

**ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE**

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

**MINUTES OF MEETING
September 26, 2008
8:00 a.m.**

Committee Members Present:

Marvin Bergeson, MD
Amber L. Briggs, Pharm.D.
Richard E. Brodsky, MD
Kelly C. Conright, MD
Lucy Curtiss, MD
Jeffrey G. Demain, MD
Traci Gale, PharmD. (telephonic)
Vincent Greear, R.Ph.
Daniel P. Kiley, DDS, MPH
Diane Liljegren, MD (telephonic)
Janice L. Stables, MSN, ANP
Trish D. White, R.Ph. (telephonic)

Committee Members Absent:

Dharna Vakharia Begich, Pharm.D.
Heidi Brainerd, MS R.Ph
Robert H. Carlson, MD
Andrzej Maciejewski, MD
Sherrie D. Richey, MD

Others Present:

David Campana, R.Ph.
Melinda Sater, Pharm.D, First Health
Edward Bako, MS, R.Ph.
Alex Malter, MD, HCS

1. Call to Order – Chair

The meeting was called to order at 8:04 a.m.

2. Roll Call

A quorum was present.

The committee reviewed the new format of the informational book and the procedures.

3. Public Comment – Local Public / Health Practitioners

Patrick Nolan, MD: Discussed Niacin. As an endocrinologist, I have rarely been able to keep patients on Niacin for an extended period of time, because the side effect profiles are huge and a major issue, but Niacin is therapeutically efficacious and well tolerated with regard to other drug interactions. Extended release Niacin has come out in single tablets and combinations. I rarely use combinations, but I have used Simcor in patients who could not tolerate Niacin and it has been successful about 90% of the time. I encourage the committee to include Simcor on the PDL. For patients who can't take aspirin or are on other drugs, I have to be careful about interactions. Simvastatin, which is well

tolerated by most patients and relatively inexpensive, should be included on the PDL. Niaspan, also an effective drug, should be included on the PDL. Niacin in the extended release form is relatively inexpensive and very efficacious and should be included on the PDL.

4. Re-review of Fibric Acid Derivatives (Green Category)

There were no public testimonies.

Dr. Sater reviewed the Fibric Acid Derivatives. There have been no changes in the clinical information. The currently preferred agents are Tricor and generic Gemfibrozil. There were 252 claims in August: 58% for Tricor and 33% for Gemfibrozil. There is very good compliance in this class. There is nothing new in this class and no reason to review it.

DR. DEMAIN MOVED TO CONTINUE THE CURRENT STANDARD FROM LAST YEAR. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.

5. Re-Review of Alzheimer's Drugs (Green Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Alzheimer's Drugs. There has been no new information in this class and no reason to review or change the clinical recommendation. The preferred agents are Namenda, Aricept and both forms of Exelon, including the patch. There were 106 claims in August. There is 100% compliance in this class.

DR. CURTISS MOVED TO CONTINUE THE CURRENT STANDARD FROM LAST YEAR. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

6. Re-Review of Bisphosphonates (Blue Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Bisphosphonates. There is no new information in this class and at the last review there was very little discussion. Fosamax, in all three forms, is the preferred agent. There were 240 claims in August. There is good compliance in this class. Since there is no new clinical information, there is no need to do a full review. In response to Dr. Brodsky's question about the dosing, Dr. Sater said extended interval Fosamax was available. The motion last year was a class effect with the inclusion of at least one extended interval product.

DR. BRIGGS MOVED TO CONTINUE THE CURRENT STANDARD FROM LAST YEAR. SECONDED BY DR. STAPLES. THE MOTION PASSED UNANIMOUSLY.

7. Re-Review of Electrolyte Depleters (Blue Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Electrolyte Depleters. Renvela has been added to this class. It has the same active ingredient as Renagel, but uses a different salt. The preferred agents are currently PhosLo, Renagel and Fosrenol. There were 50 claims in this class in August with 86% of the market share being the preferred products and the remainder for the new drug Renvela. The motion last year was to include all three drugs on the PDL, which passed with three opposed.

The committee discussed the Electrolyte Depleters. There were no comments received from the nephrology community, who primarily uses the drugs. There is no expected difference with Renvela using the different salt.

DR. LILJEGREN MOVED A CLASS EFFECT OF THE SEVELAMER PRODUCTS, RENAGEL AND RENVELA; WITH ONE OF THE SEVELAMER PRODUCTS, PHOSLO AND FOSRENOL BEING PREFERRED. SECONDED BY DR. CONRIGHT. THE MOTION PASSED UNANIMOUSLY.

8. Re-review of Anti-TNF Drugs (Blue Category)

Annie Ogostalick: A representative of Abbott Laboratories discussed Humira. Humira has three key attributes: efficacy across a broad scope of indications, consistent safety across the indications, and comparatively efficient maintenance dosing across the indications. Humira is the first fully human monoclonal antibody targeted against TNF. It is currently indicated in rheumatoid arthritis, psoriasis, Crohn's disease, psoriatic arthritis and ankylosis spondylitis. This year Humira received approval for the indication of juvenile rheumatoid arthritis. Since the last review, Humira received approval for the two new indications of Crohn's disease and psoriasis, which were discussed. Within the broad scope of indications there has been an immense amount of safety data collected in diverse patient populations. Rates of serious infections, tuberculosis and nymphetomania rates were all within the range of other documented anti-TNF inhibitors in biologic naïve RA patient incident data. A recent analysis of Humira reconfirmed the safety of the product in global clinical trials across all indications. No new safety signals have emerged over time. The recommended maintenance dose of Humira for adult patients with rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosis spondylitis and Crohn's disease is consistently 40 milligrams administered once every other week in subcutaneous injection. There is a four week induction period for patients with Crohn's disease and an initially one-time 80 milligram dose for patients being treated for psoriasis. Humira should be retained as a preferred agent on the PDL.

Joseph Cha: A representative of UCB discussed Cimzia for the treatment of Crohn's disease. Although there are no head-to-head studies directly comparing anti-TNF agents, there are some obvious characteristics that differentiate Cimzia from the other anti-TNF therapies. First is a convenient, once every four week subcutaneous dosing. Second is a sustained efficacy with a stable dose. Third, there is a more cost efficient recapture strategy for those patients who had lost response. Fourth, there are low rates of injection site reactions. In the Cimzia clinical trials, about 50% of Crohn's disease patients were in remission at six months. Of these, 75-80% had maintained response for up to a year and a half. Cimzia represents a therapy that offers sustained efficacy with a stable dosing, which may translate into a stable cost over time. Crohn's disease patients often experience exacerbation of disease, also known as flares. Given one extra dose of Cimzia in the middle of the four-week dosing interval and then returning to the once every four week dosing, approximately 60% of patients were recaptured as responders. Of these, 70% were able to maintain response up to one

year. Cimzia is very well tolerated with less than 3% of patients reporting injection site reactions. Dr. Cha discussed the Simplicity Program, which is a free patient service center that offers strategies to increase appropriate utilization and compliance. The hallmark of this program is a home health nursing program where the nurses go out to the patient, administer the drug, and report back to the physician about the quality of care.

Dr. Sater gave the First Health presentation on Anti-TNF drugs. There are four agents in this class. Each has different mechanisms of action, but dosing frequencies are similar. The indications vary between agents. The currently preferred agents are Enbrel and Humira. There were 57 claims in August: 63% for Enbrel and 33% for Humira. At the last review, the utility of a step edit was briefly discussed. Last year's motion was a class effect with Enbrel being preferentially included, which passed unanimously. New to the market this year is Cimzia, which is only indicated for Crohn's disease, is indicated for healthcare worker administration, but they are actively pursuing and expect to have a self-injected dosage form out this year.

The committee discussed the Anti-TNF drugs. There are other agents indicated for Crohn's disease other than Cimzia. There was no input from rheumatologists or other physicians. Enbrel was preferred last year based on Dr. Armstrong's input and the heavily weighted market share of Enbrel, which has not changed. Dr. Demain said Enbrel and Humira were self administered, which is an advantage. Enbrel is often the start drug, but there is a failure of the drug after a period of time and the recapture is commonly done by switching to Humira.

DR. DEMAIN MOVED A CLASS EFFECT WITH HUMIRA AND ENBREL BEING PREFERRED. SECONDED BY DR. LILJEGREN.

Dr. Demain noted that once a patient is on an agent and successfully controlled, the agent should not be switched.

THE MOTION PASSED UNANIMOUSLY.

It was noted that Dr. Conright arrived at the meeting about four classes ago.

9. Re-Review of MS Drugs (Blue Category)

Elaine Thomas: A representative with Bayer HealthCare discussed Betaseron. A new study has been submitted, which was published in Lancet. Betaseron was the first drug approved for MS and has the longest safety record. Interferon beta-1b is different from interferon beta-1a, which is the composition of the other two interferons. The benefit study led the FDA to approve Betaseron for a new indication of treating patients presenting the very first clinic event of MS. If you start on Betaseron with your first clinical event, you have a much better relapse rates and the MRI burden is reduced. There was also a three-year effect on progression on the EDSS scale. The trial has shown that NABS are transient in patients on Betaseron and have no impact on the clinical outcomes in that study at three years. There is only a 17% persistently positive NABS status in this group, because over 50% of the patients that become positive actually revert back to negative. There is also a 16-year long-term follow up of our pivotal patients that shows a highly significant affect if Betaseron was start early in the disease treatment. The data also showed a much better outcome if the patient stayed on Betaseron for a longer

period of time. The AAN Guidelines recommend a high dose, high frequency interferon over the lower dose, low frequency interferons. I respectfully request that Betaseron should remain on the PDL.

Linda Finch: A representative of Biogen-IDEC discussed Avonex. Our new data suggests that there is a significant beneficial effect on the reduction of gray matter atrophy with Avonex. Gray matter atrophy is an emerging hot topic in MS research. It has been shown to be correlated to physical disability as well as cognitive decline. Avonex treated patients have an increase in gray matter volume by .2% versus a 1.4% decline in patients on placebo over a three-year treatment period. It is the only disease modifying therapy for MS. There has been controversy about the proper dose and frequency of the interferon for some time. There are several recent studies that demonstrate the higher dose of the disease modifying therapies do not provide any additional efficacy. The differences are in compliance issues. Avonex is the only drug that is dosed once weekly and patient adherence is significantly higher than with other drugs. We also have new results on quality of life measures. This data suggests that employees treated for MS with Avonex report the least amount of sick leave and short-term disability days. These differences suggest that patients on Avonex may have a higher productivity and lower disability rate than those treated with the other drugs. We recently concluded our 15-year Avonex study, which shows that patients who started on and stayed on Avonex have reduced disability.

Dr. Sater gave the First Health presentation on MS Drugs. There are four available products in this class. All are FDA approved for the treatment of relapsing forms of MS. They have similar clinical efficacy. Avonex and Rebif may cause less formulation of neutralizing antibodies. Copaxone is not an interferon like the others in this class. It modulates immune response through a different, but not fully understood, process. Currently Rebif, Copaxone, Avonex and Betaseron are all preferred agents. There were 21 claims in August: 43% for Rebif, 24% for Copaxone, 19% for Avonex, and 14% for Betaseron. In previous discussions, this class was deemed appropriate for the use of the medically necessary clause and the committee did not feel the need to prefer everything. The motion to declare a class effect for interferons and add Copaxone passed with one opposed.

The chair determined that another public testimony could be taken.

Cathy Kincaid: Secretary of the Board for the Alaska Multiple Sclerosis Center and a MS patient discussed the classification. I have tried Betaseron and had the worse reaction possible, which is the injection site necrosis. Next week I will start on Copaxone. MS is a debilitating disease and cannot be cured; we can only hope to stem the progression. All the drug therapies for MS should be included on the PDL so the patients have the broadest access possible.

Dr. Brodsky noted that any MS drug could be prescribed by a physician utilizing the medically necessary clause.

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

The committee discussed whether Copaxone, which is not an interferon, needed to be separated from the rest of the drugs in the motion. Dr. Sater noted that last year the motion was to declare a class effect for the interferons and add Copaxone.

THE MOTION PASSED WITH FIVE OPPOSED.

10. Re-Review of LMW Heparins (Blue Category)

There were no public testimonies.

Dr. Sater said there was no new information in this class. The currently preferred agents are Lovenox and Arixtra. There were 33 claims in August. There is 100% compliance.

The committee discussed the new review process and how the bid process worked. Dr. Sater said a classification that is not re-reviewed, and a new motion is not made, would retain the same drugs on the PDL. If there is a new motion, it would go out to bid.

DR. BRIGGS MOVED TO CONTINUE THE CURRENT STANDARD FROM LAST YEAR. SECONDED BY MR. GREAR. THE MOTION PASSED UNANIMOUSLY.

11. Re-review of Hematopoietic Agents (Blue Category)

There were no public testimonies.

Dr. Sater said there was no new information in this class. The currently preferred agents are Procrit and Aranesp, which accounts for 80% of the market share. There were 20 claims in August. Last year's motion was a class effect.

DR. BERGESON MOVED TO CONTINUE THE CURRENT STANDARD FROM LAST YEAR. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

12. Re-review of Niacins (Blue Category)

Annie Ogostalick: A representative of Abbott Laboratories discussed Simcor, which is combination Simvastatin and extended release Niaspan. Trials using statins to lower LDL cholesterol consistently show reductions in major cardiac events in various prospective long-term trials. However, even with the 25-35% relative reduction in cardiovascular events, this still leaves a residual risk of 65-75% of a cardiovascular event in patients appropriately treated with statin therapy. This residual cardiovascular risk is particularly high in patients with diabetes treated aggressively with statins. To address this majority of cardiovascular events that are still occurring, despite treatment with our most powerful existing therapies, guidelines were modified to recommend a combined medication strategy for patients who have issues beyond elevated LDL. Simcor reduces LDL, non-HDL, total cholesterol, triglycerides, and increases HDL in patients with primary hyper cholesterol and other issues. The safety and efficacy of the individual components of Simcor are well established. Multiple studies were performed to establish the safety and efficacy. Several studies were reviewed. Simcor represents a proven treatment option that is safe and effective and should be retained on the PDL.

Dr. Sater gave the First Health presentation on Niacins. Simcor has been added to the marketplace. Niaspan and Simcor are currently the preferred agents. There were 38 claims in August: 36 for Niaspan and 2 for Simcor. The motion last year was for a class effect and it passed unanimously.

DR. BERGESON MOVED TO CONTINUE THE CURRENT STANDARD FROM LAST YEAR. SECONDED BY DR. CONRIGHT. THE MOTION PASSED UNANIMOUSLY.

13. Review Bile Acid Sequestrants (Red Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Bile Acid Sequestrants. There are three chemical entities in this class with many dosage forms. All agents are indicated for primary hypercholesterolemia and have similar mechanisms. WelChol is also indicated for glycemic control in patients with type II diabetes. Cholestyramine is indicated for the release of pruritus in patients with partial biliary obstruction. Because of their mechanism of action, bile acid sequestrants have a potential for significant drug interactions. There were 14 claims in August: 65% for WelChol, 21% for Cholestyramine, and 14% for various Colestipol products. This is a new classification and no physicians wanted to talk about bile acid sequestrants.

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

14. Review Calcitonins (Red Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Calcitonins. There are two available branded products in this class, but both are calcitonin-salmon and are exactly the same product. They are both indicated for the treatment of osteoporosis, although they are widely used for a non-approved indication of bone pain. There were 17 claims in August: 59% for Miacalcin and 41% for Fortical. This is a new classification. Dr. Koval does not use either product with regularity and feels they are equal in efficacy, because they are the same drug and are mostly used for bone pain. She does not prefer one drug over the other.

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

15. Review of Endothelial Receptor Antagonists (Red Category)

Evette Brooks: A representative of Actelion discussed Tracleer, an endothelial receptor antagonist used in the treatment of pulmonary arterial hypertension. Tracleer has been evaluated in multiple randomized controlled clinical trials and is the only endothelial receptor antagonist that has actually been studied in patients with congenital heart defects, pediatric patients, and patients with HIV. It is the only endothelial receptor antagonist that has long-term data available and post marketing experience in over 40,000 patients worldwide. The safety profile of Tracleer has been well defined. It has been well characterized as far as drug-drug interactions and is the only ERA that has had PK studies done with several common drugs that are known for their drug interactions. Tracleer is the only ERA that significantly improves hemodynamic parameters, functional class status, and has long-term data. It has also been proven to delay time to clinical worsening in all studies that have been done.

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

indicated for class III and IV patients while Letairis is indicated for class II and III patients. The endothelia receptor subtype specificity differs slightly between the agents. In the last quarter, we filled 6 claims for drugs in this class. This is a new classification.

The committee discussed the Endothelial Receptor Antagonists. Dr. Sater noted that they were only discussing the oral treatments, excluding Sildenafil, because there is already a significant amount of restrictions around that for obvious reasons.

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

Break from 9:19 a.m. to 9:40 a.m.

16. Review Platelet Inhibitors (Red Category)

Kirk Dezanko: A representative of Boehringer-Ingelheim discussed Aggrenox. Strokes are the third leading cause of death in the United States and the leading cause of disability. Aggrenox is a single capsule given twice daily. It is indicated for the reduction of risks of reoccurring strokes in patients who have had a previous ischemic stroke or an ischemic thrombotic stroke. The capsule contains 25 milligrams of aspirin and 200 milligrams of the dipyridamole pellet. Each dipyridamole pellet has an extended release coating and a core of tartaric acid for increased absorption. In individuals with low gastric acid, the extended release dipyridamole provides about 50% higher bioavailability than the immediate release. Aggrenox inhibits thrombosis through the combined action of its two components. It has been shown to be twice as effective for secondary stroke risk reduction as low-dose aspirin alone. Several trials were discussed. There is an increased risk of headache with dipyridamole as compared to placebo. Studies with extended release dipyridamole indicate headaches are generally mild, self limiting and transient. Dipyridamole should be avoided in the third trimester of pregnancy. Aggrenox does contain aspirin and patients who consume three or more alcoholic drinks every day should be counseled about bleeding risks involved with chronic heavy alcohol use while taking aspirin. 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 2000 Stroke Guidelines Update. Aggrenox is on the PDL of the following First Health states: Georgia, Hawaii, Kentucky, Michigan, Minnesota, Montana, New Hampshire, New York, Nevada, Rhode Island, South Carolina, and the District of Columbia.

Dan James: A representative of Bristol-Myers Squibb discussed Plavix. Plavix has new FDA indications, as well as a lot of new data. The new FDA indication includes recent myocardial infarction, recent stroke, or established peripheral arterial disease. Under the acute coronary syndrome section, that indication has been expanded to include unstable angina and non-ST elevation MI patients, as well as ST elevation MI patients. It does not extend to those treated with primary angioplasty. Plavix has a level 1-A recommendation for the initial therapy of transient ischemic attack. Several trials were discussed. The side effect profile was greater with Aggrenox than it was with Clopidogrel. There was an increase in major bleeding, as well as inter-cranial hemorrhage with Aggrenox as compared to Clopidogrel from the Profess Trial. Ischemic patients that receive a drug alluding stent, Plavix is recommended to be continued for 12 months. For patients that receive a bare metal stent, the recommendation is a minimum of one month and ideally up to 12 months. The recommendation for patients that are treated with medical therapy, without stenting, should receive

daily Plavix for a minimum of one month and up to one year. Those in that category receiving bare metal stents should receive Plavix for a minimum of one month and ideally up to a year. In that same category, patients receiving drug eluting stents, should receive Plavix for at least one year. Plavix should be used with caution with patients who may be at risk of increased bleeding from trauma surgery or co-administration with Warfarin.

Dr. Sater gave the First Health presentation on Platelet Inhibitors. There are three available single entity products and one combination with aspirin. The indications vary widely by agent. The mechanisms vary as well. All agents have been studied in combination with aspirin. The National Guidelines all recommend anti-platelet therapy of some sort. There were 242 claims in August: 227 for Plavix. This is a new classification. The Alaska Heart Institute strongly recommends that Plavix be added to the PDL. They feel this product is essential to patient care and superior to other platelet inhibitors.

Dr. Liljegren agreed that it was essential that Plavix be included on the PDL. The committee discussed a new product that should be available before the end of the year. Dr. Sater said new products were not classified as preferred or non-preferred until they are reviewed by the committee.

DR. KELLY MOVED A CLASS EFFECT WITH PLAVIX BEING PREFERENTIALLY INCLUDED ON THE PDL. SECONDED BY DR. DEMAIN. THE MOTION PASSED UNANIMOUSLY.

17. Review of Topical Agents for Psoriasis (Red Category)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Topical Agents for Psoriasis. There are three distinct chemical entities that are covered in the class review, although Tazorac will be covered in another classification. The indications vary slightly, mostly based on dosage forms. Although the mechanisms are dissimilar between the agents, the efficacy for the treatment of psoriasis is similar. There is limited systemic absorption for all agents. There were 15 claims in August: 13 for Dovonex and 2 for Taclonex. This is a new classification. Dr. Ernstrom primarily uses Dovonex and Tazorac, which will be reviewed in a different class. He would like to see at least one, and preferably both, of those agents added to the PDL as he feels they are superior products for patients.

The committee discussed the Topical Agents for Psoriasis and agreed that Dovonex should be included on the PDL.

DR. DEMAIN MOVED A CLASS EFFECT WITH DOVONEX, IN BOTH FORMS, BEING PREFERENTIALLY INCLUDED ON THE PDL. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

18. Re-review of Alpha Blockers (Red Category)

Kirk Dezanko: A representative of Boehringer-Ingelheim discussed Flomax. Flomax is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). It is not indicated for the treatment of hypertension. About 50% of men in their 60, and as many as 90% of those in their 70s

and 80s, have symptoms of BPH. Moderate to severe lower urinary tract symptoms are experienced by about 26% of men in the age group of 40-49 and increases with age. BPH is a risk factor for acute urinary retention and sexual dysfunction, including erectile dysfunction and ejaculatory disorders. Several studies were discussed. Flomax has proven safety and efficacy through various studies. Flomax is generally well tolerated and long-term data demonstrates that no new adverse events occur with chronic use. The incidence of clinically significant hypertension or cardiovascular events is low and did not differ from placebo. Patients being treated with Flomax should be cautioned to avoid situations where injury could result should syncope occur. The most common side effects were dizziness, abnormal ejaculation, and rhinitis. The adverse reactions and precautions when using Flomax were reviewed. Flomax is dosed once daily and does not require titration. Flomax demonstrates a rapid onset of action with proven long-term safety and efficacy.

Dr. Sater gave the First Health presentation on Alpha Blockers. There are four available agents in this class with five available products, including an extended release Cardura. All products are FDA approved for the treatment of BPH. Only Cardura and Hytrin are indicated for hypertension. They have similar clinical efficacy. The currently preferred agents are Flomax, Uroxatral, and generic Cardura and Hytrin. There were 160 claims in August: 54% for Flomax, 32% for generic Cardura, 8% for generic Hytrin, and 6% for Uroxatral. There was no previous discussion. The motion for a class effect and inclusion of at least one non-cardio selective agent, Flomax or Uroxatral, passed unanimously. The new information is that Avodart and Flomax were approved for use in BPH. The clinical trials that lead to that approval by the FDA showed increased efficacy in the treatment of BPH and a slight increase in the adverse drug reaction withdrawal rates.

DR. CONRIGHT MOVED TO CONTINUE THE CURRENT STANDARD FROM LAST YEAR. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

19. Re-review of Statins (Red Category)

Long Nguyen: A representative of GlaxoSmithKline discussed Lovaza, which is not a statin product. It is an omega 3 acid ethyl esters comprised of a minimum of 84% of EPA/DHA. In comparison to fish oil and most of the dietary supplement products available over-the-counter, the over-the-counter products usually contains 30% or less of EPA/DHA. EPA/DHA is the major to essential fatty acids that have been proven to reduce triglycerides as well as non-HDL, and raise HDL, at a dose of 4 grams a day. Lovaza has been used in Europe for more than 10 years for the treatment of high triglycerides and other cardiovascular benefits. Lovaza effectively lowers triglycerides by 45% and increases HDL by 9%. Compared to other lipid lowering agents, Lovaza has a low incidence of side effects and minimal drug interactions. No adjustment in liver or renal dysfunction is needed for Lovaza therapy. Several studies were discussed. Based on the difference in safety and efficacy, Lovaza should be included on the PDL for patients with very high triglycerides.

In response to Dr. Demain, Mr. Nguyen discussed the benefits of using Lovaza as compared to taking fish oil or eating salmon.

The committee discussed whether Lovaza was being included with the Statins. Mr. Campana explained that Lovaza and Zetia were lumped into this class, but probably should have been listed under Other Lipotropic Drugs.

David Gross: A representative of Pfizer discussed Lipitor. The TNT Heart Failure Trial has resulted in Lipitor being given the indication for the reduction of hospitalization for CHF in patients with coronary heart disease, which is a unique indication in the statin category. In that trial, there was a 26% reduction in the incidents of hospitalization in people who had a previous diagnosis with CHF. The TNT Heart Failure Trial was further discussed. There have also been recently published real-world observational data studies, which have complimented the clinical outcome trials that we have seen with Lipitor. Since Lipitor was put on the PDL, we have received a lot of good feedback from providers that are happy to have access to Lipitor.

An Pham: A representative of Schering-Plough discussed Vytorin and Zetia. Vytorin is an excellent choice for mild to moderate hyperglycemia patients, but for more intense treatment Zetia should be used. There were three clinical studies this year related to Zetia and Vytorin, all of which have been published in the New England Journal of Medicine. The studies were discussed.

Dr. Sater gave the First Health presentation on Statins. There are six available entities. Both Fluvastatin and Lovastatin have extended release formulations. There are four available combination products: Advicor, Vytorin, Zocor and Caduet. Three of the statins are considered high potency: Atorvastatin, Rosuvastatin and Simvastatin. Three are considered regular or lower potency: Pravastatin, Fluvastatin and Lovastatin. They are clinically equivalent up to about a 40% reduction in LDL. High potency agents are usually needed for a greater reduction. All the products are indicated for the treatment of hyperlipidemia, as well as many other indications. The currently preferred agents are Zocor, Lipitor, Crestor, Vytorin, Lovastatin, Lescol and Lescol XL. There were 1,632 claims in August. Almost 80% of the claims were for high potency agents: Zocor, Lipitor, Simvastatin or Crestor. Vytorin had about 12.5% and the rest of the agents combined was less than 10%. Zetia had 141 claims and there were 18 claims for Lovaza. In the previous discussion, the role for lower and higher potency agents on the PDL was discussed. The motion for a class effect, preferentially including one high potency agent, passed with two opposed. Since the last review, the Enhance Trial was published and there was controversy over the interpretation of that data. No physicians wanted to talk about the statin category.

The committee discussed the Statin drugs. In response to Ms. White, Mr. Campana said the PDL would depend on how the bids came out. He was not sure if the protection they had with the Zocor brand name would continue.

Dr. Brodsky noted that the committee would discuss the statins first and then come back and address Zetia and Lovaza.

DR. CONRIGHT MOVED A CLASS EFFECT AND PREFERENTIALLY INCLUDING AT LEAST ONE HIGH POTENCY STATIN. SECONDED BY DR. STABLES. THE MOTION PASSED UNANIMOUSLY.

The committee addressed Zetia and Lovaza.

MR. GREAR MOVED A CLASS EFFECT. SECONDED BY DR. BRIGGS.

The committee discussed the motion. Dr. Sater said a motion of a class effect would mean that if it is cost beneficial or cost neutral to add the drug to the PDL, it would be added. If it puts you at a cost

disadvantage, it will not be added. In response to Dr. Malter, Mr. Campana said adding a drug to the PDL does not mean we support the use of the drug, but we are making it available without using the medically necessary clause. If a drug is determined to be ineffective or dangerous, the committee can exclude that drug from the PDL. Dr. Sater said the actual clinical data did not show an increased risk of cancer with Zetia, although some of the media has suggested that.

THE MOTION PASSED UNANIMOUSLY.

The committee discussed Lovaza.

DR. CONRIGHT MOVED A CLASS EFFECT. SECONDED BY DR. BERGESON. THE MOTION PASSED WITH ONE OPPOSED.

20. Re-review of Androgen Hormone Inhibitors (Red Category)

Jennifer Bzrana: A representative of GlaxoSmithKline discussed Avodart, which is indicated for the treatment of benign prostatic hyperplasia (BPH) in men with enlarged prostates. It is well established that prostate growth is driven by DHT. Therapy for symptomatic enlarged prostates includes alpha blockers, which improve symptoms, and 5-alpha reductase inhibitors, which inhibit DHT formation. Several trials were discussed. Avodart treats the cause of BPH and does not just reduce the symptoms. It is an important option in the treatment of BPH not only to address symptoms, but also the long-term outcomes for acute urinary retention and BPH related surgery. Based on the clinical findings, we recommend that Avodart be retained on the PDL.

Dr. Sater gave the First Health presentation on Androgen Hormone Inhibitors. There are two available chemical entities. Finasteride is available as a generic product. Both products are FDA approved for the treatment of BPH. They have similar pharmacokinetic profiles and clinical efficacy. There were 40 claims in August: 24 for Avodart, 27.5% for Finasteride, and 12.5% for branded Proscar. Both branded products, Avodart and Proscar, are currently preferred. At the last review there was a brief discussion about the clinical significance of switching between products. The motion for class effect passed unanimously.

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

21. Re-review of Parkinson Drugs (Red Category)

Jennifer Bzrana: A representative of GlaxoSmithKline discussed the advantages of extended release Ropinirole, the only dopamine agonist that is administered once a day for Parkinson's disease. There are two major issues complicating Parkinson's disease therapy. Motor complications are hypothesized to arise due to stimulation of dopamine receptors in striatal. One theoretical advantage of dopamine agonists compared to Levodopa is that the longer half life of dopamine agonists results in less stimulation of receptors and may lead to reduced off time and delay or prevent onset of motor complications. Parkinson's disease requires long-term therapy with multiple medications, resulting in a significant pill burden that has been linked to poor medication adherence. Ropinirole XL is an extended release formulation and allows a steady rate of absorption with fewer fluctuations in Ropinirole concentrations over 24 hours when compared to the immediate release Ropinirole given

three times a day. Extended release may provide an advantage for patients with significant pill burden, because of its once a day dosing schedule. Ropinirole extended release is approved for the treatment of idiopathic Parkinson's disease. There are three main clinical findings when extended release Ropinirole is compared to the immediate release formulation in subjects with Parkinson's disease who are also taking Levodopa, which were discussed. Extended release formulations are available in 2, 4 and 8 milligram tablets and offers patients and providers a simpler and potentially faster initial titration. Patients already on immediate release Ropinirole can discontinue at the end of one day and start on an equivalent dose of the extended release formulation the next morning. In light of Ropinirole extended release's proven efficacy, pharmacokinetic advantage, and easy administration, we recommend that once daily extended release Ropinirole be added to the PDL.

Ann Corbin: A representative for Boehringer Ingelheim discussed Mirapex. Mirapex is indicated for the treatment of chronic symptoms of Parkinson's disease, both early and advanced symptoms. It was approved for Parkinson's disease in 1997 and in 2006 for restless leg syndrome. Parkinson's disease is a progressive disease that is debilitating and devastating with motor and non-motor symptoms. Mirapex is rapidly absorbed and has a half-life of 8 to 12 hours. Urinary excretion is the major route of elimination. Mirapex has flexible doses with ease of titration. Rapid titration may be a key to an effective dose. Mirapex is mono therapy in early disease, which is known to help improve motor function activity, helps to delay the onset of motor complications, and helps to delay the need for Levodopa. Several trials were discussed. The most commonly reported adverse events were reviewed. Mirapex should be retained on the PDL for Parkinson's disease.

Dr. Sater gave the First Health presentation on Parkinson Drugs. There are two available chemical entities in this class. They are both approved for the treatment of Parkinson's disease and restless leg syndrome. They have similar pharmacokinetic profiles, with the exception of the new extended release product, and similar clinical efficacy. The currently preferred agents are Mirapex and Requip. There were 164 claims in August: 65% for Mirapex, 25% for generic Requip, 9.76% for branded Requip, and no claims for Requip XL. There was no previous discussion. The motion for a class effect passed unanimously. Since the last review, both generic Ropinirole and Requip XL have been added to the market. Dr. Light prefers Mirapex, because he feels it is a superior product with less titration required, but he would like to see both products retained on the PDL.

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

Dr. Bergeson asked how the new product would be affected by the motion. Dr. Sater said declaring a class effect would require the classification to go through the bid process, which could result in different drugs being available on the PDL. The committee further discussed the possible outcome of the bid process. Mr. Campana said the bids were due in November and the final determination of the new PDL would be in April 2009 with implementation in July or August.

THE MOTION PASSED UNANIMOUSLY.

22. Review Minutes from April 2008 Meeting

**DR.KILEY MOVED TO APPROVE THE MEETING MINUTES OF APRIL 2008.
SECONDED BY DR. CONRIGHT. THE MOTION PASSED UNANIMOUSLY.**

23. Comments from Committee Members or Chair

Mr. Campana said the next meeting would be November 14, 2008, with the clinical submission date being October 10, 2008. The drugs that would be reviewed were listed.

Dr. Sater said she would not be available for the review of the Atypical antipsychotic drugs, but Jeff Monahan would be taking her place.

Mr. Campana said the mental health community would be involved in reviewing the Atypical antipsychotic drugs. He and Dr. Malter met with the Alaska Psychiatric Association and made a presentation, which was well received.

Dr. Curtiss, who also attended the meeting with the Alaska Psychiatric Association, felt there was a lot of confusion about what the P&T Committee does and whether a medication is available if it is not on the PDL.

Dr. Brodsky noted that there were currently four vacancies on the P&T Committee and new members were being recruited.

24. Adjourn

MR. GREEAR MOVED TO ADJOURN THE MEETING. SECONDED BY DR. CONRIGHT. THE MOTION PASSED UNANIMOUSLY.

The meeting adjourned at 10:52 a.m.