

**ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE**

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

**FINAL MINUTES OF MEETING
September 17, 2010
8:00 a.m.**

Committee Members Present:

Marvin Bergeson, MD
Amber L. Briggs, Pharm.D.
Jeffrey G. Demain, MD
Daniel P. Kiley, DDS MPH (telephonic)
John E. Pappenheim, MD
Claudia Phillips, MD
Janice Stables, MSN, ANP
Jill Reid, R.Ph. (telephonic)

Committee Members Absent:

Dharma Begich, Pharm.D.
Richard E. Brodsky, MD
Robert H. Carlson, MD
Vincent Greear, R.Ph.
Diane Liljegren, MD
Andrew Maciejewski, MD
Paul Michaud, Pharm.D.
Sherrie D. Richey, MD
Trish White, R.Ph.

Others Present:

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

1. Call to Order – Co-Chair

Co-Chair Demain called the meeting to order at 8:00 a.m.

2. Roll Call

A quorum was present. Dr. Pappenheim, a psychiatrist from Juneau, was introduced and Dr. Bergeson was thanked for agreeing to serve another term on the P&T Committee. There has been a change in administration. While it is still First Health, it is now under the flag of Magellen Medicaid Administration. Replacing Dr. Melinda Sater will be a new representative, Dr. Julie Pritchard.

A new conflict of interest statement, which needs to be filled out and returned to Mr. Campana, was distributed to the committee members.

3. Public Comment on Blue/Red Classes

DION ROBERTS: Cystic fibrosis patients often use pancreatic enzymes. Due to their other causes for mal-absorption, they use large doses and it is difficult to achieve the proper dose of the proper product. There are three licensed pancreatic enzymes, one of which is not available due to manufacturing difficulties. A cystic fibrosis patient's longevity is determined by their degree of pulmonary disease. The severity of their pulmonary disease is directly inversely proportional to their weight. If a patient's pancreatic enzymes are changed, and we do not get it right, it takes months to gain the ground that we lost, causing them to lose years off their life over a lifetime. Therefore, we do not like to make many changes. The procedure whereby you put things out for contract every year has a big chance of adversely affecting patients if they have to switch enzymes. Zenpep is the only drug used for tube feeding and needs to remain available, because between 10 and 20 percent of our population require tube feedings at any given time. Creon is the easiest pancreatic enzyme to use in newborns. It has the smallest bead and is the least likely to cause trouble. All pancreatic enzymes should be available to cystic fibrosis patients.

Dr. Demain asked whether new drugs, once they were FDA approved, should also be available or if the two products mentioned were sufficient. Dr. Roberts did not believe the FDA would approve any new pancreatic enzymes in the near future.

4. Review of New Agents for Angina (Red Category)

Dr. Sater gave the Magellen presentation on Ranolazine (Ranexa). Ranexa is the only drug in this class. It is indicated for the treatment of chronic angina. The drug may reduce hemoglobin A1c in patients with coronary artery disease and diabetes, but it should not be considered a treatment for diabetes. The mechanism of action is undetermined, however the anti-angina effects of the drug does not appear to be dependent on any blood pressure lowering effect. QT prolongation associated with Ranexa appears to be dose related. In August, there were nine claims for Ranexa. This is a new class and has not been discussed. No experts wanted to discuss Ranexa.

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

5. Re-Review of Anti-TNF Drugs (Red Category)

ANNIE OGOSTALICK: A representative of Abbott discussed Humira. There are three key attributes of Humira: efficacy across a broad scope of indications, consistent safety across indications, and comparatively efficient maintenance dosing across indications. Humira is the first fully human monoclonal antibody targeted TNF currently indicated in rheumatoid arthritis and juvenile idiopathic arthritis, psoriasis and psoriatic arthritis, Crohn's Disease, and ankylosing spondylitis. Within this broad scope, the outcomes with Humira therapy were reviewed. Regarding safety, rates of serious infections, tuberculosis and lymphoma were all within the range of other documented anti-TNF and biologic naive RA patient incident data. A recently published analysis of Humira reconfirmed its consistent safety in global clinical trials across all indications in diverse patient populations. Last November, the FDA required all manufacturers of TNF blockers to update the box warning and prescribing information to alert health care professionals of an increased risk of lymphoma and other malignancies in pediatric patients treated with TNF blockers. Additionally, registries may provide

clinical and safety information from a naturalistic or observational perspective. Care should be exercised when interpreting data from registries as they may differ in quality, standards of care, patient demographics, baseline disease characteristics, and background rates of disease. The recommended dosages of Humira were reviewed. We request that Humira be retained as a preferred agent on the PDL.

MARC JENSEN: A representative of UCB discussed Cimzia. Cimzia is an anti-TNF biologic that was approved for the treatment of patients with Crohn's Disease in 2008 and rheumatoid arthritis in 2009. Cimzia has demonstrated sustained efficacy in moderate to severe rheumatoid arthritis patients in the open label extension portion of several pivotal studies, which were reviewed. Treatment with Cimzia provided sustained, long-term inhibition of the progression of radiographic joint damage and improvements in rheumatoid arthritis signs and symptoms over two years or more. No new safety signals were observed in the open label extension of these pivotal studies. Several studies and their outcomes were reviewed. Cimzia's safety profile is similar to other anti-TNF agents in this class. New Cimzia data further demonstrates sustained remission and a predictable side effect profile in rheumatoid arthritis and Crohn's Disease. The data from the RAPID I study in rheumatoid arthritis patients indicate that a patient's response to therapy can be determined as early as week 12.

CLAIRE MERENAR: A representative of Amgen discussed Enbrel. Enbrel is the only fully human soluble TNF receptor. It mimics the action of naturally occurring TNF receptors, which is a unique mechanism of action amongst the biologics and restores a balance of TNF. It has a breadth of indications across conditions for rheumatology and dermatology. The FDA has deemed Enbrel safe and effective for moderately to severe active rheumatoid arthritis; juvenile idiopathic arthritis for patients two years and older; psoriatic arthritis for psoriasis in adult patients with chronic, moderate, and severe plaque psoriasis; and ankylosing spondylitis. Enbrel has more than 17 years of collective clinical experience and over two million patients years of exposure, including 10 years of post-marketing experience in rheumatoid arthritis and juvenile idiopathic arthritis, over 7 years in psoriatic arthritis and ankylosing spondylitis, and over 5 years in plaque psoriasis. Enbrel's safety profile was reviewed. Its consistent dosing requirements allows for a predictable dose at a predictable cost. The recommended dosages were reviewed. We request Enbrel continue to be included on the PDL.

Dr. Sater gave the Magellen presentation of Cytokine and CAM Antagonists and Related Agents. There are 10 agents in this class, but only seven for your consideration since Remicade, Actemra and Orencia are office administered infusions. Drugs in this class fall into two distinct mechanisms of action, cell-adhesion molecules and cytokine antagonists. Dosing frequency is dissimilar between agents. Indications, potential adverse reactions and contraindications vary for each agent. In August, there were 56 claims: 55% for Enbrel, 42% for Humira, and 1 claim each for Stelara, Simponi and Cimzia. At the last review, a motion to declare the drugs in this class as therapeutic alternatives carried with three opposed. Since the last review, Stelara and Actemra are new to the marketplace and Cimzia now has an indication for RA.

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

6. Re-Review Bile Acid Salts (Red Category)

There were no public testimonies.

Dr. Sater gave the Magellen review on Bile Acid Salts. There are two chemical entities in this class; three distinct Ursodiol products, all of which have generic equivalents; and Chenodal, which is available only as a branded product. Ursodiol is a naturally occurring bile acid that is formulated for therapeutic use. The indications are slightly different. In August, there were 42 claims: 88% for generic Ursodiol and 5 claims for branded URSO. At the last review, this was a new class. Without discussion, a motion to declare the drugs in this class as therapeutic alternatives, with no preference for any product, passed unanimously. Since the last review, Chenodal has been added to the marketplace. It has an indication for dissolving gallstones in patients who cannot tolerate surgery. No experts chose to speak to us about this class.

Dr. Sater explained the difference between therapeutic alternative and class effect. Class effect essentially means any drug in the class could be substituted for another drug in the class and they work the same way. Therapeutic alternative means that while the drugs may not work the same way and have slightly different mechanics of action, they are all effective for the conditions being discussed.

Dr. Demain reminded the committee that any drug in any class could be prescribed by utilizing the medically necessary clause.

DR. BERGESON MOVED THAT THE DRUGS IN THIS CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BRIGGS. WITHOUT OBJECTION, THE MOTION PASSED UNANIMOUSLY.

7. Review of Antihyperuricemics

THOM FORD: A representative of Takeda Pharmaceuticals discussed Uloric. Uloric is the first new gout medication in over 50 years. It is a xanthine oxidase inhibitor and is indicated for the chronic management of hyperuricemia in patients with gout. There are three head-to-head studies against Allopurinol looking at a specific endpoint, which was reviewed. The recommended dosages of Uloric were reviewed. The robust data shows that Uloric, at 80 milligrams, is superior to Allopurinol and an overall cost savings to patients. We request that Uloric be added to the PDL.

Dr. Sater gave the Magellen presentation on Antihyperuricemics. There are four distinct chemical entities in this class: Colchicine, Allopurinol, the branded product Uloric, and Probenecid. Currently, Colcris is the only FDA approved branded Colchicine. The generic Colchicine, which has been around for many years, is not FDA approved. While the FDA has not yet issued guidance on the removal of the unapproved product, it will be coming. Colcris is indicated for both the treatment and prevention of gout flares. Uloric is a xanthine oxidase inhibitor indicated for chronic management of hyperuricemia in patients with gout. Due to the high risk of adverse events, Colchicine should be used for second line therapy when NSAIDs or corticosteroids cannot be used. After an initial gout attack, Probenecid, the combination of Colchicine and Probenecid, or a xanthine oxidase inhibitor are the drugs of choice for lowering uric acid. Colcris has a slightly different dosing regimen than the old Colchicine as well. In August, there were 257 claims: 82% for Allopurinol, 16% for the generic Colchicine products, and 2% for branded Uloric. This is a new class and has not been previously discussed.

In response to Dr. Demain's question about monitoring other medications a patients uses that may cause an interaction with this class, Dr. Sater said there were edits in the point of sale system that would remind the pharmacist of possible drug-to-drug interactions, but there are no hard denials.

DR. BERGESON MOVED THAT THE DRUGS IN THIS CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILLIPS. WITHOUT OBJECTION, THE MOTION PASSED UNANIMOUSLY.

8. Re-review of Multiple Sclerosis Agents (Red Category)

Brian Hutchinson: A representative of Acorda discussed Ampyra extended release tablets. At 10 milligrams, Ampyra is a first in class, broad-spectrum potassium channel blocker indicated to improve walking in patients with Multiple Sclerosis as demonstrated by an increase in walking speed. Ampyra's mechanism of action has not been fully elucidated, but in animal studies, Ampyra has been shown to increase conduction of action potentials through inhibition of potassium channels. Efficacy was established in two phase-three clinical trials, which were reviewed. Efficacy was independent of MS type, concurrent treatment with Immunomodulators, body mass index, age, gender, and degree of impairment. The clinical meaningfulness of improved walking speed was best using a validated patient self-assessment of the impact of MS on walking, the 12-Item Multiple Sclerosis Walking Scale. Ampyra is a 10 milligram extended release tablet and the maximum recommended dose is 10 milligrams, twice daily, approximately 12 hours apart, with or without food. The tablet should be taken whole and should not be crushed, chewed, or dissolved prior to taking. Ampyra is contraindicated in patients with a history of seizures, as well as moderate or severe renal impairment. The adverse events include urinary tract infections, insomnia, dizziness, headache, and nausea. Ampyra is not a disease-modifying agent and should not replace existing disease modifying agents.

Elaine Thomas: A representative of Bayer Biologic discussed Betaseron. Betaseron, as well as all of the currently approved immunomodulating therapies, should be retained on the PDL. Betaseron was first approved in 1993 and there is 700 patient years of safety data. Recently published was a 16-year long-term follow-up and we are working on a 21-year publication on the safety of Betaseron. Recommended dosages were reviewed. Betaseron does not have approvals for secondary progressive MS, but this drug is efficacious across the whole disease spectrum. Several studies were reviewed. We have a 30-gauge needle, which is the smallest one in MS to date. It is refrigeration free and can easily be used for travel or by patients who do not have access to a refrigerator. The 16-year long-term follow up study, which supported the long-term safety of Betaseron, was reviewed. Mortality was significantly lower for patients who originally started on the Betaseron arm of our pivotal trial as compared to those who were randomized to receive placebo. Please keep all of the drugs available on the PDL for your patients.

Rosalynde Finch: A representative of Biogen Indec discussed Avonex. Prevention or postponement is really the most important endpoint for patients with MS, which is our therapeutic goal. Avonex is the only disease modifying therapy that had the prevention of disability progression as its primary endpoint. We showed a 37 percent relative reduction in disability progression sustained over six months, which is the most stringent endpoint used in these trials. We have indications in three key areas: slowing disability progression, reducing relapses, and prevention of second attacks. The long-term data on the safety and efficacy of Avonex was reviewed. Several trials and their outcomes were reviewed. Patients showed a higher quality of life and a greater sense of self-sufficiency and

independence when using Avonex. After 15 years, 80 percent of the patients were still on Avonex. The overall benefits to patients on Avonex are the long-term efficacy that it provides and the convenience of a once-weekly injection.

Heidi Edwards: A patient with Multiple Sclerosis and a young daughter described her life with MS. Since being diagnosed at age 18, I have had many exacerbations. One MS attack kept me in the hospital for seven weeks and was so severe that I had to learn how to talk, walk, and become self-sufficient again. I worried that I would not be able to care for my daughter or myself. There is nothing worse than feeling helpless and being forced to dependent on someone else. I was fortunate to have treatment options when I was first diagnosed. I tried Betaseron, Avonex, and Rebif, but they did not work for me. I used Copaxone successfully for many years, but then the exacerbations returned. My doctor predicted that I would be in a wheelchair within five years if we did not find a therapy that worked for me. I have been successfully using Tysabri for three years. My life with MS is the best that I could ask for. I am able to take care of my daughter and myself. My insurance covers 80 percent of the drugs cost and I am liable for the remainder. I am not here to advocate which medicine is best, but to tell you that MS patients need to have all medication choices available to them to help them lead a productive life. The medical expenses incurred by MS patients could easily outweigh the cost of covering the treatment medications.

Kathy Kincaid: A member of the Board of Directors of the Alaska Multiple Sclerosis Center described her life with MS. I was diagnosed with MS at age 20 and will be 63 very soon. I had a problem finding medications that I could take, because I am highly allergic. Many MS patients also take medications for other things such as psoriasis, arthritis, asthma, and diabetes so it is very difficult to find MS drugs that do not interact. MS drugs are very harsh on the system so patients have to go from one drug to the next to find one that helps them without hurting them more. It is necessary that all the drugs are available to MS patients since the disease is so debilitating. I have gone from relapsing into the secondary progressive stage. There are not very many drugs indicated for this stage, because the group of patients is small and do not warrant the large studies that bring FDA approval. I hope that you will make all of the drugs, current and future, available to MS patients.

Dr. Sater gave the Magellen presentation on Multiple Sclerosis agents. There are six available products and four available chemical entities. All products are FDA approved for the treatment of relapsing forms of MS. The BEYOND study showed similar outcomes for Betaseron and Copaxone for both primary and secondary endpoints. All drugs in the class are interferon products except Copaxone and Ampyra. In August, there were 19 claims: 32% for Copaxone, 30% for Rebif, 21% for Betaseron, and 16% for Avonex. At the last review and after some discussion, a motion to declare the drugs in this class as therapeutic alternatives passed with two opposed. Since the last review, Ampyra and Extavia are new to the marketplace. Ampyra does not retard the disease progression, but may improve impairment in walking, is used primarily as an add-on therapy in MS, and is the only oral preparation. Copaxone, Rebif, Betaseron, and Avonex are the currently preferred agents.

In response to Dr. Hope, Dr. Sater said Extavia and Betaseron were considered equivalent.

In response to Dr. Malter's question about the lack of trials to study drugs indicated for the secondary progressive stage, Dr. Sater said there was a very small subset of patients who have that particular type of disease, but she did not know if the trials were not done because they could not find enough patients or if they were denied the indication, but she doubted they were denied the indication.

Dr. Phillips noted that Ampyra was not a disease-modifying agent and was not equivalent to the other drugs in the class.

DR. BERGESON MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILLIPS. THE MOTION PASSED WITH FIVE OPPOSED AND ONE ABSTAINING.

9. Re-review of Pancreatic Enzymes (Red Category)

ANNIE OGOSTALICK: A representative of Abbott discussed Creon. Creon is indicated for the treatment of exocrine pancreatic insufficiency, or EPI, due to cystic fibrosis or other conditions. It is the only pancreatic enzyme with an indication to treat pancreatic insufficiency due to chronic pancreatitis. There are three key concepts. Creon is the first FDA approved, delayed release pancreatic enzyme replacement product to the U.S. marketplace, with a market presence since before the FDA Cosmetic Act of 1938. It is not interchangeable with any other currently available Pancrelipase products. It is the only pancreatic enzyme indicated for the treatment of EPI. The three key concepts were further explained. Several studies and their outcomes were reviewed. We request that Creon be maintained on the PDL.

Dr. Sater gave the Magellen presentation on Pancreatic Enzymes. All the products in this class contain some combination of Amylase, Lipase, and Protease in various combinations and strengths. The products are not interchangeable. Creon and Zenpep are the only two brand name agents that are FDA approved at this time. A generic equivalent of Zenpep is FDA approved, but currently has serious availability issues. In August, there were 67 claims: 37.3% for Creon, 33% for Zenpep, 13.4% for the generic Pancrelipase, 13.4% for Pancrease, and 2 claims for Pancreaze. At the last review, a motion to declare the drugs in this class as therapeutic alternatives passed unanimously. The FDA approval process has forced many products that were included in the last review to be removed from the market. Dr. Roberts spoke to us, but stated his comments earlier in the meeting.

Dr. Demain said patients with cystic fibrosis require considerably higher doses of the pancreatic enzymes. He asked if there were trends related to that as far volume of drug utilization. Dr. Sater said the claims for cystic fibrosis patients taking these drugs were for massive quantities.

Dr. Demain said small changes in the makeup of the pancreatic enzyme in cystic fibrosis patients not only affect the absorption, but also weight, which could tremendously affect prognosis and life expectancy. Therefore, small variances can have dire consequences. Dr. Sater said lung function in a cystic fibrosis patient was inversely proportional to their weight and any weight loss could take years off their life according to Dr. Roberts.

DR. BERGESON MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BRIGGS.

Dr. Malter asked if being thin or malnourished caused a patient's lungs to malfunction or if patients that had malfunctioning lungs became thin or malnourished. Dr. Demain said that the current thinking was weight seemed to be the precipitator of the pulmonary disease. Dr. Roberts also feels strongly that it is a causal effect.

THE MOTION PASSED UNANIMOUSLY.

10. Re-Review of Benign Prostatic Hyperplasia (BPH) Treatments (Red Category)

Brian Streng: A representative of GlaxoSmithKline discussed Jayln. Jayln combines the dual 5 α reductase inhibitor Avodart, which reduces prostate size for the treatment of BPH in men with an enlarged prostate. Together, through differing mechanisms, symptom improvement occurs early in therapy and overall produces superior symptom improvement over either component alone. Additionally, by combining these agents into a once-a-day capsule, you also achieve a reduction in pill burden. The COMBAT trial and its outcomes were reviewed. The side effect profile includes impotence, decreased libido, ejaculation disorders, breast disorders and dizziness. The data demonstrates superior symptom benefits by combining these two drugs.

Dr. Sater gave the Magellen presentation on Benign Prostatic Hyperplasia (BPH) Treatments. The alpha-blockers for BPH have five available entities and six available products, including one extended release, Cardura XL. Tamsulosin is available in the combination product, Jayln. All products, except Prazosin, are FDA approved for the treatment of BPH. Doxazosin, Terazosin, and Prazosin are also indicated for hypertension. All agents show similar efficacy. Flomax, Uroxatral and Rapaflo are alpha 1a selective and may have a slightly more attractive ADR profile. Rapaflo is contraindicated for patients with severe renal impairment. In August, there were 399 claims for alpha-blockers: 39% for generic Flomax, 29% for Prazosin, 19% for Doxazosin, 7% for Terazosin, 3% for branded Flomax, 1.5% for Uroxatral, and 1% for Rapaflo. At the last review, a motion for class effect, to include at least one alpha 1a selective agent, passed unanimously. Since the last review, generic Flomax became available.

In response to Dr. Demain, Dr. Sater said that if Tamsulosin and Avodart were approved, Jayln would not automatically be included unless it was not cost beneficial or cost neutral. The committee had previously decided not to address combination products specifically.

DR. BERGESON MOVED A CLASS EFFECT, TO INCLUDE AT LEAST ONE ALPHA 1A SELECTIVE AGENT. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

Dr. Sater gave the Magellen presentation on 5-Alpha Reductase Inhibitors. There are two available chemical entities. Both are FDA approved for the treatment of BPH. They have similar pharmacokinetic profiles and clinical efficacy. Avodart has more potential for drug interactions than Finasteride. To date, there are no comparative trials. In August, there were 86 claims: 58% for Avodart and 41.86% for generic Finasteride. At the last review and without discussion, the motion for a class effect passed unanimously.

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

11. Re-review of Lipotropics, Statins (Red Category)

Jamie Hurst: A representative of AstraZeneca discussed Crestor. In October of 2009 and based on the PLUTO trial, the FDA approved Crestor for use in pediatric patients 10 to 17 years of age with heterozygous familial hypercholesterolemia. In February 2010, the FDA approved Crestor to reduce the risk of strokes and heart attacks in arterial revascularization procedures in individuals without clinically evident coronary heart disease, but at an increased risk of cardiovascular disease. The JUPITER trial and its outcome was reviewed. The most common adverse reactions reported for Crestor versus placebo were reviewed. Previous studies have demonstrated that Crestor is highly efficacious at lowering LDL, raising HDL, and slowing the progression of atherosclerosis.

Steven Chang: A representative of Eli Lilly discussed Livalo (Pitavastatin). Livalo was approved last year in the United States, but has been available in Japan and other Asian countries since 2003. It is FDA indicated for patients with primary hyperlipidemia, as an adjunctive therapy to diet, to reduce total cholesterol, LDL and triglycerides, as well as to increase HDL. It is dosed once daily, available in three strengths, and can be taken with or without food at any time of the day. The recommended dosages and mechanism of action of Livalo were reviewed. The difference in Livalo's metabolism from other statins may offer a potential to reduce drug-to-drug interactions for patients who have concerns with multiple medications that are metabolized. Several trials and their outcomes were reviewed. In regards to safety, there are no new significant adverse events that were dramatically different from the currently commonly prescribed statins. Liver enzymes need to be monitored before and after treatment to observe for any abnormalities. The most frequent adverse reactions were reviewed. We request that you consider Livalo as an additional option for your patients.

Dr. Demain noted that Livalo was approved last month before the materials were provided to the P&T Committee. Since Livalo should be considered, the Lipotropics class would be tabled to the next meeting.

Dr. Demain recognized Dr. Alex Malter, a medical director for Medicaid from Juneau, and thanked him for attending the meeting.

Recess from 9:40 a.m. to 10:00 a.m.

12. Re-review Alzheimer's Agents (Blue Category)

David Gross: A representative of Pfizer discussed Aricept. Aricept has a new dosage strength and formulation, which is the 23-milligram tablet. It is indicated for the treatment of Alzheimer's dementia. It has efficacy demonstrated in mild, moderate and severe dementia. The recommended dosages were reviewed. In the United States, it is estimated that more than 5.3 million American have Alzheimer's disease with the vast majority being over the age of 65. Direct health care costs for Alzheimer's disease is expected to reach \$172 billion in 2010. Several trials and their outcomes were reviewed. The most common adverse events for Aricept 23 versus Aricept 10 milligrams were reviewed and showed increased GI type side effects with the higher dosage form, but most occurred within the first month. The discontinuation rate was a little bit higher with Aricept 23. The safety information was reviewed.

Dr. Sater gave the Magellen presentation on Alzheimer's Agents. There are five available agents. Namenda has a unique mechanism of action, an NMDA receptor antagonist. Blockage of this major

glutamate receptor may prevent nerve death resulting from excess glutamate release. Galantamine also modulates nicotinic Acetylcholine receptors. Cognex, or Tacrine, is not used very often due to modest effects and increased toxicity. Exelon has significant interaction with food. Exelon is also available as a transdermal product. In August, there were 65 claims: 91% for Aricept, 5 claims for the Exelon patch, and 1 for generic Glantamine. At the last review, the motion to continue a class effect passed unanimously. Since the last review, there is a new 23-milligram dose of Aricept.

In response to Dr. Malter, Dr. Sater said the percentage of claims reviewed during the meeting were patients that had only Medicaid coverage and did not include patients with Part D coverage.

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

13. Re-review of Erythropoiesis Stimulating Proteins (Blue Category)

There were no public testimonies.

Dr. Sater gave the Magellen presentation on Erythropoiesis Stimulating Proteins. There are two entities and three branded products. Epogen and Procrit are identical recombinant human erythropoietin products. Aranesp differs slightly. Prescribers in hospitals must enroll in the ESA Apprise Program before they can use Aranesp. All of the agents have several black box warnings. The dosing guidelines have been revised based on target levels. In August, there were 16 claims: 87.5% for Procrit and 2 claims for Aranesp. Both Procrit and Aranesp are currently preferred agents. At the last review and without discussion, a motion to continue class effect passed unanimously. The National Comprehensive Cancer Network guidelines have changed to recommend the lowest possible dose for the shortest amount of time due to increased mortality associated with use of these drugs.

Dr. Briggs questioned what Medicaid could do to ensure that the REMS Program process was completed. Mr. Campana did not know if there was a way to review the data to ensure the process was completed and suggested that the manufacturer could tell us who was administering the REMS Program.

Dr. Demain asked if the DUR targeted drugs that had box warnings or a greater risk of inappropriate use. Mr. Campana said the DUR could choose to run any kind of criteria against patient profiles, including black box warnings, but that would not be their only criteria.

In response to Dr. Malter, Dr. Sater said they did not know if the majority of the patients were on these agents due to cancer or kidney disease.

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

14. Re-review of Anti-Parkinson's Agents (Blue Category)

There were no public testimonies.

Dr. Sater gave the Magellen presentation on Anti-Parkinson's Agents. There are two available chemical entities. 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 have some increased incidence of hypertension. Mirapex may be associated with increased risk of hallucinations. Head-to-head comparative trials are limited. The two generic products, Ripinirole and Pramipexole, are currently preferred. In August, there were 183 claims: 46% for generic Ripinirole, 33.3% for Pramipexole, 20% for branded Mirapex, and 1 claim each for Mirapex ER and Requip XL. At the last review, a motion for class effect passed unanimously.

The committee reviewed the currently preferred agents, which includes Mirapex instead of the generic Pramipexole. Dr. Sater explained that when this decision was made, Pramipexole was in the six-month exclusivity period when generics are extremely expensive. If a class effect were declared, the two generics would likely be included on the PDL.

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

15. Re-review of Bisphosphonates (Green Category)

Dr. Sater gave the Magellen presentation on Bisphosphonates. The currently preferred agents were reviewed. In August, there were 245 claims: 76% for generic Alendronate, 10.6% for Fosamax Plus D, 6.5% for Actonel, 6% for Boniva, and 1 claim for Fosamax solution. At the last review, a motion for class effect passed unanimously. The new agent Prolia is not on the list because it is administered in a physician's office and not considered for PDL inclusion.

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

16. Re-review of Calcitonins (Green Category)

Dr. Sater gave the Magellen presentation on Calcitonins. There are two available branded products. They are both indicated for the treatment of osteoporosis, although they are widely used in bone pain as well. In August, there were 15 claims: 47% for generic Calcitonin, 40% for Fortical, and 13% for Miacalcin. At the last review and without discussion, a motion for class effect passed unanimously.

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

17. Re-review Phosphate Binders (Green Category)

Dr. Sater gave the Magellen presentation on Phosphate Binders. There are four single entities available. Two are different salts of the same active drug. In August, there were 80 claims: 50% for Renvela, 34% for Calcium Acetate, 11.2% for Renagel, and 5% for PhosLo. At the last review, a motion to declare the drugs in this class as therapeutic alternatives passed with four opposed. Since the last review, Renvela is now available as 800 mg or 24 mg powder packets in addition to the tablets. The manufacturer has delayed the decision to remove Renagel from the market for now.

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

18. Re-review of Pulmonary Arterial Hypertension (PAH) Agents (Green Category)

Dr. Sater gave the Magellen presentation on Pulmonary Arterial Hypertension (PAH) Agents. There are two distinct mechanisms in this class, which were described. In August, there were 7 claims: 71% for Revatio and 1 claim each for Tracleer and Letairis. At the last review, a motion to declare the drugs in this class as therapeutic alternatives passed unanimously. In addition to the oral agents, Ventavis and Tyvaso are inhaled agents for pulmonary hypertension, which appear in the packet but are not part of the PDL consideration.

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

19. Re-review of Non-Statin Lipotropics (Blue Category)

Dr. Sater gave the Magellen presentation on Non-Statin Lipotropics. There are four branded and one generic Fenofibrates, a Fenofibric acid and generic Gemfibrozil available. Lovaza, an omega-3-acid ethyl ester product, is also considered in this grouping. In August in the Fenofibrates, there were 401 claims: 36% for Tricor, 28% for Lovaza, 24% for generic Gemfibrozil, 10.2% for Trilipix, 1.25% for Fenofibrate and 1 claim for Antara. At the last review, a motion to declare the drugs in this class as therapeutic alternatives, with at least one Fenofibrate and one Gemfibrozil product included, passed unanimously.

In response to Dr. Malter's question of why one Fenofibrate and one Gemfibrozil product was included in the motion, Dr. Sater said the discussion was several years ago and she did not recall the specific reasons. The committee discussed whether they needed to be included in the new motion.

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

Dr. Sater gave the Magellen presentation on Lipotropics, Niacin. The Niacin product available as a prescription product for your consideration is Niaspan. In August, there were 89 claims for Niaspan and 1 claim for the Simcor combination product. At the last review, a motion for class effect, with one extended release Niacin product to be included, passed unanimously.

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

Dr. Sater gave the Magellen presentation on Zetia. In August, there were 133 claims. At the last review, a motion for class effect passed unanimously.

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

20. Re-review of LMW Heparins (Blue Category)

Dr. Sater gave the Magellen presentation on LMW Heparins. There are three available agents. In August, there were 57 claims: 75% for Lovenox, 23% for generic Enoxaparin, and 1 claim for Fragmin. At the last review and with little discussion, a motion to declare the drugs in this class as therapeutic alternatives, with Lovenox preferentially included, passed unanimously. Since the last review, generic Lovenox has become available.

In response to Dr. Briggs, Dr. Sater said the generic Lovenox was fairly new and could be a brand and generic problem, which would be filtered out by the bids. It is conceivable that you could end up with a brand being preferred over a generic. Manufacturer's have to commit to three years of flat pricing during the bidding process. Those that were not accepted on the PDL can alter their bids, but it cannot be any higher.

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

21. Re-review Platelet Aggregation Inhibitors (Green Category)

Dr. Sater gave the Magellen presentation on Platelet Aggregation Inhibitors. There are four single entity products and one combination with aspirin. In August, there were 309 claims: 93% for Plavix, 5% for Aggrenox, 1.3% for Effient, and 1 claim each for Dipyridamole and Ticlopidine. At the last review, a motion for class effect, with Plavix preferentially preferred, passed unanimously.

In response to Dr. Demain, Dr. Sater said there was a brief period when generic Plavix was available, but there is no defined date for when we might see more generic Plavix. It was noted that a generic Clopidogrel was anticipated in 2011.

MS. STABLES MOVED THAT THE DRUGS IN THIS CLASS WERE THERAPEUTIC ALTERNATIVES.

The committee discussed whether Plavix should be preferentially included in the motion. Dr. Briggs recommended that Clopidogrel or Pasugrel be included, without specifically including Plavix.

The motion failed due to lack of a second.

DR. PAPPENHEIM MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES WITH CLOPIDOGREL OR PASUGREL BEING PREFERENTIALLY INCLUDED. SECONDED BY DR. BRIGGS. THE MOTION PASSED UNANIMOUSLY.

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

Dr. Sater gave the Magellen presentation on Topical Agents for Psoriasis. There are three distinct chemical entities. One is also available as a combination with Bestamethozone. In August, there were

16 claims: 56% for Dovonex, 25% for Vectical, and 3 claims for generic Dovonex solution. At the last review, a motion for class effect passed unanimously.

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

23. Review Minutes from April 2010 Meeting

Mr. Campana reviewed the corrections to be made to the April 2010 meeting minutes.

DR. BRIGGS MOVED TO APPROVE THE APRIL 2010 MEETING MINUTES AS CORRECTED. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

31. Comments from Committee Members or Chair

Dr. Demain noted that the next meeting was scheduled for November 19, 2010.

Mr. Campana thanked Dr. Demain for the outstanding job of running the meeting.

Dr. Sater said this was her last meeting as the regularly scheduled presenter. It has been a privilege to work for the P&T Committee over the last six years.

32. Adjourn

DR. BRIGGS MOVED TO ADJOURN THE MEETING. SECONDED BY DR. PAPPENHEIM. THE MOTION PASSED UNANIMOUSLY.

The meeting adjourned at 10:50 a.m.