ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

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

MINUTES OF MEETING
September 19, 2014
8:00 a.m.

Committee Members Present:
Marvin Bergeson, MD
Robin Cooke, Pharm.D.
Robert Carlson, MD (telephonic)
Jeffrey Demain, MD, Chair
Diane Liljegren, MD (telephonic)
Jenny Love, MD
John O'Riley, PA-C
John Pappenheim, MD
Claudia Phillips, MD
Maggie Rader, CNM
Chuck Semling

Committee Members Absent:
Vincent Greear, R.Ph.
Jill Reid, R.Ph.
Greg Salard, MD
Trish White, R.Ph.

Others Present:
Chad Hope, Pharm.D.
Tolu Balogun, Magellen Medicaid Administration
Julie Pritchard, Magellen Medicaid Administration
Deborah Crawford
Lynda Finch
Caroline Hoffman
Deborah Profant
Erin Narus, State of Alaska

1. Call to Order – Chair

Dr. Demain called the meeting to order at 8:01 a.m.

2. Roll Call

A quorum was present. Tolu Balogun, who will replace Julie Pritchard of Magellen, was introduced. Dr. Demain reviewed the rules of the meeting.

3. Public Comments - Local Public/Health Practitioners

There were no public comments. A letter was received from Dr. Roberts, which will be read during the review of pancreatic enzymes.

4. Re-Review of Antiemetics/Antivertigo Agents (Red Category)

There were no public testimonies.

Ms. Pritchard gave the Magellen presentation on Antiemetics/Antivertigo Agents. Chemotherapy-induced nausea and vomiting can significantly impact a patient's quality of life, leading to poor compliance with future chemotherapy or radiation treatments. Nausea and vomiting can also lead to several other adverse events such as nutrient depletion, metabolic imbalances, anorexia, diminished performance in mental status, and others. The goal of antiemetic therapy is to prevent nausea and vomiting. Pregnancy vomiting can occur any time of the day and can affect pregnant women at varying degrees. Agents used include NK_1 receptor antagonists, 5-HT_3 antagonists, cannabinoids, antihistamines, and phenothiazines. In July, there were 647 claims. There are no new significant clinical changes for 2014. At the last review, the antivertigo agents were dropped from review and the focus was on antiemetics only. A motion for therapeutic alternatives passed unanimously.

Dr. Hope said this was a red category because there is a new product called Diclegis.

Ms. Pritchard said Diclegis became available in 2013. It is indicated for the treatment of nausea and vomiting in pregnant women who are not responding to conservative management. It can cause somnolence. It is a pregnancy category A drug. It is given at bedtime on the first day and titrated to the desired effect with doses of up to four tablets daily. It is available as a 10-milligram-by-10-milligram delayed-release tablet.

Ms. Pritchard reviewed the market shift report. A new column for relative cost was added to the report. Symbols, rather than dollar amounts, were used since the actual pricing is confidential. One dollar sign ($) indicates the reference product, which is the least expensive. Two $$ would mean that product is twice as expensive as the reference product, and as many as five dollar signs can be used. An exclamation point (!) means the product would be six times more expensive than the reference product. A mark of 50! would indicate 50 exclamation points.

The committee discussed the new drug Diclegis. Ms. Pritchard said the American College of Obstetricians and Gynecologists and the Association of Professors of Gynecology and Obstetrics has recommended these drugs as first line therapy for years.

DR. LOVE MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILLIPS.

Dr. Liljegren felt the motion should be amended to include at least one antiemetic that is a class A in pregnancy drug.

DR. LOVE AMENDED THE MOTION AND MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE AT LEAST ONE PREGNANCY

CATEGORY A AGENT. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Dr. Hope discussed the problems they were experiencing with the telephone lines. He suggested a discussion at the end of the meeting on whether there should be a call-in line for committee members only and require everyone else to be present in person.

5. Re-Review of Multiple Sclerosis Agents (Red Category)

DR. DEBORAH CRAWFORD, a representative of Acorda, discussed Ampyra. Since November 2013, no new information or data was added or removed from the Ampyra PI January 2014 label. The PI is the same as the January 2013 version when major changes were made to include a contraindication or history of hypersensitivity to Ampyra, as well as a warning that Ampyra can cause anaphylaxis and should be discontinued and not restarted if this occurs. As required by the FDA, the special recent major events listing, as well as the markings that drew attention to the new text in the January 2013 label, were removed in January 2014. The information on hypersensitivity and anaphylaxis still appears in the highlights section of the contraindication section, as well as in the warnings and precautions section. The FDA removed the REMS requirement for Ampyra in June 2013 because they believe that Acorda has successfully completed the communication goal of the REMS program regarding contraindications, the risk of seizure, and counseling patients. The annual DEER prescriber and DEER pharmacists letters are no longer required to ensure that the risks associated with Ampyra use are adequately conveyed.

DR. DEBORAH PROFANT, a representative of Teva Pharmaceuticals, discussed Copaxone. There are two approved versions of Copaxone, Copaxone 20-milligrams given daily and Copaxone 40-milligrams given three times a week, which was approved in January 2014. Both doses are now in one package insert and approved January 2014. The doses are not interchangeable. A study on Copaxone 40-milligrams given three times a week and its outcome was reviewed. Copaxone, in both its formulations, is the only agent that is pregnancy category D.

DR. CAROLINE HOFFMAN, a representative of Novartis, discussed Gilenya. We request access to Gilenya for patients and providers, which would be an improvement from its current status which requires a medical necessity form. Gilenya has data on all four MS measures, which includes disability, relapse rates, MRI activity, and brain volume loss. Gilenya is the only oral agent with a head-to-head study, the results of which were reviewed. Based on the head-to-head study that shows superiority, knowing that Gilenya has efficacy across all four MS measures and there have been no new safety signals, we request enhanced access for Gilenya.

DR. LYNDA FINCH, a representative of Biogen Idec, discussed Plegridy and Tecfidera. Plegridy is the first pegylated beta interferon 1A approved for relapsing forms of MS. It has a prolonged half-life. It is given subcutaneously every two weeks. It comes as a prefilled syringe or an auto-injector. We have 1,932 patient years' exposure with 4,125 patients who have received this drug for at least two years. A phase-three clinical trial and its outcomes were reviewed. Plegridy has the same profile as the other subcutaneous interferons. The most common adverse reactions include injection site reactions, headaches, and so forth. As Plegridy is a twice a month subcutaneous interferon with high efficacy, we request that it be included on the PDL. Tecfidera was approved a year and a half ago. It has now been utilized in 65,000 patients worldwide. There are more than 2,600 patients in clinical trials. It has a

well-defined safety profile with no contraindications, cardiovascular warnings, or REMS requirements. A study and its outcomes were reviewed. Tecfidera is consistently effective across a wide spectrum of MS patients with a varied demographic and disease characteristics.

In response to Dr. Finch, Dr. Demain said information pertaining to the next PDL, which is currently out for public comment, would have to be submitted separately.

Ms. Pritchard noted that Plegridy was not being reviewed as it missed the June cutoff date. A single agent review of Plegridy could be done at the next meeting at the committee's discretion.

Ms. Pritchard gave the Magellen presentation on Multiple Sclerosis Agents. MS is an autoimmune-type inflammatory disease of the central nervous system. Etiology is unknown, but it is characterized by demyelination and axonal degeneration, resulting in a wide variety of symptoms. Severe cases may result in partial or complete paralysis. Cognitive impairment is also seen in about 50 percent of patients. The injectables include either 1A or 1B interferons. The oral agents are Ampyra, Gilenya, Aubagio, and Tecfidera. The interferons and Copaxone have similar clinical utility. All of the oral and injectables are indicated for relapsing forms of MS to reduce frequency of exacerbations, except for the oral agent Ampyra which is indicated to improve walking in patients with MS. In July, there were 13 claims. Significant changes include Copaxone is now available in 40-milligram per ML strength, which is given three times a week. Generic Copaxone 20-milligrams per ML was due out, but the launch of generics has not yet occurred. Tecfidera is indicated for treatment of patients with relapsing forms of MS. Warnings includes lymphopenia and a baseline CBC is recommended. There are no significant drug interactions and flushing is the most common adverse effect. Tecfidera is pregnancy category C and is given as 240 milligrams, twice daily. Administration with food may reduce the incidence of flushing. It also comes in a 120-milligram and a 240-milligram tablet. At the last review, a motion for therapeutic alternatives to include one injectable and one oral passed unanimously.

Dr. Hope said that until the recent hepatitis C pricing issues, the MS drug class promised to be the source of a lot of controversy as oral agents, while their efficacy is arguably higher or different, the price is also considerably different. The potential introduction of generic Copaxone 20-milligrams, not the 40-milligrams it was switched to, really could put stress or renewed attention on this drug class. This could be a hot topic issue in the next 12 months.

Dr. Liljegren felt it was important to have many treatment options for MS because it was such a devastating disease and Ampyra is completely different from the other drugs in this class. She did not like last year's motion, but was unsure how to word the motion.

Dr. Hope said there was no prior authorization requirement for the oral products in this class, except that Ampyra has a detailed prior authorization requirement, as it is not a treatment for the disease and is completely adjunctive.

The committee reviewed last year's motion of therapeutic alternative to include one injectable and one oral agent. Dr. Demain noted that in last year's discussion it was determined that the oral agent would not be Ampyra. Dr. Liljegren felt every drug in the class should be approved.

Dr. Hope noted that approving all the drugs in the class would significantly impact the rebate bids because the manufacturers would have an incentive to provide a price break. He recommended having at least one option from each category to create competition between the various products.

DR. O'RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPUTIC ALTERNATIVES TO INCLUDE ONE INJECTABLE AND ONE DISEASE-MODIFYING ORAL AGENT. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

6. Re-Review Phosphate Binders (Red Category)

There were no public testimonies.

Ms. Pritchard gave the Magellen presentation on Phosphate Binders. These agents are used in chronic kidney disease, end-stage renal disease, to reduce serum phosphorous, and to prevent hyperphosphatemia. Velphoro, which came out in February 2014, is a pregnancy category B. All of the other agents are pregnancy category C. In July, there were 92 claims. Significant changes include Velphoro, or Sucroferric Oxyhydroxide, is indicated for the control of serum phosphorous levels in patients with chronic kidney disease on dialysis. In approval studies, warnings include the exclusion of patients with peritonitis, significant gastric or hepatic disorders, recent major gastrointestinal surgery, or a history of hemochromatosis or other iron-accumulation diseases. Velphoro is dosed as one tablet, three times daily with meals. It comes in a 500-milligram chewable tablet. There is no comparative data available. The package insert listing measured Velphoro against Renagel and Renvela as active controls and found Velphoro to be effective. As of April 2014, Renvela is available as a generic. At the last review, a motion for therapeutic alternatives passed unanimously.

DR. SEMLING MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. LOVE. THE MOTION PASSED UNANIMOUSLY.

7. Re-Review of Pulmonary Arterial Hypertension (PAH) Agents (Red Class)

LISA ROESSEL, a representative of Actelion Pharmaceuticals, discussed Opsumit. Opsumit is an agent for the treatment of PAH, a seriously progressing cardiopulmonary disease. Opsumit has a new indication for PAH medications to delay disease progression, which we have seen in clinical trials to improve exercise capacity. Several trials and their outcomes were reviewed. Opsumit demonstrated a 50 percent reduction in the risk for hospitalization. Similar to the other agents, Opsumit has a black boxed warning for embryo-fetal toxicity, and a REMS program is in place. Opsumit does not have a black boxed warning for LFT elevations, but it is recommended baseline LFT be obtained and monitored clinically as indicated. Decreases in hemoglobin have been observed among all the agents in this class including Opsumit. There is no black boxed warning, but there is a recommendation to check hemoglobin levels prior to initiation and then as needed or indicated throughout treatment. The drug interaction profile was reviewed. Strong inducers of CYP3A4 significantly reduce macitentan levels and concomitant use should be avoided. Strong inhibitors of CPY3A4 significantly increase macitentan levels and concomitant use should be avoided. Recently published guidelines have put Opsumit as a level 1-A. We encourage the committee to place Opsumit on the PDL for our PAH patients.

DR. JASON WICKLUND, a representative of Gilead Sciences, discussed Letairis. Since last year, there have been numerous studies that continue to confirm the beneficial effects of Letairis in patients with PAH. Several studies and their outcomes were reviewed.

Ms. Pritchard gave the Magellen presentation on Pulmonary Arterial Hypertension (PAH) Agents. Pulmonary hypertension is characterized by an increase in pulmonary arterial pressure and secondary right ventricular failure. The prevalence varies substantially depending on the type, etiology, and underlying conditions. The prevalence is about 15 per million people. It does not have a cure. If left untreated, it is a life-threatening disease with poor prognosis. The World Health Organization (WHO) classifies pulmonary hypertension patients into five groups based on etiology. In July, there were 9 claims. The significant changes include the addition of three new products to the class. Orenitram ER, which became available in March 2014, is indicated for the treatment of pulmonary arterial hypertension, which is WHO group 1, to improve exercise capacity. It is contraindicated in severe hepatic impairment. Warnings include abrupt discontinuation and increased risk of bleeding. Patients with moderate to severe hepatic impairment should not take Orenitram ER. It is available in a 0.125-, 0.251-, and 2.5-milligram tablets. Adempas, which became available in the fall of 2013, is indicated for the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension, which is WHO group 4, after surgical treatment or inoperable CTEPH to improve exercise capacity and functional status. There is a boxed warning for embryo-fetal toxicity. Common adverse events include headaches, dizziness, dyspepsia, nausea, diarrhea, hypertension and others. It is dosed three times daily and is available as a 0.51-, 1.152-, and 2.5-milligram tablets. It is not recommended for administration in patients with severe hepatic impairment due to lack of data. Opsumit, which became available in the fall of 2013, is indicated for the treatment of WHO group 1 patients to delay disease progression and reduce hospitalization. It is contraindicated in pregnancy and has a boxed warning for embryo-fetal toxicity. Strong CYP3A4 inducers and inhibitors will affect exposure to Opsumit so co-administration should be avoided. Common adverse events include anemia, nasopharyngitis, pharyngitis, bronchitis, and headaches. Opsumit is dosed once daily and comes as a 10-milligram tablet. The Tracleer patent expiration is expected in the fall of 2015. The American College of Cardiology update to their treatment algorithm does not distinguish amongst the available products in the class, but lists all of them as treatment options. At the last review, there were two motions: a motion for class effect for the endothelia receptor antagonists and a motion for therapeutic alternatives for the PDE5 inhibitors.

In response to Dr. Demain, Ms. Pritchard said the addition of the three new agents would not change the two subcategories from last year.

In response to Dr. Phillips, Dr. Hope said there was an FDA mortality warning regarding Sildenafil usage in children less than 18 years of age, and there is a prior authorization requirement, but we are frequently asked to override it. The utilization report does not show medications that are compounded into a solution or suspension for a young child, because they are billed and reported differently. We have a fair amount of utilization for Sildenafil for really young children based on conflicting data or data that does not align with what the FDA issued.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE PDE5 INHIBITOR, ONE ORAL NON-PDE5 INHIBITOR, AND ONE INHALED PRODUCT. SECONDED BY DR. PAPPENHEIM. THE MOTION PASSED UNANIMOUSLY.

Break from 9:00 a.m. to 9:10 a.m.

8. Re-Review of Pancreatic Enzymes (Green Class)

Dr. Demain noted that Pancreatic Enzymes were held over from the April meeting.

Dr. Hope read a letter received from Dr. Roberts on pancreatic enzymes related to cystic fibrosis. He recommended retaining Pancreaze, Zenpep, and Creon on the PDL.

Ms. Pritchard gave the Magellen presentation on Pancreatic Enzymes. The products in this class supplement pancreatic enzymes when indigenous function is lost. This occurs in situations of cystic fibrosis, chronic pancreatitis, pancreatic tumors, and absence of all or parts of the pancreas. In July, there were 72 claims. There is no new clinically significant information for this class in 2014. At the last review, a motion for therapeutic alternatives passed with one opposed.

Dr. Demain noted that Dr. Roberts' letter did not express a need to consider the new agents in the class.

In response to Dr. Pappenheim, Dr. Hope said the three agents requested by Dr. Roberts could be prescribed by utilizing the medically necessary clause and there are no prior authorization requirements. The bid process was reviewed.

DR. LILJEGREN MOVED A CLASS EFFECT TO INCLUDE AT LEAST ONE PEDIATRIC PREPARATION. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

9. Re-review of Alzheimer's Agents (Green Class)

Ms. Pritchard gave the Magellen presentation on Alzheimer's Agents. Alzheimer's disease is the most common type of dementia accounting for 60 to 80 percent of dementia disorders in the elderly and is the sixth leading cause of death in the United States. It is characterized by progressive cognitive decline associated with impairment of activities of daily living and behavioral disturbances. Three acetylcholinesterase inhibitors commonly utilized for the treatment of Alzheimer's are Glantamine, Rivastigmine, and Donepezil. Each of these drugs has shown cognitive benefit over placebo. However, it remains unclear if their use slows disease progression, cognitive decline, delays placement in nursing homes, or alters mortality. In July, there were 151 claims. Significant changes include the production of Namenda IR has been extended by the manufacturer to an unknown point beyond their original date where the immediate release was first announced to be discontinued in August 2014, but they have changed that and the IR is going to remain available. Aricept 23-milligrams became available as a generic in August 2013. At the last review, a motion for therapeutic alternatives passed unanimously.

Dr. Hope said Namenda IR's twice-daily formulation has been available for many years. The manufacturer obtained a patent for an extended release once-daily product. The patent of the immediate release is set to expire next year. To continue the brand-name utilization, the manufacturer planned to discontinue the immediate release product a year prior to the patent running out to get all patients switched over. This was too successful and they could not keep up with the production of the

new extended release product so they continued to produce the immediate release. If that practice translates to other medications, there will be significant clinical outcomes when forcing patients to change medications, as well as financial impacts on the system. We are keeping an eye on this new occurrence.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE FROM EACH MECHANISM OF ACTION. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

10. Re-Review of Antihyperuricemics (Green Class)

Ms. Pritchard gave the Magellen presentation on Antihyperuricemics. Hyperuricemia can occur due to either an overproduction of uric acid, an under excretion of uric acid, or a combination of the two mechanisms. Gout is the crystal deposition of monosodium urate associated with elevated levels of uric acid. Crystals are deposited in joints, tendons, and surrounding tissues. Treatment of gout is managed in three stages: acute treatment, prophylaxis to prevent acute flares, and lowering excess stores of urate. After an initial gout attack, the choice of urate-lowering medications is uricosuric drugs or xanthine oxidase inhibitors. Probenecid promotes uric acid excretion and can increase the number of it, but it can increase the number of acute goudy attacks occurring in the first six to 12 months of therapy. The xanthine oxidase inhibitors inhibit uric acid production. With Allopurinol, serum urate concentrations begin to decrease within one to two days; however, significant reductions may not be immediately apparent due to the dissolution of uric acid deposits. In July, there were 290 claims. There are no new significant changes. Guidelines were set in 2012. Krystexxa is an option only for patients with severe gout who are refractory to or have intolerance to urate-lowering therapy. At the last review, a motion for therapeutic alternative to include at least one xanthine oxidase inhibitor, one Colchicine product, and one uricosuric product passed unanimously.

DR. O'RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE AT LEAST ONE XANTINE OXIDASE INHIBITOR, ONE COLCHICINE PRODUCT, AND ONE URICOSURIC PRODUCT. SECONDED BY DR. (NOT NOTED ON RECORD). THE MOTION PASSED UNANIMOUSLY.

11. Re-Review of Antimigraine Agents (Green Class)

Dr. Demain noted that only the Triptans would be reviewed at this meeting.

Dr. Pritchard gave the Magellen presentation on Antimigraine Agents. Due to well-established efficacy, the Triptans have become the drugs of choice for treating actual migraine attacks. The U.S. Headache Consortium, the American Academy of Family Physicians, and the American College of Physicians have recognized that Triptans are effective agents for the acute treatment of migraine. The therapeutic activity of the Triptan derivates can be attributed to agonist effects on the vascular and neuronal serotonin receptor subtypes in the trigeminal system. Relief of migraine headache may result from one intracranial vessel constriction via stimulation of vascular 5-HT_{1B} receptors, inhibition of vasoactive neuropeptide release through stimulation of presynaptic 5-HT_{1D} receptors, or interruption of pain signal transmission within the brainstem through stimulation of 5-HT_{1D} receptors. In July, there were 266 claims. No new significant changes for 2014. In 2013, Maxalt and Maxalt MLT became

available as generics. Zomig is now available as a generic. At the last review, a motion for class effect passed unanimously.

DR. PHILLIPS MOVED A CLASS EFFECT TO INCLUDE AT LEAST ONE ORAL AND ONE SUBCUTANEOUS FORMULATION. SECONDED BY DR. PAPPENHEIM. THE MOTION PASSED UNANIMOUSLY.

12. Re-Review of Psoriasis Agents, Topical (Green Class)

Ms. Pritchard gave the Magellen presentation on Psoriasis Agents, Topical. Psoriasis is a chronic, autoimmune disease that appears on the skin effecting approximately 7.5 million people in the United States. There are five types of psoriasis: plaque, guttate, inverse, pustular, and erythrodermic. The most common type is plaque psoriasis in which patches or lesions of skin become inflamed and is covered by silvery white scale. In July, there were 13 claims. There are no recent significant clinical developments. In the spring of 2014, Taclonex ointment became available as a generic. At the last review, a motion for class effect passed with one opposed.

In response to Dr. Demain, Ms. Pritchard said only the Taclonex ointment was now available as a generic, not the other formulations.

In response to Dr. Pappenheim, Dr. Demain said there were specific treatments for each type of psoriasis. However, the committee is only covering the topical formulations. Most of the other therapies are injectable therapies.

DR. O'RILEY MOVED A CLASS EFFECT. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

13. Re-Review of Benign Prostatic Hyperplasia (BPH) Treatments (Green Class)

Ms. Pritchard gave the Magellen presentation on Benign Prostatic Hyperplasia (BPH) Treatments. BPH is one of the most common conditions in aging men. The symptoms are induced by hyperplasic changes in prostate tissue, leading to prostatic enlargement, which results in obstruction of urinary outflow and results in an impaired detrusor muscle response. The 2010 guidelines are still the most recent. They state that the 5a-reductase inhibitors are appropriate and effective treatments for patients with lower urinary tract symptoms. In July, there were 502 claims. There is no recent information of significance in this class. At the last review, a motion for therapeutic alternatives to include at least one alpha-blocker and androgen hormone inhibitor passed unanimously.

Dr. Hope noted that there was a prior authorization requirement for PDE5 inhibitors. Medicaid does not pay for erectile dysfunction treatments, but they are required to cover it for BPH.

In response to Dr. Phillips, Dr. Hope said there were current no duration edits on these products.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE ALPHA-BLOCKER AND ONE ADROGEN HORMONE INHIBITOR. SECONDED BY DR. LOVE. THE MOTION PASSED UNANIMOUSLY.

14. Re-Review of Bone Resorption Suppression and Related Agents (Green Class)

Ms. Pritchard gave the Magellen presentation on Bone Resorption Suppression and Related Agents. Osteoporosis is characterized by the deterioration of bone tissue and low bone mass. There are three categories of osteoporosis: postmenopausal, age-related, and secondary osteoporosis. The primary goal of osteoporosis management is to reduce fracture risk. This can be done by reducing bone loss, increasing bone mass, or improving bone architecture to maintain bone strength, and minimizing or eliminating factors that may contribute to fractures. The 2013 National Osteoporosis Foundation Clinician's Guide to Prevention and Treatment of Osteoporosis continues to recognize all U.S. FDA-approved medications as possible options. In July, there were 190 claims. Significant changes include Actonel and Evista is now available as a generic. At the last review, a motion for therapeutic alternatives to include one from each of the three classes, excluding formulations administered daily, passed unanimously.

Dr. Hope explained that the exclusion of formulations administered daily was based on the desire to have a weekly option for the Bisphosphonates rather than Fosamax's daily dosage.

DR. LILJEGREN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE NON-DAILY USE BISPHOSPHONATE. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

15. Re-Review of Erythropoiesis Stimulating Proteins (Green Class)

Ms. Pritchard gave the Magellen presentation on Erythropoiesis Stimulating Proteins. Erythropoietin is produced in the kidneys and stimulates red blood cell production from bone marrow. The 2014 National Comprehensive Cancer Network guidelines state that erythropoiesis-stimulating agents are associated with an increased risk of thrombosis, decreased survival, and shortened time to tumor. Physicians are advised to use the lowest dose possible to maintain hemoglobin levels sufficient to avoid blood transfusions, to prescribe according to FDA guidelines using the REMS program, and to obtain patient consent. These products should be discontinued once the course of chemotherapy has been completed and anemia resolves. In July, there were 4 claims. There are no significant changes other than the 2014 guidelines regarding these products. At the last review, a motion for therapeutic alternatives passed unanimously.

DR. O'RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

16. Re-Review of Antiparkinson's Agents (Green Class)

Ms. Pritchard noted that within this category, Alaska would be reviewing only those with an indication for Restless Leg Syndrome. Restless Leg Syndrome (RLS) is a neurological sensory disorder in which patients experience irrepressible sensations in the legs or arms while sitting or lying still that causes them to move their arms or legs. Providers would need to rule out other movement disorders with similar symptoms to RLS in order to correctly medicate. The 2012 American Academy of Sleep Medicine recommends the generic Pramipexole and Ropinirole for RLS. Gabapentin is also

recommended. In July, there were 208 claims. There are no recent clinical updates for this class. At the last review, a motion for therapeutic alternatives passed unanimously.

In response to Dr. Pappenheim, Ms. Pritchard explained why Gabapentin, although a recommended medication for RLS, was not listed on the market shift report. Not all Gabapentin products are used for RLS, just Horizant. If a brand-name drug has no utilization in the class, it is not included in the market shift report.

Dr. Hope noted that other Gabapentin products were included in other categories such as anticonvulsants or neuropathic pain agents.

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

17. Re-Review of Acne Agents, Topical (Green Class)

Ms. Pritchard gave the Magellen presentation on Acne Agents, Topical. In May 2013, the American Acne and Rosacea Society developed the first detailed, evidence-based clinical guidelines for the management of pediatric acne including issues of special concern when treating pediatric patients. In July, there were 275 claims. Significant changes include the new products added to the list, which were reviewed. At the last review, a motion for therapeutic alternatives to include one drug from each subclass passed unanimously.

The committee discussed the fact that there were numerous drugs available in this class and more are added every week.

DR. O'RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE DRUG FROM EACH SUBCLASS. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

18. Re-Review of Steroids, Topical (Green Class)

Dr. Demain noted that the topical steroids were broken down into four subcategories.

In response to Dr. Phillips, Dr. Hope explained why the topical steroids were broken down into four subcategories. In 2011 and 2012, the committee felt there were too many drugs grouped together, so we broken them down, which would also help to simplify the motions. We may have gone too far and would support handling the topical steroids as a single category.

The committee discussed what the motion would include if topical steroids were reviewed as a single category to ensure multiple dosage forms were included in each subclass.

Ms. Pritchard gave the Magellen presentation on Steroids, Topical. These products all have the same indications of relief of inflammatory and pruritic manifestations of corticosteroid steroid responsive dermatoses. Treatment of mild to moderate atopic dermatitis and treatment of seborrheic dermatitis of the scalp, with the caveat of seeing individual PIs for specific product indications. In July, the claims were as follows: low potency, 233 claims; medium potency, 93 claims; high potency, 560 claims; and

very high potency, 67 claims. The only changes in each subclass were the addition of brand-name products. At the last review, there were motions for each subclass of class effect and each passed unanimously.

In response to Dr. Demain, Dr. Hope said the topical steroids would continue to be listed under the four subcategories, but one motion would cover them all.

DR. PHILLIPS MOVED A CLASS EFFECT TO INCLUDE AT LEAST ONE FROM EACH POTENCY SUBGROUP. SECONDED BY (NOT NOTED ON RECORD).

The committee discussed the motion in relation of specifying a variety of formulations. Dr. Hope said a variety of formulations would be included in the PDL based on the motion that was made.

THE MOTION PASSED UNANIMOUSLY.

Off the record from 9:54 a.m. to 9:56 a.m. The committee then went into closed session.

Dr. Hope discussed the problems they had at recent meetings with the open call-in line. Dr. Love suggested having one conference call-in line at the beginning of the meeting for public comment. After public comments are complete, a second call-in line would be available to committee members only for the remainder of the meeting.

John from Imig said there had been equipment issues at the beginning of the meeting that were resolved during the meeting.

Dr. Hope said there have been ongoing disruptions of meetings due to this problem, and he felt they could no longer have a single call-in line for everyone.

Ms. Pritchard said all of the other states require both industry and committee members to attend the meetings in person and do not offer call-in participation. Dr. Hope felt the call-in option was necessary in Alaska due to travel challenges.

Dr. Love felt it was important that there was an opportunity for the public to speak to the committee, which would require call-in participation due to travel challenges in Alaska.

Dr. O'Riley asked if there was a way to stream the meetings so people could listen without participating in the meetings.

Dr. Hope discussed the upgrades to the conference room and the sound equipment. He suggested putting the digital phone line on "lecture only mode" for the entire meeting, except the public comment section, which would allow people to listen to the meeting without creating feedback or participating in the meeting after completion of the public comment section.

19. REVIEW MINUTES FROM APRIL 18, 2014 MEETING

Dr. Hope said he made minor spelling corrections on the meeting minutes, but he did not have his copy available to review them.

DR. BERGESON MOVED TO APPROVE THE MEETING MINUTES OF APRIL 18, 2014, AS CORRECTED. SECONDED BY DR. (NOT NOTED ON RECORD). THE MOTION PASSED UNANIMOUSLY.

20. Comments from Committee Member or Chair

Dr. Hope discussed significant changes recently made in Medicaid. In May, a regulation project that had been worked on for three years was finalized and put into production. Some of the changes were reviewed. Some over-the-counter medications are no longer covered, because it is less expensive to buy them off the shelf than pay the dispensing fees. The PDL is currently out for comments, which closes soon. The updated PDL will bring us back up to date.

Dr. Pappenheim asked if a notice was sent out of Medicaid recipients informing them of the Medicaid changes. Dr. Hope said there have been multiple public comments, public notices, and other avenues of notifying patients of the changes. The only thing that we did not do, and cannot do, is send a letter to every Medicaid recipient. Co-pays were also changed. Instead of $2 for every single prescription, we now have a tiered system and co-pays are based on the total claim and not individual prescriptions. There is now an online list of generic medications that, for the first time, a 90-day supply will be covered, which reduces dispensing fees.

Dr. Hope said Hydrocodone-containing products were being moved to Schedule 2 by the DEA. The impact on physicians is they can no longer call in the prescriptions and no refills will be available, except for a six-month phase where prescriptions written prior to October 6 can be legally refilled until April. However, several major pharmacy chains will stop providing refills on October 6 due to software limitations.

21. Adjourn

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

The meeting adjourned at 10:21 a.m.