

**ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE**

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

**FINAL MINUTES OF MEETING
September 28, 2007
8:00 a.m.**

Committee Members Present:

Marvin Bergeson, MD
Heidi Brainerd, MS R.Ph.
Amber L. Briggs, Pharm.D.
Richard E. Brodsky, MD
Robert H. Carlson, MD
Kelly C. Conright, MD
Lucy Curtiss, MD
Traci Gale, R.Ph. (telephonic)
Vincent Greear, R.Ph.
R. Duane Hopson, MD
Daniel P. Kiley, DDS, MPH
Diane Liljegren, MD (telephonic)
Andrzej Maciejewski, MD
Gregory R. Polston, MD
Janice L. Stables, MSN, ANP (telephonic)
Trish D. White, R.Ph. (telephonic)

Committee Members Absent:

Mark Bohrer, R.Ph.
Jeffrey G. Demain, MD
Sherrie D. Richey, MD

Others Present:

David Campana, R.Ph.
Melinda Sater, Pharm D, First Health

1. Call to Order – Chair

The meeting was called to order at 8:00 a.m.

2. Roll Call

A quorum was present.

3. Public Comment – Local Public/Local Physicians

Dr. Doug Haghghi: A gastroenterologist from Anchorage spoke in favor of Humira, which is currently on the preferred drug list as a first line agent for Crohn's Disease. Humira can be injected subcutaneously. Remicade, another medication for Crohn's Disease, needs to be infused over several

hours. Humira is very well tolerated and the studies in the last year have supported its efficacy for Crohn's disease. Since people in Alaska cannot always get to a center to be infused, Humira would be optimal.

Dr. Kevin Maguire: A private practitioner in Anchorage spoke about the Nicotinic Acid products in relation to his diabetes and lipidology work. Metabolic syndrome is very prevalent in Alaska. HDL is a derivative of cholesterol and has been demonstrated to be beneficial to cardiovascular profiles across the board. The current Nicotinic Acid product, in the extended release form, is very beneficial. A recent product change in Niaspan has allowed many people with flushing side effects to remain on the medication. Use of Fenofibrate is beneficial, because it does not interfere with metabolism and provides a greater safety profile than Gemfibrozil. Nicotinic Acid and Fenofibrate should remain on the preferred drug list. Crestor and Lipitor are the more powerful statins. Combination products, like Vytorin, are also very valuable.

Dr. Stefano Emili: A physician with Aurora Kidney, Inc., discussed Atorvastatin. As a physician treating patients with chronic kidney disease and transplants, Atorvastatin is my statin of choice. The class is not a uniform class effect, because there are differences. Atorvastatin is the most studied statin in the world with a huge clinical track record. It is efficacious and prevents vascular events. Atorvastatin, being the most prescribed statin in the world, should be on the Medicaid preferred drug list.

Dr. Patrick Nolan: Agreed with Dr. Emili that Atorvastatin was the statin of choice. I have had to switch hundreds of patients from other agents to Atorvastatin just to get to goal. It is also safe with other drug combinations. The outcomes data for renal failure patients is very important, because our patients have the same risk of a heart attack as a patient who has already had a heart attack. Atorvastatin is by far the most widely used agent. We would like to have Atorvastatin available as a first line drug rather than having patients fail other statins. A generic form of Atorvastatin will be released soon. Regarding Tricor, almost all of our diabetic patients require combination therapy. It is unusual to get somebody to lipid goals with only one drug. Tricor is safe to use with other drugs, whereas Gemfibrozil is not. The only major complications I have seen with diabetic patients in the last 25 years of practice is with combinations with Gemfibrozil and statins. I use Tricor exclusively for patients with diabetes or on combination drugs. Tricor is not only safer; it is also more effective.

Dr. Jeremy Gitomer: A physician from Anchorage calling from Fairbanks discussed Procrit and Aranesp. Procrit allows me to dose my patients every two or three weeks. This drug has gotten a lot of press lately with concerns about increased cardiovascular events. Having choices is important in order to maintain our patients at their appropriate goals. With 100 patients on Aranesp, my office is keeping about 80% of our patients in the accepted target range. With Procrit, our averages are about the same. It would be beneficial to have a choice of using either Aranesp or Procrit if there were no cost differences for Medicaid. Regarding statins, Atorvastatin is our drug of choice. Regarding the phosphate binder agents, the majority of the patients in Alaska use PhosLo and Renagel. A significant amount of patients cannot tolerate one drug or the other so it is important to have choices. Patients taking these drugs generally take between 6 and 24 pills a day. Patients need the option to take the drug that works best for them, because it has such a huge impact on their lives.

In response to Dr. Brodsky, Dr. Gitomer said the two approved drugs for pre-dialysis were Procrit and Aranesp. He recommended including both drugs on the PDL if the price was reasonable.

In response to Dr. Carlson, Dr. Gitomer felt the medically necessary clause worked pretty well. However, some of the outlying pharmacies refuse to order a specific drug that is not on the PDL.

In response to Dr. Brodsky, Jeremy Gitomer discussed Atorvastatin. Care needs to be individualized. My patients have a lot of kidney disease, which is a predictor of cardiovascular events. I aim for a goal of LDL of less than 100 or less than 70 for patients with advanced kidney disease. Years ago, the only drug that would reach these goals was Lipitor, but now there are other choices.

4. Anticoagulants, Injectable Review

Kyle Downey: A medical liaison from Sanofi Aventis discussed Lovenox, which is the most widely used low molecular weight heparin. It has the most approved indications in the class. To date over 100 million patients in 96 countries have used Lovenox. Its indications encompass both prophylaxis and treatment of venous thrombosis, as well use for acute coronary syndromes. This year Lovenox was approved for ST segment elevation MI and is now indicated across the acute corners syndrome spectrum. Lovenox is proven safe and effective for the outpatient use of post hip replacement surgery, as well as outpatient DVT treatment, thus providing tremendous advantages for transitioning patients into the outpatient setting. Numerous organizations, including the FDA, have position statements that indicate low molecular weight heparins are not interchangeable. Lovenox has an excellent risk benefit profile. Analyses have demonstrated cost neutrality to other agents, as well as cost savings when looking at transitioning into outpatient treatment for DVT. Lovenox is the only low molecular weight heparin that has an FDA approved dosage adjustment for patients with severe renal impairment and data and literature around pediatric and pregnant patient populations. Lovenox is a cost effective, injectable anticoagulant with extensive trial and practice experience in a wide range of patients and indications. It has a simple dosing strategy, which minimizes healthcare professional time and enhances patient compliance. For the treatment of outpatient DVT, the ability to seamlessly transition patients to the outpatient setting can reduce costs for the entire healthcare system, especially in the Medicaid population, while maintaining quality of patient care. Lovenox should be added as a preferred agent to the preferred drug list.

Dr. Sater gave the First Health presentation on Anticoagulants, Injectable. There are three low molecular weight heparin agents before the committee for review. Arixtra has a slightly different mechanism than Lovenox and Fragmin. FDA approved indications vary between agents. Although they are not interchangeable, the efficacy is similar for all agents. Arixtra carries contraindications, which the others do not, for patients less than 50 kilograms and patients with severe renal impairment. In August there were 36 claims for this class, 35 of which were for Lovenox. This classification has not been previously discussed. Dr. Mary Stewart uses primarily Lovenox in her patients and has a high level of comfort with the drug. She uses Arixtra in patients who cannot use Lovenox and rarely uses Fragmin. She would like to see at least one, if not all of these drugs, added to the preferred drug list.

DR. BRIGGS MOVED A CLASS EFFECT. THERE WAS NO SECOND.

Dr. Liljegren felt Lovenox should be included on the preferred drug list, because it has the broadest number of indications and physicians are used to using it.

Dr. Conright felt an important consideration was that Lovenox could be used in an outpatient setting.

DR. MACIEJEWSKI MOVED A CLASS EFFECT WITH LOVENOX BEING INCLUDED ON THE PDL. SECONDED BY DR. CONRIGHT. THE MOTION PASSED UNANIMOUSLY.

5. Erythropoiesis Stimulating Proteins Review

Gary Okano: A pharmacist and health outcomes and pharmacoeconomics medical liaison with Amgen discussed Aranesp. It has a unique molecular structure that allows for less frequent dosing. It offers established patient experience and multiple administration options. It is safe and effective when used in accordance with the product labeling. Aranesp's unique structure results in a serum half-life that is approximately three times longer, which can result in increased dosing flexibility, the ability to synchronize with the majority of chemotherapy regimens, and it allows for fewer drug administrations for patients. This can decrease the administrative burden for offices, as well as decrease the number of trips required for patients to receive their injections. This may be particularly advantageous in Alaska where patients may have to travel a long distance to receive their care. Through March of 2007 approximately 2.7 million patients have received Aranesp across indications and all dosing regimens. In addition, Aranesp administration options include vials, pre-filled syringes, and a sure-click auto injector. The sure-click auto injector is a secure and simple device that automatically delivers a complete subcutaneous injection in a single use. Sure-click offers an advantage to those patients who cannot visit a clinic due to distances. Regarding efficacy, Aranesp is effective at decreasing hemoglobin levels and reducing transfusion requirements in patients with chronic renal failure and nonmyeloid malignancies that are anemic due to the effects of concomitantly administered chemotherapy. Regarding safety, the prescribing information was updated last March to reflect safety data arising from clinical trials. However, these clinical studies were conducted in investigational areas such as anemia of cancer without concurrent chemotherapy or where the hemoglobin target was above the recommended package insert recommendation of 12 grams per desolator. When used in accordance with the product labeling, Aranesp is safe and effective. Aranesp should be placed on the preferred drug list for those patients in need to therapy.

In response to Dr. Maciejewski, Gary Okano said he would provide information on the long-acting Aranesp versus other shorter acting agents. It shows that for the reduction in transfusion, the hemoglobins were similar.

Dr. Sater gave the First Health presentation on Erythropoiesis Stimulating Proteins. There are two entities and three branded products for consideration. Epogen and Procrit are identical recombinant human erythropoietin products. Aranesp differs slightly. Efficacy and adverse event profiles are similar. All agents have several black box warnings, which are detailed in the packets. In August there were 32 claims for this class: 73% for Procrit, 14% for Aranesp, and 12% for Epogen. Dr. Mary Stewart uses all the drugs in this class. She feels that Aranesp may have a small advantage due to less frequent dosing, but would like to see both products added to the preferred drug list.

Dr. Liljegren said people with very complicated health problems needed to have all the drug options available including Procrit and Aranesp.

The medically necessary clause was discussed. Dr. Liljegren noted that an earlier speaker said he had problems with pharmacies refusing to order non-preferred drugs. Dr. Briggs said those cases were probably Medicare patients versus Medicaid patients. Dr. Brodsky requested anyone that had problems with pharmacies refusing to order drugs bring it forward so it could be investigated.

Dr. Maciejewski said the population with chronic kidney disease was relatively larger than the dialysis population. The dialysis population was typically on Medicare whereas the pre-dialysis patients were generally not on Medicare unless they were older.

In response to Dr. Carlson, Dr. Sater agreed that determining a class effect and letting the physicians utilize the medically necessary clause was the best option, because the overall effect on the providers would be minimal. There is not a huge volume of claims in this classification, but it is a very high dollar classification.

Dr. Maciejewski said he was comfortable using all of the agents within the class. We need to be cautious how we dose those agents, because there are significant risks for cardiovascular events as well as the potential for lawsuits.

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

6. Re-review Phosphate Binders.

There were no public testimonies.

Dr. Sater gave the First Health presentation on Phosphate Binders. There are three agents in this class. All three agents are FDA approved for the treatment of elevated phosphate levels in renal disease. All of the agents are currently preferred. In August there were 42 claims in this class: 83% for PhosLo, 17% for Renagel, and no claims for Fosrenol. At the previous review there was very limited discussion. The motion to add Renagel and PhosLo preferentially passed unanimously.

Dr. Maciejewski said he did not use Lanthanum, but he did use Renagel and PhosLo. He recommended both Renagel and PhosLo be included on the preferred drug list. One delivers extra calcium while the other does not. One is tolerated better due to GI symptoms whereas the other is not. PhosLo is more potent than Renagel, but some patients cannot use PhosLo.

Dr. Sater said Dr. Gitimer reserves Fosrenol for patients who have failed the other two drugs and would like to see all three drugs on the preferred drug list.

DR. LILJEGREN MOVED TO INCLUDE ALL THREE DRUGS ON THE PDL. SECONDED BY DR. MACIEJEWSKI.

In response to Dr. Carlson, Dr. Sater said there were a small number of claims in this class, so declaring a class effect and utilizing the medically necessary clause would not have a great impact on physicians.

Dr. Maciejewski said there was not a class effect, because the drugs were so different.

In response to Dr. Conright, Dr. Maciejewski said he does not use Fosrenol, but it is an extra option for patients who cannot use either PhosLo or Renagel. However, the medically necessary clause could be used when prescribing Fosrenol.

In response to Dr. Polston, Dr. Sater said if the committee decided they needed PhosLo, Renagel and whatever else was available, Fosrenol would also be included if it was financially beneficial. However, if a motion states just one drug then only one drug would be added to the PDL.

THE MOTION PASSED WITH 3 OPPOSED.

7. Re-review of Bone Resorption Suppression and Related Agents

Frank Wollaeger: A medical representative for Roche Laboratories discussed Boniva, the only once monthly bisphosphonate for the treatment and prevention of postmenopausal osteoporosis. Last fall we discussed the efficacy of Boniva, as well as the available adherence data showing increased persistence with monthly over weekly bisphosphonate regimens. In the Pivotal Bone Study there was a reduction of vertebral fractures by 52% over three years and reduction in non-vertebral fractures of 69% in high-risk patients. Although no head-to-head efficacy studies had been completed at that time, those results were consistent with the class. We now have head-to-head data comparing Boniva with Fosamax. The Motion Study was a non-inferiority efficacy and safety study comparing the once monthly oral Ibandronate regimen with the weekly oral Alendronate regimen in women with postmenopausal osteoporosis. This study was presented in abstract form last week. The primary endpoints were the relative mean percent change from baseline to lumbar spine and total hip BMD at one year. Being a one-year study, fracture was not an endpoint of this trial. However, all clinical fractures that occurred during the trial were captured and reported as adverse events. Over the 12-month period, the once monthly Ibandronate and weekly Alendronate regimens demonstrated a mean relative change from baseline and lumbar spine BMD of 5.1% and 5.8%, respectively, for no statistically significant difference. Total hip BMD increased 2.9% and 3%, respectively. Overall, patients receiving once monthly Boniva achieved BMD increases clinically comparable to those seen with once weekly Fosamax at all sites measured. Incidents of clinic fracture was reported in 3.1% of patients treated with Ibandronate and 2.7% of patients treated with Alendronate, which was clinically comparable. Incidents of osteoporosis fractures were 2.1% and 2%, respectively. This data should not be interpreted as efficacy endpoints or evidence of fracture risk reduction, but as a similar outcome with respect to fracture risk and adverse event. The overall adverse event profile was also comparable. The Mobile Trial was our registration trial for once-monthly Boniva. The 150-miligram monthly doses were found to be optimal with respect to efficacy and tolerability and not just a linear multiplication of the daily dose from the Pivotal Bone Study. The monthly regimen not only demonstrated non-inferiority to the once-daily regimen, but was also found to be significantly better than the daily dose based on BMD gains. This study has an ongoing three-year, long-term extension arm to further evaluate the efficacy and safety of monthly Boniva. Results from the first year of this extension study have shown further

significant increases in lumbar spine BMD from 6.6% at the end of the two-year Mobile Study to 7.6% after an additional one-year on therapy. Our BMD continued to increase at all hip sites as well. Boniva is continuing to show benefit with longer-term use. A very important issue with osteoporosis is adherence and persistence to therapy. We know that medication adherence is critical to insuring positive patient outcomes. Studies have consistently shown that about 50% of patients stop taking their once weekly bisphosphonate within one year of having been prescribed them. Non-compliance with osteoporosis therapy, which is defined as patients taking less than 80% of prescribed medication, resulted in a 26% increase in fractures. This would include patients missing one weekly pill per month. We have a nine-month data presented at ISCD in March evaluating the real world adherence to monthly versus weekly bisphosphonates. The results suggest that women receiving monthly Ibandronate are 38% more likely to stay on therapy as those taking a weekly bisphosphonate. Boniva monthly also offers a great tool to help with persistence. It is a free monthly reminder program and we are the only product to offer such a support program. When patients enroll, they choose how and when they want to receive their reminder via phone, email or regular mail. Another benefit of Boniva is that with the 30-day supply offered by a once monthly pill, patients only need to get their prescription filled 12 times per year. However, it is 13 times per year with the 28-day packaging of the weekly bisphosphonates. This saves Medicaid one full month of drug cost per patient, per year. In summary, the increased persistence to and preference for the once-monthly Boniva demonstrated efficacy, along with the only available patient reminder program, should help Alaska Medicaid patients be more successful in staying on their therapy and optimizing their osteoporosis treatment. I urge the committee to offer your Medicaid patients the benefits of once-monthly Boniva.

Dr. Sater gave the First Health presentation on Bone Resorption Suppression and Related Agents. There are three oral bisphosphonates and two combination products for review. FDA indications vary between agents. They have similar adverse event profiles. Boniva is given once monthly. Actonel and Fosamax are given once weekly. Currently, all forms of Fosamax are preferred. In August there were 253 claims in this class: 71% for Fosamax weekly, 11.5% for Actonel, 10% for Fosamax +D, 6% for Boniva, 4 claims for Fosamax solution and 1 claim for Actonel with calcium. In previous discussions, the significance of bone marrow density surrogate markers of bone turnover and fracture rate was discussed. There was a significant discussion of the actual definition of class effect. The motion for class effect with inclusion of at least one extended interval product passed unanimously. Dr. Janice Koval uses all drugs in this class and would like to see them all preferred. She does not see great utility for the combination products, but spoke at length about the importance of not switching preferred agents within classes frequently. She feels this is a poor practice and would like to see the classes stay as consistent as possible.

In response to Dr. Liljegren, Dr. Brodsky said only the oral agents were being considered.

Dr. Briggs agreed that changing the drugs on the preferred drug list was frustrating, but the physician could always use the medically necessary clause.

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

Dr. Sater said there was an extended discussion at the last review of this class on the definition of class effect. The concern was that Fosamax Daily would be the only choice if a class effect was declared.

Dr. Liljegren said she would like to see at least one long-acting bisphosphonate on the PDL.

Dr. Greear felt the daily bisphosphonates should not be considered as part of the class effect or the review. Only the weekly and monthly ones should be considered.

In response to Dr. Briggs, Dr. Sater said typically all the formulations would be considered when a class effect was declared. However, there were instances where a company chooses not to include all formulations of their product.

DR. BRIGGS AMENDED THE MOTION TO DECLARE A CLASS EFFECT AND INCLUDE AT LEAST ONE EXTENDED VERSION. DR. BERGESON ACCEPTED THE AMENDMENT. THE MOTION, AS AMENDED, PASSED UNANIMOUSLY.

8. Re-review of Benign Prostatic Hyperplasia (BPH) Treatments (5-Alpha Reductase Inhibitors)

William Schmidt: A medical scientist with GlaxoSmithKline discussed Avodart. September is prostate cancer awareness month. Avodart is preferred on the preferred drug list. It is indicated for the treatment of symptomatic BPH. It is also currently being studied in combination with alpha-blockers for the treatment of BPH and the prevention of prostate cancer. It is well established that prostate growth is driven by the androgen dihydrotestosterone or DHT. Testosterone is converted into DHT by two isoforms of the enzyme 5 α -reductase, both of which are found in the prostate. The established therapy for enlarged prostate includes alpha-blockers, which improve urinary symptoms, and these 5 α -reductase inhibitors to inhibit DHT, which shrink the prostate, arrest the disease prostate and the improved urinary symptoms. The two 5ARIs currently available are Finasteride and Avodart. There have not been any long-term head-to-head trials comparing Finasteride and Avodart so conclusions cannot be drawn regarding the relative efficacy and safety of one agent over the other. But there are important differences between the two. To achieve near complete DHT suppression, inhibition of both type-I and type-II of these enzymes is required. Avodart does inhibit both forms of the enzyme, but Finasteride only inhibits the type-II enzyme. In dose ranging trials that compared various doses of Avodart with Finasteride, DHT reduction by Avodart was significantly greater and less variable than in patients receiving Finasteride. At 24 weeks, Avodart reduced DHT by about 95%, plus or minus only 3%, while Finasteride reduced DHT only by about 71% with a variability of plus or minus 18%. Among patients who receive Avodart in a three-month prospective, non-randomized study to evaluate Avodart versus Finasteride there were significantly greater reductions in symptoms scores compared with Finasteride. Recently there was a retrospective analysis that looked at inpatient and outpatient claims to assess the severity and complications from enlarged prostates in men treated with either Avodart or Finasteride. In the patients taking Avodart, there was a 45% less likelihood of having acute urinary retention compared with the patients on Finasteride. Also 25% more patients taking Avodart were actually able to discontinue their alpha-blocker therapy over one year as compared with the patients on Finasteride. The newest data on Avodart is from the ongoing combination Avodart/Flomax Trial, which is a four-year trial designed to evaluate whether combination therapy with Avodart and Flomax is more effective than either monotherapy alone. At month 15, improvement with Avodart and Flomax was equal. Avodart improvement was statistically greater compared with Flomax from month 21 onwards. We are currently at the 2-year point in that study. Avodart resulted in significantly greater maximum flow rate improvement compared with Flomax from month 12 onwards. As one would

expect, Flomax had no significant effect on prostate volume. Most adverse events in the placebo-controlled trials were mild or moderate and generally resolved while on treatment in both Avodart and placebo groups. Avodart should be maintained on the preferred drug list.

Dr. Sater gave the First Health presentation on Benign Prostatic Hyperplasia (BPH) Treatments, 5-Alpha Reductase Inhibitors. There are two available chemical entities for consideration. Finasteride is also available as a generic product. Both products are FDA indicated or approved for the treatment of BPH. They have similar profiles and clinical efficacy. There are no long-term comparative trials to date. In August there were 55 claims in this class: 69% for Avodart, 16% for Finasteride, and 15% for Proscar. At the last review there was a brief discussion about the clinical significance of switching between products. A motion for class effect passed with two opposed. There have not been significant changes to any of the drugs in this class. Dr. Paul (Indiscernible) feels Avodart is a superior product, but would like to see both products preferred.

In response to Dr. Liljegren, Dr. Brodsky said nobody really knew the implications of changing the drugs on the PDL in this class, because there were no trials to show what happens when people switched between the drugs. The provider can always use the medically necessary clause.

Dr. Sater noted that both Avodart and Proscar were currently preferred.

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

9. Re-review of Benign Prostatic Hyperplasia (BPH) Treatments (Alpha-Blockers)

John Robinson: An associate director with Boehringer Ingelheim discussed Flomax. Flomax is indicated for the treatment for the signs and symptoms of BPH. Flomax is not indicated for the treatment of hypertension. It is dosed once daily and does not require titration. In invitro studies, Flomax was significantly more selective for alpha 1-A and 1-D than for alpha 1-B. Studies have demonstrated both rapid onset and sustained improvement in symptoms of flow rate and quality of life, supporting the long-term efficacy of Flomax. The most common side effects of Flomax are dizziness, abnormal ejaculation and rhinitis. Patients beginning treatment with Flomax should be cautioned to avoid situations where injury could result should syncope occur. However, the incidents of clinically significant hypotension of other cardiovascular events recorded during trials were low and did not differ from placebo. Overall, the incidents of treatment emergent adverse events declined over the course of long-term use. Unlike its competitors, Flomax does not interact with commonly used hypertensive agents and can be used with PDE-5 inhibitors. Overall, Flomax demonstrates rapid onset of action with proven long-term safety and efficacy.

Dr. Sater gave the First Health presentation on Benign Prostatic Hyperplasia (BPH) Treatments, Alpha-Blockers. There are four available entities and five available products, including one extended release product, Cardura XL. All products are FDA approved for the treatment of BPH. Only Cardura and Hytrin are indicated for hypertension. The agents show similar clinical efficacy and adverse drug reaction profiles. In August there were 168 claims in this class: 48% for Flomax, 36% for generic Doxazosin, 9.5% for generic Terazosin, and 6% for Uroxatral. There were no claims for Cardura XL.

All agents, except Cardura XL, are preferred. In previous discussions, the importance of including one agent not used to treat hypertension was discussed. The motion for class effect and inclusion of at least one non-cardio selective agent, Flomax or Uroxatral, passed unanimously. Dr. Andrew Maciejewski uses Flomax and Uroxatral as first line agents in his practice, but he uses more Flomax. Dr. Paul Ferucci feels that all drugs in this class should be preferred, but if one agent must be chosen then he would prefer Flomax.

DR. CONRIGHT MOVED TO DECLARE A CLASS EFFECT AND INCLUDE ONE NON-CARDIO SELECTIVE AGENT. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.

10. Re-review of Alzheimer's Agents

David Gross: A clinical education manager for Pfizer discussed Aricept, which is currently on the preferred drug list. The only change from last year is that it now has a new indication and covers all three spectrums of Alzheimer's disease from mild to moderate and now severe Alzheimer's disease. Aricept is the only agent in the class to have all three indications. According to the CMS website, Aricept currently has about 91% of the prescriptions in Alaska when compared to the other agents. Aricept should remain on the preferred drug list.

Dr. Sater gave the First Health presentation on Alzheimer's Agents. There are five available agents. There are two distinct mechanisms. Last year you elected to consider Namenda as its own agent. Galantamine also modulates acetylcholinesterase inhibitors. Cognex is not used much anymore, because of its modest effects and increased toxicity. Exelon has a significant interaction with food, decreases bioavailability, delaying t-max, increasing c-max and increasing area under the curve. In August there were 64 claims, 63 of which were for Aricept and 1 for Exelon. There were also 43 claims for Namenda. There was very little previous discussion. The motion for a class effect with inclusion of Namenda and a preferential exclusion of Cognex passed with two opposed. The Exelon patch was approved since our last review. Dr. Mary Downs uses Aricept, Exelon and Namenda and would like to see all retained on the preferred drug list. She said some newer evidence suggests that patients who stop responding to Aricept may respond to Exelon. She felt Namenda was a very important tool in this class and should remain on the preferred drug list. She feels the Exelon patch shows some promise in patients and requested that be added as well. Currently everything but Razadyne and Cognex is preferred.

Dr. Liljegren felt Namenda should be considered by itself due to its different mechanism of action.

In response to Dr. Malter, Dr. Brodsky said they looked at each class separately, because they may have different mechanisms of action, efficacy or indications. However, it depends on the circumstances. These drugs are not very effective, but patients want to use them so they should be included on the preferred drug list.

Dr. Liljegren questioned if Aricept should be included on the preferred drug list since it was the only drug indicated for severe Alzheimer's disease.

DR. POLSTON MOVED TO PREFER NAMENDA AND ARICEPT WITH MORE TO BE INCLUDED IF COST EFFECTIVE. SECONDED BY DR. CONRIGHT.

Dr. Liljegren felt Namenda be considered in a separate classification due to its different mechanism of action.

THE MOTION PASSED UNANIMOUSLY.

11. Re-review of Multiple Sclerosis Agents

Elaine Thomas: A medical scientific liaison with Bayer Healthcare Pharmaceuticals asked that Betaseron be maintained on the preferred drug list. The Benefits Study, which was published this summer, led to an expanded label for Betaseron. Betaseron is indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Patients with multiple sclerosis, in whom efficacy has been demonstrated, include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis. Betaseron is the only high dose, high frequency interferon that is FDA approved for the use in this disease category, the earliest stages of multiple sclerosis. The Benefit Trial involved 468 patients. Betaseron significantly delayed progression from the first single clinical event to the time where there was evidence of a clinically definite multiple sclerosis. The cumulative probability of progressing was 28% in the Betaseron group versus 45% in the placebo group. The P value of that change was less than 0.0001 at 2 years. The proportional hazards regression analysis also showed that there was 50% reduction in the risk of progression to CDMS. Betaseron treated patients had improved cognition outcomes in that study. The 3-year integrated analysis from the data from the Benefit Trial shows a sustained effect of early treatment with Betaseron reduces the risk of progression to CDMS. At the 3-year mark of the study, 51% of patients in the delayed treatment group reached CDMS versus 37% of patients in the immediate group. The P value is 0.0011. Immediate treatment of Betaseron resulted in a 40% reduction in the risk of sustained disability progression, which is measured by the EDSS, with a P value is 0.0218, as compared to delaying the treatment until the patient suffered a second clinical event. Betaseron is the only drug proven to delay disability when used at the earliest stage of multiple sclerosis. Betaseron has the longest evaluation period of any of the drugs, being approved in 1993, and it is a very safe drug. One of the current controversial issues around these therapies is neutralizing antibodies (NABS). NABS interfere with or effect the clinical efficacy of interferon beta. However, recent data presented in this benefit study demonstrates that the NAB presence is transient. In this study, positive NABS were detected in at least once in 30% of the patients, yet 23% of these patients later became totally negative for NABS. In summary, the Benefit Trial demonstrates that NABS associated with the use of Betaseron are often transient and have no significant outcome on the conversion to CDMS.

Rosalynde Finch: A medical scientist with Biogen Idec advocated for open and equal access to all of the approved therapies for multiple sclerosis. We know that multiple sclerosis is not the same in all patients and it depends on their genetic background. We also know that patients respond differently to the drugs available. Some patients do not tolerate some of the drugs as well as others. It, again, depends on their genetic background. The treatment decision should be made at the clinical level. It should be a collaboration between the physician and the patient in terms of deciding which therapy is most efficacious for them and best fits within their lifestyle. Having said that, Avonex is the only MS

treatment that has FDA indications in three key areas: reduction in disability progression, reduction in relapse rate, and use after a first clinically isolated syndrome. The American Academy of Neurology, MS Council, has issued a position statement saying that the most important therapeutic aim of any disease modifying treatment in MS is to prevent or postpone disability progression. Most MS patients would agree with that statement. In support of his idea, Avonex is the only self-injectable MS therapy where disability progression was measured as a primary endpoint in their pivotal phase II trial. It is the only disease modifying treatment with Class-1 evidence in this area showing a 37% reduction in disability progression. Avonex prevents the loss of efficacy that may be seen long-term due to neutralizing antibodies. Avonex is dosed once weekly, which is important in terms of adherence. Compliance is a big issue with injectable drugs. There have been two studies that show that Avonex has the best adherence rate. Over the last 8 years, we have seen that 75% of the patients stay on therapy with Avonex. We offer pre-filled syringes that may be stored at room temperature for 7 days and a powder that is stable for 30 days without refrigeration. MS is a chronic, disabling disease. If they are stable on their medication and compliant with that medication then they really should not be forced to switch medications. There is data from 5,000 patients that shows there is no benefit to switching between the interferons.

Shawn Murphy: A medical science liaison for EMD Serono discussed Rebif. In 2002, the American Academy of Neurology published an article reviewing all of the modifying drugs with an emphasis on each of the product pivotal trials. The most important therapeutic gain of any of these therapies is to prevent or postpone long-term disability. The article also defined the three keys as delaying the progression of disability as measured by EDSS, (indiscernible) reduction, and (indiscernible) volume change on MRI. When looking at each of the modifying therapy pivotal trials, only Rebif had an effect on all three key parameters. While Rebif was approved outside the United States in 1998, it was not allowed to enter the U.S. marketplace, because Avonex held open drug status. To gain entrance into the marketplace, Serono undertook the Evidence Trial, which was the only published class I head-to-head trial on these modifying therapies. Based on the results, Rebif was allowed to overturn open drug protection of Avonex and enter the U.S. marketplace in 2002. It is the first time in the 20-year history of the Open Drug Act that the protection was overturned based on clinical superiority as defined by the FDA. In the Evidence Trial, the side effects, the adverse events and drug discontinuation were comparable between both Rebif and Avonex. The Drug Effectiveness Review Project at Oregon Health Sciences University reviewed two studies to compare Rebif and Betaseron. Documents state that Rebif had superior tolerability as measured by fewer injection site reactions, fewer flu-like syndromes, and less depression when compared to Betaseron. Thank you for your time.

Dr. Sater gave the First Health presentation on Multiple Sclerosis Agents. There are four available branded products for consideration. They are all FDA approved for the treatment of relapsing forms of MS. They show similar clinical efficacy. Avonex and Rebif may cause less formation of neutralizing antibodies. Copaxone is not an interferon; it modulates the immune response through a different, yet not fully understood, process. In August there were 23 claims for this class: 6 claims each for Avonex, Betaseron and Copaxone. Rebif had 5 claims. In previous discussions, a grandfather clause was discussed. The motion to declare the interferons equivalent and include Copaxone and at least one interferon passed with one opposed. Currently all the drugs in this class are preferred. Dr. Mary Downs uses all of the drugs in this class. MS is such a devastating disease in primarily young patients that she would like to see all the drugs retained on the PDL, as not all patients respond in the same way to all drugs in this class.

DR. KILEY MOVED TO PREFER ALL THE DRUGS IN THIS CLASS. SECONDED BY DR. MACIEJEWSKI.

Ms. Brainerd said the committee recognized the debilitating nature of MS and other diseases. They have worked very hard to allow open access to care by continuing to keep the medically necessary clause. This class of drug has an extremely high cost, but they are available as needed by writing medically necessary.

Dr. Carlson felt utilizing the medically necessary clause might be the best option. I would not want to restrict the practice of medicine in this very difficult arena, but we may not be doing the right thing by preferring all the drugs in this class.

Dr. Brodsky noted that there were very few claims for this classification and writing medically necessary would not be egregious.

Dr. Carlson noted that people would be excluded from Medicaid next year if the committee was not judicious in their budgeting.

THE MOTION FAILED WITH THREE IN FAVOR.

DR. CONRIGHT MOVED TO CONSIDER THE INTERFERONS A CLASS EFFECT AND INCLUDE COPAXONE. SECONDED BY DR. BERGESON. THE MOTION PASSED WITH ONE OPPOSED.

12. Re-review of Antiparkinson's Agents.

John Robinson: An associate director with Boehringer Ingelheim discussed Mirapex, which is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease for moderate to severe primary restless leg syndrome. Mirapex is a non-ergot dopamine agonist which binds to and activates dopamine receptors in the brain the mimic the actions of endogenous dopamine. Parkinson's disease is a devastating disease. Mirapex is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease in both early and advanced stages. In the Com PD Clinical Trials it helped to delay the onset of dyskinesias and wearing off. It also helped to increase on time when used as an adjunct to Levodopa. Mirapex can be rapidly titrated to an effective dose, 1.5 to 4.5 milligrams per day, in three weeks in patients with normal renal function. Three-times daily dosing can be given with or without Levodopa. Mirapex has no predicted P-450 interactions due to renal excretion. A dosage adjustment is required in patients with a creatinine clearance of less than 60 milliliters per minute. In restless leg syndrome clinical trials, Mirapex has been shown to help relieve restless leg symptoms including sensory motor and has delivered improvements during the evening sleep and day, as well as demonstrated by effective doses as low as 0.125 milligrams. No dosage adjustment is necessary for those with hepatic insufficiency. As Mirapex is renally excreted with 90% of the dose recovered in the urine, dosage adjustment may be necessary in patients with renal failure and hemodialysis. Mirapex has flexible dosing with ease of titration that ranges from 0.125 milligrams to 0.75 milligrams. Four trials were done in Europe and the United States demonstrating the value of Mirapex and restless leg syndrome. Mirapex showed efficacy across several validated patient and

clinician rated symptom scales and delivered rapid and sustained efficacy for the signs and symptoms of restless leg syndrome. It also improves sleep satisfaction, mood disturbance associated with restless leg symptoms, and delivered improvement in quality of life parameters. The use of Mirapex has been shown to be safe and effective in the treatment of moderate to severe restless leg syndrome and idiopathic Parkinson's disease. Facilitating access for Mirapex allowed the State of Alaska to provide physicians and patients with an effective and safe agent for the treatment of both restless leg syndrome and idiopathic Parkinson's disease.

Jennifer Brzana: A regional medical scientist from GlaxoSmithKline discussed Requip. Patients using Ropinirole experience significantly fewer dyskinesias. The most common adverse events in patients receiving Ropinirole were nausea and insomnia. In patients with advanced PD, the addition of Ropinirole to their Levodopa therapy was associated with a greater percentage of patients achieving both a 20% reduction in Levodopa dose and a 20% reduction in awake time spent off when compared to those offered only placebo. Ropinirole is a progressive therapy for Parkinson's disease and can be titrated from .75 milligrams a day up to 24 milligrams a day to meet changing patient needs. This is a distinct advantage for Ropinirole as not all FDA approved dopamine agonists are indicated for the treatment of advanced PD. Ropinirole is also approved for the treatment of signs and symptoms of primary, moderate to severe restless leg syndrome. An improvement in symptoms was achieved as early as night two and long-term studies show continued efficacy up to nine months. The starting dose of Ropinirole in the RLS Trials was .25 milligrams every evening and can be titrated up to 4 milligrams based on tolerability and symptoms. The most common adverse events in these RLS Trials were nausea, vomiting, dizziness and fatigue. Ropinirole has demonstrated safety and efficacy in the treatment of Parkinson's disease as both initial monotherapy and as adjunctive therapy in late PD. It is approved for the treatment of moderate to severe primary RLS with significant symptom improvement as early as two nights out to nine months. It offers flexible dosing to allow clinicians to adjust therapy to meet the needs of patients with Parkinson's disease or restless leg syndrome.

Dr. Sater gave the First Health presentation on Antiparkinson's Agents. There are two available products for consideration. Both are FDA approved for the treatment of Parkinson's disease and restless leg syndrome. They have similar pharmacokinetic profiles and clinical efficacy. Requip may be associated with an increased incidence of hypertension. Mirapex may be associated with an increased risk of hallucinations. Head-to-head comparative trials are limited. In August there were 152 claims in this class: 51% for Mirapex and 49% for Requip. There was no previous discussion. The motion to consider this a class effect passed unanimously. Dr. Mary Downs considers these drugs virtually interchangeable. However, patients may tolerate or respond to one or the other after treatment failure with other agents. Requip may have a lower incidence of hallucinations, which is important in older, demented patients. Dr. Bill Lucht said he preferred Mirapex and requested that both drugs be added to the preferred drug list. Currently, both agents are preferred.

DR. LILJEGREN MOVED THAT THE DRUGS BE CONSIDERED THERAPEUTICALLY EQUIVALENT. SECONDED BY DR. GREAR. THE MOTION PASSED UNANIMOUSLY.

13. Re-review of Cytokine and CAM Antagonists and Related Agents

Gary Okana: A regional medical liaison with Amgen discussed Enbrel. As the only fully human soluble TNF receptor, it has a mechanism of action that is unique among TNF inhibitors. Enbrel has a

broad range of indications that includes rheumatoid arthritis, juvenile rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and psoriasis. Of the TNF inhibitors, Enbrel is the only agent with an FDA approved indication for juvenile rheumatoid arthritis. During the past year, the nine-year data for Enbrel and the eight-year data in juvenile rheumatoid arthritis were presented at two key professional meetings. The presentation showed that improvement in clinical responses, laboratory values and other measures of disease activity were sustained with Enbrel therapy. The seven-year clinical trial data on Enbrel and rheumatoid arthritis, which was published in the Journal of Rheumatology last year, showed that Enbrel continued to demonstrate durable clinical responses and allowed patients to decrease the use of steroids through the years. Enbrel can now be administered using a number of different delivery options including multiple-use vials, single-use pre-filled syringes, and the single-use pre-filled sure-click auto injector. The sure-click auto injector is a secure and simple device that automatically delivers a complete subcutaneous dose for one-time use. This device broadens the current administration options and allows healthcare professionals to select the most appropriate option for their patients. Enbrel is well tolerated and its safety profile has been established with over 14 years of collective clinical trial experience. Enbrel has been used in more than 450,000 patients worldwide across all indications. It is still the only TNF inhibitor without a black box warning. Enbrel should remain on the preferred drug list.

Dr. Carlson recognized Amgen, as well as many of their competitors, for helping patients that have neither insurance or Medicaid. He thanked all of the companies that have worked with the Patient Assistance Programs.

Dr. Sater gave the First Health presentation on Cytokine and CAM Antagonists and Related Agents. There are three agents in this class for consideration. Each has a different mechanism and dosing frequency. The indications vary between agents so the tables in the packets should be consulted. In August there were 64 claims for this class: 75% for Enbrel, 23% for Humira, and 1 claim for Kineret. In previous discussions, the utility of a step edit in this class was briefly discussed. The motion to prefer Enbrel and Humira passed unanimously. There have been no significant changes in this class. Dr. Michael Armstrong feels that these agents warrant judicious use and should not be prescribed by everyone. He uses Humira and Enbrel in his rheumatoid arthritis patients, but does not have a preference for one over the other. Kineret has very limited utility in RA patients. He would like to see at least Humira and Enbrel retained on the preferred drug list.

In response to Dr. Brodsky, Dr. Sater explained the step edit. A patient would have to fail one of the agents before being prescribed another one.

Dr. Malter asked for an explanation on the difference between the step edit and utilizing the medically necessary clause.

Mr. Campana said the prescription would still require medical necessity, but it would be setup in the system that a prescription for one drug would have to be on file before going to another drug. Due to the limited number of drugs and claims in this class, last year it was decided that a set edit was unnecessary.

DR. CONRIGHT MOVED A CLASS EFFECT WITH EMBREL BEING INCLUDED ON THE PDL. SECONDED BY DR. LILJEGREN. THE MOTION PASSED UNANIMOUSLY.

14. Re-review of Lipotropic, Statins

An Pham: A medical science liaison with Schering-Plough discussed Vytorin and Zetia. Treating high-risk patients to prevent major cardiovascular events by reducing LDL cholesterol to below 70 milligram is now recommended as a therapeutic option with high priority and urgency in lipid management. Zetia is a unique compound that blocks the absorption of cholesterol, including cholesterol from both dietary and/or other resources. Zetia is indicated as monotherapy or in combination with a statin for the reduction of elevated LDL cholesterol. The results of several recently conducted clinical studies have shown a remarkable therapeutic success in lowering LDL cholesterol as much as 70% with the help of Zetia. Vytorin is a high potency lipid lowering therapy and is available in a once-a-day tablet. Vytorin is the first and only first line lipid-lowering agent approved to simultaneously treat the two primary sources of hyperglycemia. First by inhibiting the production of cholesterol in the liver and secondly by uniquely blocking the absorption of cholesterol in the small intestine through Zetia. The complimentary dual acting mechanism of Vytorin reduces LDL cholesterol by 72% on average at a starting dose of 10 milligrams. Vytorin is indicated to increase HDL cholesterol and lower triglycerides. Vytorin demonstrates superior efficacy to both Lipitor and Crestor in achieving mean LDL cholesterol reduction across the entire dosing range. Several large outcome studies are underway to assess the additional benefit of Vytorin on cardiovascular morbidity and mortality. The safety profile for Vytorin was generally well tolerated across the entire dosing range. Contradictions, warnings and precautions for Vytorin are consistent with established tolerability profiles. Vytorin has not demonstrated an adverse event profile significantly greater in quantity or scope than statin monotherapy. Vytorin, in a single tablet, offers superior lipid lowering efficacy from a starting dose of 10 to 20 milligrams and provides a critical therapeutic option for patients and physicians to achieve the new end-set treatment goals. Vytorin will compliment your generic cost savings strategy rather than compete with it. Vytorin and Zetia should be maintained on the preferred drug list.

Kris Norenberg: A regional scientific manager for Astra Zeneca discussed Crestor, which is currently on the preferred drug list. Three changes have been made to Crestor's labeling since the last review. There was originally some verbiage in drug-drug interactions stating that there was no interaction with Ezetimibe and that language has been removed. In the post-marketing experience, there are very rare cases of memory loss, which is now reflected in our labeling. We undertook a pharmacokinetic study in healthy volunteer investigating levels of Rosuvastatin when co-administered with an anti-retroviral for the treatment of HIV. Anti-retrovirals are extensively metabolized by 3-A4 pathway making these other statins that are similarly metabolized problematic. We found that even though Crestor doesn't have a 3-A4 interaction, there was a two-fold increase in area under the curve and a five-fold increase in C-max of Rosuvastatin when given with the anti-retroviral drug. We do not have an explanation for this. Because of these elevations, the FDA has seen fit to limit the dose of Crestor to 10 milligrams. We continue to monitor the safety of Crestor both in our clinical trials programs and other studies. In the studies, we saw no increases in adverse events and no safety signals. In our studies, we see that all statins cause some proteinuria in around 1% of patients. At our 40-milligram dose that jumps up to about 2% of patients. However, that has not been associated with increased renal adverse events. Based on that data, we are not benefiting the kidney, but we certainly are not hurting it. We continue to provide head-to-head trials in high-risk populations with other statins, which is strictly LDL lowering and HDL rising. Crestor is the most effective statin monotherapy available on a per milligram basis.

We continue to monitor different ethnic populations with studies in Asians, Hispanics and Blacks. Another studies have demonstrated Crestor's safety in the Japanese population. We also have ongoing outcome studies that will be completed very soon.

David Gross: A clinical education manager for Pfizer discussed Lipitor. There are three important things you need to consider when making a decision of what drugs to prefer in this class. You need to look at patients in the State of Alaska. According to the July 2006 Update of the Burden of Heart Disease and Stroke in Alaska more Alaskans died from heart disease and stroke combined than any other cause. One-third of Alaskans have two or more risk factors for heart disease and stroke. The prevalence of high cholesterol is upwards of 40%. Hospitalization for heart disease in 2004 cost the State of Alaska \$322 million dollars. The stroke death rate is 10% higher than the national average. The percentage of obese and overweight Alaskans is 63%, which is higher than the U.S. overall. With a drug like Lipitor, you have a product that is proven to reduce strokes and other cardiovascular events as based on the outcome studies that we have today. The committee knows that Lipitor, at least for the branded statins, is the one with the most conclusive evidence-based outcome data. During last year's review, some it was agreed that even though the final decision was a class effect, some of you mentioned that Lipitor had an overwhelming amount of evidence-based outcomes data and didn't think that justified a class effect. The providers in Alaska continue to request that Lipitor be made accessible with no restrictions to the Medicaid population. The providers continue to prescribe the product, even though it is a non-PDL status at a higher rate than the other branded statins currently available on the preferred drug list. Once this information is taken into account, Lipitor should be a preferred product on the preferred drug list.

Dr. Sater gave the First Health presentation on Lipotropic, Statins. There are six available drug entities in this class. Fluvastatin and Lovastatin are also available in extended release formulations. There are three combination products: Advicor, Vytorin and Caduet. In previous years, we considered three high-potency statins: Atorvastatin, Rosuvastatin and Simvastatin; and three regular or lower-potency statins: Pravastatin, Fluvastatin and Lovastatin. The drugs are clinically equivalent up to about a 40% LDL reduction. High-potency agents are needed for greater reduction. All agents are indicated for the treatment of hyperlipidemia, as well as other indications as documented in the packets. In August, there were 1,701 claims for this class: 25% for branded Zocor, 21% for generic Simvastatin, nearly 18% for Lipitor, 14% for Vytorin, 14% for Crestor, and the rest of the drugs and combinations combined were less than 9%. Currently branded Zocor, Vytorin, Crestor, Lovastatin, Lescol branded, Lescol, Advicor and Lescol XL are preferred. In previous discussions, the committee decided that concern over safety issues was largely resolved. There was significant discussion of the meaning of class effect and the limited need to include lower-potency agents on the PDL. A motion was made to add Simvastatin or Rosuvastatin to the PDL in addition to anything else that was available and the motion passed with two opposed. We received numerous letters from physicians asking that Lipitor be added to the PDL. Dr. Janice Koval uses Lipitor in her practice and would like to see it added to the PDL. She also uses Simvastatin and some Crestor. She reiterated the idea that she would like to see the classes stay consistent to promote good patient care.

Dr. Carlson said the organization with the best cardiovascular outcomes in the state of California was Northern California Kiser, which used a step program. They get more than 80% of their patients to the target goal with the old Mevacor and Lovastatin. If you are looking for a cost effective method of dealing with a large population, a step method should be considered. If you exclude strokes and

combined strokes and heart attacks, cancer is still the leading cause of death in Alaska, which makes it unique in the United States.

Ms. White spoke in favor of including generic Simvastatin on the PDL instead of trying to carry the brand names.

Dr. Briggs felt lower-potency statins had a significant role and should be considered.

Dr. Sater said 1,323 of the claims were for high potency agents, 113 were for regular potency, and 265 were for combination products.

The committee discussed whether there should be two categories, high potency and lower potency statins. Dr. Briggs said she would use a low potency statin first, if it would be effective to lower the patient's cholesterol. Dr. Conright noted that the cost was not only for the medication, but also for the monitoring to insure that the drug was working. The committee further discussed the percentage of prescriptions that went off the PDL, which was 18% for Lipitor. Dr. Sater said over the course of a year, they averaged about 80% to 90% compliance in this classification.

DR. CONRIGHT MOVED TO DECLARE A CLASS EFFECT AND INCLUDE AT LEAST ONE HIGH-POTENCY STATIN ON THE PDL. SECONDED BY DR. CURTISS. THE MOTION PASSED WITH TWO OPPOSED.

15. Re-review of Lipotropics, Other (Fibric Acid Derivatives)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Lipotropics, Other (Fibric Acid Derivatives). There are two available chemical entities in this class: four branded and one generic Fenofibrate, and generic Gemfibrozil. Both entities are approved for hypertriglyceridemia. Other indications are outlined in the packets. In August there were 210 claims: 53% for Tricor, 44% for Gemfibrozil, and less than 3% for the rest of the drugs. Previous discussions revolved around the bioavailability of different Fenofibrate formulations. The overall effect on cardiovascular mortality was briefly discussed. The motion to add Gemfibrozil and one Fenofibrate product passed unanimously. Another Fenofibrate products, Lofibrin, is expected to launch later this year. Dr. Koval uses primarily Tricor and prefers it to other Fenofibrate brands and Gemfibrozil given the complicated nature of her patients and Gemfibrozil's potential for drug interactions.

DR. BRIGGS MOVED TO DECLARE A CLASS EFFECT WITH THE FULL UNDERSTANDING OF THE DIFFERENCES BETWEEN DRUG INTERACTIONS AND SAFETY. SECONDED BY DR. GREAR.

Dr. Curtiss asked for clarification on the "with full understanding of the differences between drug interactions and safety."

Dr. Briggs said she knew there would be discussion on the safety or decreased interactions with Fenofibrates versus Gemfibrozil and wanted to acknowledge that she understood that, but felt that a class effect was acceptable.

THE MOTION PASSED WITH ONE OPPOSED.

16. Re-review of Lipotropics, Other (Niacins)

There were no public testimonies.

Dr. Sater gave the First Health presentation on Lipotropics, Other (Niacins). There are many over-the-counter Niacin products available. We are only considering the one prescription product Niaspan. In August there were 31 claims for Niaspan, which is currently the only approved drug in this class. There was no previous discussion. The motion for a class effect passed unanimously. There have been no significant changes in this classification since the last review.

DR. BERGESON MOVED TO DECLARE A CLASS EFFECT. SECONDED BY DR. MACIEJEWSKI. THE MOTION PASSED UNANIMOUSLY.

17. Cholesterol Absorption Inhibitor

Dr. Sater gave the First Health presentation on the cholesterol absorption inhibitors. There is only one entity, Zetia. There were 143 claims in August.

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

18. Re-review of Macrolides

There were no public testimonies.

Dr. Sater gave the First Health presentation on Macrolides. There are three available agents in this class. Erythromycin has many distinct dosage forms. Indications vary among agents as reflected in the table in the packets. The standard Erythromycin is not well tolerated due to gastrointestinal adverse effects. Azithromycin and Clarithromycin are dosed fewer times daily and have fewer adverse drug reactions. They also show similar efficacy and have a little bit better tissue penetration than then standard Erythromycin. In August there were 917 claims: nearly 50% for generic Azithromycin tablets, 26% for generic Azithromycin suspension, less than 9% for Zithromax suspension, 3.7% for generic Clarithromycin tablets, and the rest of the drugs in this class amounted to less than 6%. In previous discussion, the motion was that macrolides were equally efficacious, but an Azithromycin product must be included. The motion passed unanimously. Changes in this class include Biaxin XL generic has been on and off the market due to patent infringement lawsuits. The current preferred drugs were reviewed. No expert was consulted on Macrolides.

DR. BERGESON MOVED TO DECLARE A CLASS EFFECT. SECONDED BY DR. CONRIGHT.

DR. LILJEGREN MOVED TO AMEND THE MOTION TO INCLUDE THE TABLETS AND SUSPENSIONS. DR. BERGESON ACCEPTED THE AMENDMENT.

THE MOTION, AS AMENDED, PASSED UNANIMOUSLY.

19. Review Minutes from January 2007 and May 2007

Mr. Campana said there were no changes needed for the May 2007 meeting minutes. The errors in the January 2007 meeting minutes were reviewed and corrected.

DR. BERGESON MOVED TO APPROVE THE JANUARY 2007 AND MAY 2007 MEETING MINUTES AS AMENDED. SECONDED BY DR. GREAR. THE MOTION PASSED UNANIMOUSLY.

20. Final Comments by Chair or Other Members

Mr. Campana discussed tamper-resistant prescription pads, which Congress determined had to be used for all written prescriptions. A bill that is currently in Congress could change that or delay it until April 1, 2008. As of this morning, the bill had passed through the Senate and the House, but had not yet been signed by the President.

Dr. Curtiss asked Mr. Campana to follow up on this issue with pharmacies. She has had faxed prescriptions rejected saying that this had gone into effect retroactive to April 1, 2007.

Mr. Campana said the Pharmacy Association has been very active on sending out the appropriate information, however one of the chain stores was sending out incorrect information. Hopefully, this will be delayed until April 1, 2008 and then we can move forward on it. There is a state regulation being written and going out for public comment on the same subject. If the National Tamper Resistant Act were delayed, the state would probably continue with that regulation process. The regulation will be open for public comment through October 10, 2007. Dr. Hunt has resigned from the committee. Dr. Keller has completed his term. We appreciate the services of both Dr. Hunt and Dr. Keller over the last three years. The next meeting will be November 16, 2007. The classes to be reviewed are: Growth Hormone, SSRI, SNRI, Other Antidepressants, Sedative Hypnotics, ADD/ADHD, Anticonvulsants - 1st Generation, Anticonvulsants - 2nd Generation, Long Acting Opioids, Fentanyl Buccal, PPIs, H2RA, Urinary Track Antispasmodics, and COX-2 Inhibitors.

The committee discussed the amount of time allocated for the representatives' testimony.

DR. BRIGGS MOVED TO CHANGE THE TIME LIMIT FOR THE REPRESENTATIVES TESTIMONY TO THREE MINUTES. SECONDED BY DR. STABLES. THE MOTION PASSED UNANIMOUSLY.

Dr. Bergeson discussed the hassle factor for approvals when prescribing Xopenex MDI and not Albuterol. Dr. Brodsky said he would look into the situation.

Dr. Liljegren suggested moving the non-controversial drug classifications to the front of the agenda since there were so many things to review at the next meeting. Mr. Campana said the agenda could be changed if it was the will of the committee. The committee agreed to change the agenda.

Dr. Sater said the NMPI bid process had changed so the drugs that made it to the preferred drug list would be announced at the November meeting or later.

The committee discussed the re-review of drug classifications. Mr. Campana asked whether the committee wanted to continue to re-review classes on a yearly basis or whether they wanted to re-review a class if there was a major change or a new bid. Dr. Bergeson was in favor of reviewing the classifications less often. Dr. Briggs felt the classes needed to be reviewed if there was any significant information that became available. Dr. Conright noted that a number of providers had said it was a hassle to change the preferred drug list every year. Mr. Campana said there would only be a change to the PDL if there were a yearly bid change or a significant drug issue that came up. Dr. Sater said the classes would only be reviewed when there was new information to consider or the bid changed significantly. However, the PDL would not be changed unless the committee reviewed the classification. Mr. Campana said the only exception to that would be if a drug that was on the PDL came out with a new line extension, but did not change any of the current bids on the list, then the drug would be added to the PDL. Dr. Sater said she would provide the bid information and it would be up to the committee to decide when a classification needed to be re-reviewed. Mr. Campana said before a drug classification could be reviewed, it had to be posted at least 10 days. New information packets would also have to be distributed to the P&T Committee, which we want to do at least 30 days in advance of the meeting. It would probably be better to stay on our present schedule for this year and consider a change for next year. Dr. Sater said changes were made about 25% of the time, or less, after a re-review. However, when there is a change, it is usually a fairly big one. Dr. Conright suggested setting a minimum review period of every two to three years. Dr. Carlson suggested keeping everything the same, but allowing the chair to propose a list of items that did not need to be re-reviewed at each meeting. Mr. Campana suggested a review of each meeting's agenda to determine what classifications could be postponed for a year. The details of when a class would be re-reviewed if it had been postponed and then new information became available still needed to be worked out. It was decided that this issue would be discussed at the next meeting once the committee had time to think about it.

The meeting adjourned at 12:00 noon.