excellent safety demonstrated. With this positive outcome and safety data in both primary and secondary prevention patients in a wide variety of patient populations using high and low dose regimens, the evidence behind Lipitor is unmatched and should be available on the Alaska PDL.

**DR. JAMIE HURST:** A representative of AstraZeneca discussed Crestor (Rosuvastatin). Previous studies have shown Crestor to be highly efficacious at lowering LDL cholesterol, raising HDL cholesterol, and slowing the progression of Atherosclerosis. AstraZeneca does not recommend the use of Crestor in any manner other than that prescribed in the full PI. The JUPITER study was discussed. It was a primary prevention study designed to determine if Rosuvastatin, 20 milligrams, decreased the risk of major cardiovascular events in patients with low to normal LDL, but who are at an increased risk as identified by elevated high-sensitivity C-reactive protein and age. The outcomes were reviewed. The ASTEROID trial was discussed. It evaluated the effects of Rosuvastatin, 10 milligrams, versus placebo in cardiovascular events in patients with end-stage renal disease undergoing chronic hemo dialysis. The outcomes were reviewed.

**DR. TIM EVANS:** An associate professor of medicine at the University of Washington, Seattle, discussed Vytorin. Coronary artery disease and ischemic cardiovascular disease is the leading cause of death in our country. The evidence has increasingly indicated that the lower the LDL, the better. At the same time, it has been apparent that there are many more people, other than those that have established coronary artery disease, who are in the highest risk group. When the third edition of the Adult Treatment Panel made their recommendations, they added people with peripheral vascular disease, symptomatic cerebral vascular disease, abdominal aortic aneurisms, and everyone with diabetes to that group. In the intermediate category where there were two risk factors, but not established coronary heart disease prevalent, the Framingham data is now used to sub-stratify those people. Consequently, we have a lower goal for LDL in these highest risk people and millions more who are in that highest risk group. Statins have been our most effective LDL lowering agent. They have a long track record, they work, and they are quite safe. However, statins are often insufficient to get patients of their lower target goal, even when titrating statins to their highest dosages. A combination of a statin and a cholesterol absorbing inhibitor, Ezetimibe has really been a major advance in our ability to get people to goal. It is currently our most effective way to lower LDL cholesterol. Vytorin, which is a combination of Ezetimibe and Simvastatin, will lower LDL cholesterol effectively to low levels and add a starting dose so that the statin component can be kept at a lower dose. It is possible to titrate it up, if necessary. At any titration level, the addition of Ezetimibe to a statin is more potent than the

statin alone. Vytorin should remain on the Alaska PDL, both for those patients who cannot get to goal on a statin, as well as people who have a very low target and a significant LDL starting point.

**DR. AN PHAM:** A representative of Merck-Schering-Plough discussed Vytorin. In the last 12 months, two new clinical data trials have been published. With these studies, as well as previous studies, the data continues to suggest and support excellent safety and efficacy profiles for Vytorin, especially for high-risk patients who need to bring their LDL level below 70. The two new studies and their outcomes were discussed. Vytorin should remain on the Alaska PDL.

Dr. Sater gave the First Health presentation on Statins. There are six available entities in the statin class. Fluvastatin and Lovastatin have XL formulations. There are four combination products: Advicor, Vytorin, Simcor and Caduet. There are three high potency products: Atorvastatin, Rosuvastatin and Simvastatin. There are three regular/lower potency products: Pravastatin, Fluvastatin and Lovastatin. They are clinically equivalent up to about a 40% LDL-c reduction. Higher potency agents are needed for greater reductions. All agents are indicated for the treatment of hyperlipidemia, however they have numerous secondary indications as outlined in the packet. In July there were 1,728 claims: 47% for Simvastatin, 24% for Lipitor, 18% for Crestor, 6% for Lovastatin, and less than 5% for the rest of the drugs. For the combination drugs, there were 22 claims for Caduet and 189 for Vytorin. After a brief discussion, the motion for class effect, including at least one high potency agent, passed unanimously. Since the last review, Livalo (Pitavastatin) was approved by the FDA, but is not yet commercially available. The JUPITER and the SEAS study were published. No physicians wanted to talk to us about statins.

**DR. KILEY MOVED A CLASS EFFECT, TO INCLUDE AT LEAST ONE HIGH POTENCY PRODUCT. SECONDED BY MS. STABLES. THE MOTION PASSED UNANIMOUSLY.**

## **7. Re-review of Anti-TNF Drugs (Red Category)**

**FRED SEGO:** A representative of Centocor discussed Simponi, which was approved in April 2009. Simponi is a full humanized anti-TNF that has a high affinity and specificity for both soluble and membrane-bound forms of TNF alpha. It has a half-life of about two weeks. It is available in a 100 milligram per milliliter solution. It is the first once monthly anti-TNF marketed and approved by the FDA. It is dosed at 50 milligrams subcutaneously and is available as pre-filled syringe or as an auto injector for self-administration. It is approved for three indications: moderately to severely active rheumatoid arthritis in adults in combination with methotrexate therapy, active psoriatic arthritis in adults alone or in combination with methotrexate, and active ankylosing spondylitis in adults. Simponi was studied in over 2,300 patients in five phase-three clinical studies. The studies were reviewed. Simponi should be added to the Alaska PDL.

**MARC JENSEN:** A representative of UCB Pharma discussed Cimzia. It is a unique anti-TNF agent in that it is the only pegylated anti-TNF biologic. The pegylation prolongs the circulation time of the protein and allows for reduced dosing frequency. In addition, it is the only anti-TNF biologic without an FC portion. Cimzia was approved for the treatment of Crohn's Disease in April 2008 and for the treatment of adult patients with moderately to severely active rheumatoid arthritis in May 2009. For the treatment of rheumatoid arthritis, its initial dose is 400 milligrams at weeks 0, 2 and 4, and then it can be dosed at 200 milligrams every other week or 400 milligrams once a month. It can be used as either monotherapy or in combination with methotrexate. Cimzia offers long-term, stable dosing. Several

studies and their outcomes were reviewed. Cimzia is now available as a liquid in a specially design pre-filled syringe to make it easier for patients to use. Cimzia should be added to the Alaska PDL.

**ANNIE OGOSTALICK:** A representative of Abbott discussed Humira. Humira has efficacy, safety and efficient maintenance dosing across a broad scope of indications. It is the first fully human monoclonal antibody targeted against TNF currently indicated in rheumatoid arthritis and juvenile idiopathic arthritis, psoriasis, psoriatic arthritis, Crohn's Disease, and ankylosing spondylitis. Within this broad scope of indications, key outcomes were reviewed. There has been immense amounts of safety data collected in diverse patient populations across indications. Rates of serious infection, tuberculosis, and lymphoma rates were all within the range of other documented data. Several studies and their outcomes were reviewed. The recommended dosing rates of Humira were reviewed. Humira is unique among the self-injected TNF inhibitors with its broad scope of indications, proven efficacy, in depth safety data across multiple indications, and efficient maintenance dosing across indications. Humira should be retained on the Alaska PDL.

**CARRIE JOHNSON:** A representative of Amgen discussed Enbrel. Enbrel has more than 16 years of collective clinical trial experience and has been used by more than 600,000 patients worldwide across indications. It just surpassed its 1.8 million patient years of post marketing exposure. Enbrel has five key attributes that makes it unique among the class of TNF antagonists. It is the only fully human soluble TNF receptor and mimics the effects of naturally occurring TNF receptors. It has not been shown to cause cell lysis of TNF expressing immune system cells. It has not been shown to induce neutralizing antibodies, which may affect drug efficacy over time. It has a broad scope of indications crossing both rheumatology and dermatology including rheumatoid arthritis, psoriatic arthritis, psoriasis, ankylosing spondylitis, and juvenile idiopathic arthritis. The length of Enbrel's safety and efficacy data for various indications was reviewed. It has demonstrated sustained clinical responses, which were reviewed. Another unique aspect of its efficacy is in retreatment. When psoriasis patients stop their therapy for periods up to five months, retreatment is effective and generally well tolerated. Enbrel provides predictable and stable dosing. There is no labeling allowing for increased doses of Enbrel in rheumatoid arthritis or other rheumatologic diseases. Enbrel's safety profile was reviewed. Rates of serious adverse events and serious infection over the last 10 years has remained low, stable, and not significantly different from placebo or methotrexate.

Dr. Sater gave the First Health presentation on Anti-TNF Agents. There are five agents in this class. The mechanism of action and dosing frequencies are dissimilar between agents and the indications vary as well. In July there were 59 claims: 71% for Enbrel, 29% for Humira, and one claim for Cimzia. After a brief discussion, the motion for class effect, preferentially including Humira and Enbrel, passed unanimously. Since the last review, Simponi has been added to the market. Cimzia has been approved for rheumatoid arthritis. All agents in the class added boxed warnings to their labeling regarding increased risk of lymphoma and other malignancies in children and young patients. Drs. David Grauman and Richard Burger wrote letters supporting the addition of Cimzia to the Alaska PDL mainly for the treatment of Crohn's Disease.

In response to Dr. Kiley, Dr. Sater said the preference of Enbrel and Humira was largely due to previous expert testimony from a dermatologist who preferred Enbrel.

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

Dr. Liljegren expressed concern that declaring a class effect was not a true statement, because not all of the drugs were indicated for Crohn's Disease. It was noted that the medically necessary clause could be used for patients with Crohn's Disease.

**THE MOTION FAILED WITH SIX OPPOSED.**

**DR. BERGESON MOVED THAT THE DRUGS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. KILEY.**

Dr. Liljegren felt the new motion was a correct statement, but should include medications with specific indications for rheumatoid arthritis, Crohn's Disease, and psoriatic arthritis.

**THE MOTION PASSED WITH THREE OPPOSED.**

**8. Re-review of Platelet Inhibitors (Red Category)**

**DR. JON BEATY:** A representative of Boehringer-Ingelhelm discussed Aggrenox. Aggrenox, 1 capsule BID, is indicated for the prevention of recurrent stroke in patients who had a previous ischemic stroke. It is not interchangeable with the individual components of aspirin. It has been shown to be twice as effective for stroke prevention as aspirin alone. There is an increased risk for headache with dipyridamole compared to placebo. Studies with extended release dipyridamole show headaches are generally mild and transient. Aggrenox should be avoided during the third trimester of pregnancy. Since it contains aspirin, patients who consume three or more alcoholic drinks every day should be counseled about the bleeding risks involved with chronic heavy alcohol use while taking aspirin. Most of the drug-drug interactions noted in the Aggrenox product insert concern aspirin. Dipyridamole has been reported to increase the plasma level in cardiovascular effects and an adjustment of dosage may be necessary. Several studies were discussed. Extended release dipyridamole and aspirin is recommended as a first line therapy for the prevention of non-cardio embolic cerebral ischemic events in the American Stroke Association's 2008 Stroke Guidelines Update. Aggrenox should be retained on the Alaska PDL.

**DAN JAMES:** A representative of Bristol-Myers discussed Plavix. Plavix is indicated for the reduction of thrombotic events in patients with acute coronary syndrome, recent stroke, or established peripheral arterial disease. The Plavix package insert has recently been changed by the FDA. The updated drug interaction data was reviewed.

**JOHN BROKARS:** A representative of Eli Lilly discussed Effient. It is indicated for the reduction of thrombotic cardiovascular events. The dosages were reviewed. Several studies and their outcomes were reviewed. There is no relevant effect of genetic variation on CYP enzymes or its inhibition of platelet aggregation. It can be administered with drugs that are inducers or inhibitors of CYP-450 enzymes. The side effects and safety profile was reviewed. It is not recommended for patients who are older than 75 years of age. Effient should be added to the Alaska PDL.

Dr. Sater gave the First Health presentation on Platelet Inhibitors. There are four available single entity products and one combination with aspirin. Indications vary widely by agent. Mechanisms vary as well. All agents have been studied in combination with aspirin. National guidelines for stroke, unstable angina, ST-segment and non-ST-segment elevation myocardial infarction and post-stent placement all

recommend anti-platelet therapy. In July there were 278 claims: 92% for Plavix, 5% for Aggrenox, 3% for Cilostazol, and 1 claim for Dipyridamole. At the last review, the importance of having Plavix on the PDL was briefly discussed. The motion for a class effect, preferentially including Plavix, passed unanimously. Since the last review, Effient (Prasugrel) was approved by the FDA. Alternative dosing for Aggrenox was approved for intractable headaches. Evidence to suggest a decreased anti-platelet activity with Plavix co-administered with PPIs was released in early 2009, but is a very controversial topic. No physicians wanted to discuss platelet inhibitors.

**MR. GREAR MOVED A CLASS EFFECT, PREFERENTIALLY INCLUDING PLAVIX. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.**

### **9. Re-Review of Endothelin Receptor Antagonists (Red Category)**

**EVETTE BROOKS:** A representative of Actelion discussed Tracleer. Tracleer is indicated for the treatment of pulmonary arterial hypertension. It is the only ERA indicated for functional classes two, three, and four, with functional class two being added since the last review. Tracleer has been evaluated in six randomized controlled trials in various patient populations, which were reviewed. It is the only ERA that has been shown to significantly improve key hemodynamic parameters in three randomized placebo-controlled trials. It is also the only ERA, to date, that's been studied in a trial dedicated solely to functional class two patients. In this study, it significantly reduced the risk of clinical worsening in early stage patients, thereby slowing down disease progression, which has not been seen before. It is the only ERA that significantly improves functional class. The safety profile has been established in over 55,000 patients. All ERAs have black box warnings for potential liver injury and pregnancy so risk evaluation strategies are in place, including monitoring requirements and patient education. The drug interaction profile was reviewed. There is no dosage adjustment necessary for use with common PH drugs. Tracleer has been shown to be safe and effective across a wide spectrum of PH functional classes and patient segments. Tracleer should be placed on the Alaska PDL or grandfathering provision be put in place for patients that are currently stable on Tracleer.

**AARON HUWA:** A representative of Gilead Sciences discussed Letairis. Letairis is indicated for the treatment of pulmonary hypertension patients exhibiting WHO function class two or three symptoms. It has been shown that class two and three patients comprise about 70% of all PAH patients. Several trials and their outcomes were reviewed. Letairis' product labeling includes two ERA black box warnings for potential liver injury and pregnancy, requiring monthly monitoring of both LFTs and pregnancy. Due to the risks of liver and birth defects, Letairis is available only through a restricted distribution program, Letairis Education and Access Program (LEAP). Only prescribers and pharmacies registered with LEAP may prescribe and distribute Letairis. It received the potential liver injury box warning despite a very low incidence of LTFs, 0.8% at 12 weeks. Letairis is pregnancy category X and may cause fetal harm if taken during pregnancy. Pregnancy must be excluded before the start of treatment and prevented during treatment using two reliable forms of contraception. The side effects were reviewed. Letairis lacks drug interactions with other commonly prescribed medications for PAH. It remains the only once daily ERA approved for PAH patients and is available at two FDA-approved doses. The current guidelines recommends Letairis for functional class two and three patients.

Dr. Sater gave the First Health presentation on Endothelin Receptor Antagonists. There are two unique agents in this class, both are indicated for the treatment of pulmonary arterial hypertension. Tracleer is

indicated for class two, three and four, while Letairis is indicated for class two and three patients. The receptor subtype specificity is different between the agents. No evidence is currently available suggesting one agent's superiority over the other. In July there were 2 claims, 50% for Tracleer and 50% for Letairis. At the last review, there was a very brief discussion. The motion for class effect passed unanimously. Since the last review, the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the AHA released a 2009 Expert Consensus Document on pulmonary hypertension, including recommendation for use of ERAs. Adcirca was added to the market, although not part of this discussion. Tracleer was approved for WHO class two PAH patients. No physicians wanted to discuss endothelia receptor antagonists.

**DR. KILEY MOVED A CLASS EFFECT. SECONDED BY MR. GREAR.**

Dr. Liljegren felt that therapeutic alternative would be more correct than class effect.

**DR. KILEY WITHDREW HIS MOTION. THE SECOND CONCURRED.**

**DR. KILEY MOVED THE DRUGS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY MR. GREAR. THE MOTION PASSED UNANIMOUSLY.**

**10. Re-Review of Fibric Acid Derivatives (Red Category)**

**ANNIE OGOSTALICK:** A representative of Abbott discussed Trilipix. It is indicated as an adjunct in combination with statins to reduce triglycerides and increase HDL in patients with mixed dyslipidemia and coronary heart disease, or a coronary heart disease risk equivalent that are on optimal statin therapy to achieve their LDL goal. It is also indicated as monotherapy to reduce triglycerides in patients with severe hypertriglyceridemia and to reduce elevated LDLs, as well as increase HDL in patients with primary hyperlipidemia or mixed dyslipidemia. No incremental benefit of Trilipix on cardiovascular morbidity and mortality over and above that demonstrated for statin monotherapy has been established. It is a single daily dose. The recommended dosages were reviewed. Several trials and their outcomes were reviewed. Trilipix is the only fibric acid derivative extensively studied and FDA approved for combination use with statins. Trilipix should be added to the Alaska PDL.

Dr. Sater gave the First Health presentation on Fibric Acid Derivatives. There are four available entities; four branded and one generic Fenofibrate, one Fenofibric Acid; and one generic Gemfibrozil. All are approved for the treatment of hypertriglyceridemia. Gemfibrozil is also approved for reducing coronary heart disease risk. Fenofibrate is also approved for hypercholesterolemia. Fenofibric acid is also indicated for combination therapy with statins, primary or mixed dyslipidemia. Lovaza, an omega-3-acid ethyl ester combination, is approved for the treatment of hypertriglyceridemia (over 600 mg/dL) in adults. In July there were 350 claims: 43% for Tricor, 30% for Gemfibrozil, 22% for Lovaza, 5% Trilipix. At the last review, without discussion, the motion to continue the currently preferred agents passed unanimously. Trilipix has been added to the marketplace since the last review. No physicians wanted to discuss fibric acid derivatives.

In response to Dr. Brodsky, Dr. Sater said at the last meeting this was a green class so there was no review. The previous motion was to include one Fenofibrate and Gemfibrozil.

Dr. Liljegren felt Gemfibrozil was an inferior drug and should not be included in the motion.

**DR. LILJEGREN MOVED A CLASS EFFECT WITH ONE FENOFIBRATE BEING INCLUDED. THERE WAS NO SECOND.**

**MR. GREER MOVED THE DRUGS WERE THERAPEUTIC ALTERNATIVES WITH AT LEAST ONE FENOFIBRATE AND GEMFIBROZIL BEING INCLUDED. SECONDED BY MS. STABLES. THE MOTION PASSED UNANIMOUSLY.**

There were no blue categories for consideration.

**11. Re-review of Alpha Blockers (Green Category)**

Dr. Sater gave the First Health presentation on Alpha Blockers. There have been no changes since the last review. In July there were 276 claims: 46% for Flomax, 24% for Prazosin, 20% for Doxazosin, and 6% for Terazosin. Last year there was no discussion. The motion to continue the previous year's motion, which was a class effect including at least one alpha 1-A selective agent, passed unanimously.

In response to Dr. Bergeson, Dr. Sater said there was a good probability that an alpha 1-A selective agent would be included on the PDL if a class effect was declared.

**DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. KILEY.**

Dr. Liljegren felt the motion should include at least one alpha 1-A selective agent.

**THE MAKER OF THE MOTION AND THE SECOND WITHDREW THE MOTION.**

**DR. BERGESON MOVED A CLASS EFFECT, INCLUDING AT LEAST ONE ALPHA 1-A SELECTIVE AGENT. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.**

**12. Re-review of Androgen Hormone Inhibitors (Green Category)**

Dr. Sater gave the First Health presentation on Androgen Hormone Inhibitors. There have been no changes since the last review. In July there were 51 claims: 69% for Avodard and 31% for Finasteride. At the last review and without discussion, a motion for class effect passed unanimously.

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

**13. Re-review of Electrolyte Depleters (Green Category)**

Dr. Sater gave the First Health presentation on Electrolyte Depleters. There are four single entities in this class. Two are different salts of the same active drug. There is nothing new in this class since the last review, with the possible exception of generic PhosLo. In July there were 81 claims: 35% for Renvela, 27% for PhosLo, 21% for generic PhosLo, and 17% Renagel. At the last review, there was very little discussion. The motion for class effect with regard to Sevelemer products, and to preferentially include Fosrenol and PhosLo, passed unanimously.

Dr. Liljegren felt the drugs were therapeutically equivalent and that none of the drugs should be preferred.

**DR. LILJEGREN MOVED THE DRUGS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY MS. STABLES.**

Dr. Kiley felt there had been solid arguments at the last review to support including preferential choices in the motion. In the absence of compelling testimony, he was disinclined to change last year's motion. Dr. Liljegren said prescribing for this class was very complex, because many patients needed multiple drugs. Preferentially including any drug would not make a difference, because the physicians would prescribe what their patients needed utilizing the medically necessary clause.

**THE MOTION PASSED WITH FOUR OPPOSED.**

**14. Re-review of Niacins (Green Category)**

Dr. Sater gave the First Health presentation on Niacins. There are many available OTC products. There are two combination products: Advicor and Simcor. Niaspan is also available. There have been no changes since the last review. In July there were 68 claims: 87% for Niaspan and 13% for Simcor. At the last review, there was no discussion. The motion to continue with the currently preferred agents passed unanimously.

In response to Dr. Brodsky, Dr. Sater said a motion to continue with the currently preferred agents would keep the same agents on the PDL regardless of the outcome of the bid.

**DR. LILJEGREN MOVED A CLASS EFFECT, WITH AT LEAST ONE EXTENDED RELEASE NIACIN BEING INCLUDED. SECONDED BY DR. KILEY. THE MOTION PASSED UNANIMOUSLY.**

*Break from 9:37 a.m. to 10:03 a.m.*

Dr. Carlson arrived at the meeting.

**15. Re-review of LMW Heparins (Green Category)**

Dr. Sater gave the First Health presentation on LMW Heparins. There have been no changes since the last review. There are three available agents. In July there were 28 claims: 27 for Lovenox and 1 for Fragmin. At the last review, there was very little discussion. The motion to continue currently preferred agents passed unanimously.

In response to Dr. Brodsky, Dr. Sater said the original motion for this class was for Lovenox and whatever else bid out, based on lots of testimony from different provider groups in the community.

**DR. LILJEGREN MOVED THE DRUGS WERE THERAPEUTIC ALTERNATIVES WITH LOVENOX BEING PREFERENTIALLY INCLUDED ON THE PDL. SECONDED BY DR. BEGICH. THE MOTION PASSED UNANIMOUSLY.**

**16. Re-review of Hematopoietic Agents (Green Category)**

Dr. Sater gave the First Health presentation on Hematopoietic Agents. There are two entities and three branded products available. There have been no changes since the last review. In July there were 9 claims: 67% for Procrit, 22% for Epogen, and 11% for Aranesp. The currently preferred agents are Procrit and Aranesp. At the last review and without discussion, the motion to continue the currently preferred agents passed unanimously.

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

**17. Re-review of Alzheimer's Drugs (Green Category)**

Dr. Sater gave the First Health presentation on Alzheimer's Drugs. There are five available agents, including Namenda, which is not a cholinesterase inhibitor, but an NMDA receptor antagonist. There have been no changes since the last review. In July there were 71 claims: 97% for Aricept and Aricept ODT. There were also 42 claims for Namenda, an NMDA receptor. The currently preferred agents are Aricept, Namenda, and Exelon. At the last review and without discussion, the motion to continue the currently preferred agents passed unanimously.

In response to Dr. Brodsky, Dr. Sater said the committee specifically included Aricept and Namenda in previous discussions.

Dr. Carlson said the clinical efficacy was modest at best when looking at the most positive literature. He felt the drugs could be deemed therapeutic equivalents, but then some patients might require a medication change.

**DR. LILJEGREN MOVED A CLASS EFFECT, PREFERENTIALLY INCLUDING NAMENDA. SECONDED BY DR. BERGESON.**

The committee discussed last year's motion. The previous year's motion was a class effect, preferentially including Aricept and Namenda. Dr. Sater felt there would not be much change in this class regardless of the motion.

**THE MOTION PASSED UNANIMOUSLY.**

**18. Re-review of Bile Acid Sequestrants (Green Category)**

Dr. Sater gave the First Health presentation on Bile Acid Sequestrants. There are three chemical entities available with many dosage forms. All agents are indicated for primary hypercholesterolemia and have similar mechanisms. There have been no changes since the last review. In July there were 10 claims: 50% for Colestipol, 30% for Welchol, and 20% for Colestid. At the last review and without discussion, a motion for class effect passed unanimously.

**DR. KILEY MOVED A CLASS EFFECT. SECONDED BY MR. GREEAR. THE MOTION PASSED UNANIMOUSLY.**

**19. Re-review of MS Drugs (Green Category)**

Dr. Sater gave the First Health presentation on MS Drugs. There are four available products. There have been no changes since the last review. In July there were 20 claims: 40% for Copaxone, 35% for Rebif, 20% for Avonex, and 5% for Betaseron. At the last review and after a brief discussion of whether or not Copaxone should be a separate class, the motion for a class effect passed with five opposed.

**DR. LILJEGREN MOVED A CLASS EFFECT WITH COPAXONE BEING PREFERENTIALLY INCLUDED IN THE PDL. SECONDED BY DR. WHITE. THE MOTION FAILED WITH FIVE OPPOSED.**

**DR. BERGESON MOVED THE DRUGS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY MS. STABLES.**

Dr. Liljegren said Copaxone was a different molecule mechanism of action. Although it is a therapeutic alternative, not having it included on the PDL is not an option since many patients cannot tolerate the interferons. It was noted that the medically necessary clause could be used to prescribe Copaxone.

**THE MOTION PASSED WITH TWO OPPOSED.**

**20. Re-review of Parkinson Drugs (Green Category)**

Dr. Sater gave the First Health presentation on Parkinson Drugs. There are two available products in this class. There have been no changes since the last review. In July there were 180 claims: 64% for Mirapex, 34% for generic Requip, 1 claim each for branded Requip and Requip XL. At the last review, there was a brief discussion of how class effect would include new products. The motion for a class effect passed unanimously.

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

**21. Re-review of Bisphosphonates (Green Category)**

Dr. Sater gave the First Health presentation on Bisphosphonates. There are three oral Bisphosphonates single agents and two combination products. There have been no changes since the last review. In July there were 275 claims: 70% for generic Fosamax (Alendronate), 12% for Fosamax Plus D, 7% for Actonel, 7% for Boniva, 4% for Fosamax Tablet, and less than .5% for Fosamax Solution. At the last review and without discussion, a motion to continue the currently preferred agents passed unanimously.

In response to Dr. Brodsky, Dr. Sater said two reviews ago, the motion had been for a class effect.

**MS. STABLES MOVED A CLASS EFFECT. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.**

**22. Re-review of Lipotropics Other (Green Category)**

Dr. Sater gave the First Health presentation on Lipotropics Other. There have been no changes since the last review. In July there were 133 claims for Zetia. At the last review and without discussion, a motion for class effect passed unanimously.

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

**23. Re-review of Topical Agents for Psoriasis (Green Category)**

Dr. Sater gave the First Health presentation on Topical Agents for Psoriasis. There are three distinct chemical entities in this class, one is available as a combination with Betamethosone. There have been no changes since the last review. In July there were 11 claims: 45% for Dovonex, 27% for Calcipotriene Soln, 18% for Vectical and 9% for Taclonex. At the last review and after a brief discussion, the motion for class effect, preferentially including Dovonex in both forms, passed unanimously. Dr. Peter Ehrnstrom uses primarily Dovonex and Tazorac. He would like to see at least one and preferably both included on the PDL. He feels they are superior products for patients with limited psoriatic disease.

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

**24. Re-review of Calcitonins (Green Category)**

Dr. Sater gave the First Health presentation on Calcitonins. There are two available products in this class. There have been no changes since the last review. In July there were 13 claims: 54% for generic Calcitonin, 23% for Miacalcin, and 23% for Fortical. At the last review and without discussion, a motion for class effect passed unanimously.

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

**25. Review Minutes from April 2009 Meeting**

Mr. Campana reviewed the corrections to be made to the April 2009 meeting minutes.

**DR. KILEY MOVED TO APPROVE THE APRIL 2009 MEETING MINUTES AS CORRECTED. SECONDED BY MS. STABLES. THE MOTION PASSED UNANIMOUSLY.**

**26. Comments from Committee Members or Chair**

Mr. Campana said after polling the committee members, everyone decided to stay on the committee except for three people. Certificates recognizing their service on the Pharmacy and Therapeutics Committee will be sent to Dr. Gale, for serving 6 years; Ms. Brainerd, for serving 6 years; and Dr. Curtiss, for serving 3 years. The replacement committee members should be announced at the November 20 meeting.

**27. Adjourn**

**DR. BERGESON MOVED TO ADJOURN THE MEETING. SECONDED BY DR. KILEY.  
THE MOTION PASSED UNANIMOUSLY.**

The meeting adjourned at 10:33 a.m.