ALASKA MEDICAID

PHARMACY AND THERAPEUTICS COMMITTEE

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

MINUTES OF MEETING
April 17, 2015
8:00 a.m.

Committee Members Present:
Jeffrey Demain, MD, Chair
Robin Cooke, Pharm.D.
Marvin Bergeson, MD
Robert Carlson, MD
Vincent Greear, R.Ph.
Jenny Love, MD
John Pappenheim, MD
Claudia Phillips, MD
Maggie Rader, CNM
John Riley, PA-C
Chuck Semling, Pharm.D.

Committee Members Absent:
Diane Liljegren, MD
Jill Reid, R.Ph.
Trish White, R.Ph.

Others Present:
Chad Hope, Pharm.D.
Tolu Balogun, Pharm.D.
Erin Narus, Pharm.D.

1. Call to Order – Chair

Dr. Demain called the meeting to order at 8:02 a.m.

2. Roll Call

A quorum was present. Dr. Demain reviewed the rules of the meeting.

3. Public Comments - Local Public/Health Practitioners

There were no public comments.

4. Re-Review of Pancreatic Enzymes (Red Category)

MARCUS SHIN, a medical science liaison with Actavis, discussed Zenpep. Zenpep consists of porcine-derived lipases, proteases and amylases. It is indicated for exocrine pancreatic insufficiency due to cystic fibrosis and other conditions. Exocrine pancreatic insufficiency (EPI) occurs when there is a lack of food exposed to pancreatic enzymes that result in mal-digestion, especially of fats. Maldigestion can lead to nutrient malabsorption and ultimately malnutrition, which is a significant concern for cystic fibrosis (CF) patients. To prevent malnutrition and associated complications, these patients require pancreatic enzyme replacement therapy. As a pancreatic enzyme replacement therapy, Zenpep helps digest food to address the nutritional needs of patients suffering from EPI. According to the Cystic Fibrosis Foundation Patient Registry, the average life expectancy for a CF patient is increasing, and approximately half of CF patients are now adults. Data presented at the 2014 North American Cystic Fibrosis Conference and published in the Journal of Pediatrics was reviewed. Zenpep dosing formulations were reviewed. Actavis has had a long-standing commitment to support the nutritional needs of CF patients. We not only provide Zenpep, but we have a comprehensive patient nutritional program to supply high core foods and food supplements. Other published data shows that chronic CF patients who were diagnosed with more severe EPI showed a statistically significant improvement in their coefficient of fat absorption and decreased in the number of systematic days when given Zenpep. The safety profile of Zenpep was reviewed.

Dr. Balogun gave the Magellan presentation on Pancreatic Enzymes. The pancreas excretes enzymes necessary for digestion. Pancreatic secretions also neutralize gastric acid in the duodenum and achieve an appropriate pH for maintaining the activity of the enzymes. The agents in this class supplement pancreatic enzymes when indigenous function is lost, such as in conditions of cystic fibrosis, chronic pancreatitis, pancreatic tumors, and absence of all or part of the pancreas. These agents are available in a variety of formulations and strengths. The enzymes contained in these preparations are amylase, lipase and protease. All formulations are measured by the content of these enzymes. Pancreaze, Ultresa, and Zenpep are indicated for the treatment of pancreatic insufficiency due to cystic fibrosis or other conditions in both adults and children. Creon is indicated for these conditions as well as pancreatic insufficiency due to chronic pancreatitis and pancretectomy. Viokace tablets should be swallowed whole and not crushed. Viokace's safety and effectiveness in pediatric patients is not established. All products in this class are Pregnancy Category C. In January 2015, there were 58 claims. At the last review, a motion for class effect, to include at least one pediatric preparation, passed unanimously.

Dr. Hope noted that the utilization sheets were now up-to-date. The regulations were implemented in March.

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

Dr. Hope said the medically necessary clause had not been changed. We do not know what will happen with the budget, but any changes will be made through the committee. We have not changed any of the standard operating rules. Mr. Hope has accepted a position at Utah Medicaid as their director of pharmacy and this will be his last meeting with the Alaska Medicaid P&T Committee.

5. Re-Review of Ophthalmics, Glaucoma Agents (Red Category)

There were no public testimonies.

Dr. Balogun gave the Magellan presentation on Ophthalmics, Glaucoma Agents. Glaucoma is the second most common cause of permanent blindness in the United States. The prevalence of this condition in adults over 40 years old is estimated at 2%. Subgroups in this drug class include beta-blockers, miotics, sympathomimetics, topical, carbonic anhydrase inhibitors, and prostaglandin analogs. All medications used for the management of glaucoma attempts to limit further damage to the optic nerve. According to the American Academy of Ophthalmology 2014 summary benchmark, prostaglandin analogs are the most effective drugs at lowering IOP. They can be considered as initial medical therapy unless other considerations prevent their use. Adequate treatment of glaucoma requires a high level of adherence to therapy. In January 2015, there were 81 claims. Since the last review, Rescula and Simbrinza have been added to the class. Both are indicated for the treatment of open-angle glaucoma or ocular hypertension. Simbrinza is a combination product of 0.2% Brimonidine and 1% Brinzolamide. It is contraindicated in neonates and children less than 2 years of age. It has not been studied in patients with acute angle-closure glaucoma. Rescula is a prostaglandin analog with 0.15% Unoprostone. It is indicated for twice-daily administration, while Simbrinza is thrice daily formulation. Both agents are classified as Pregnancy Category C. At the last review, a motion for therapeutic alternatives, to include one drug from each subclass, passed unanimously.

In response to Dr. Carson, Dr. Hope said he had not received any feedback on whether there were issues with physicians prescribing medications within the class.

Dr. Pappenheim arrived at the meeting.

DR. CARLSON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE ONE DRUG FROM EACH SUBCLASS. SECONDED BY MR. RILEY. THE MOTION PASSED UNANIMOUSLY.

6. Re-Review of Androgenic Agents (Red Category)

There were no public testimonies.

Dr. Balogun gave the Magellan presentation on Androgenic Agents. The agents in this class are indicated for the treatment of males for conditions associated with deficiency or absence of endogenous testosterone, such as primary or secondary hypogonadism, which can be congenital or acquired. The drugs in this class are available in a gel solution or transdermal patch. In January 2015, there were 8 claims. Since the last review, Vogelxo was added to the class. There have been safety concerns associated with this drug class. The FDA is investigating the risk of stroke, myocardial infarction, and death in men taking FDA-approved testosterone products. This is based on two recent studies that suggest an increased risk of cardiovascular events among men prescribed testosterone therapy. Agents in this class all carry an updated warning citing reports of venous thromboembolic events, including deep vein thrombosis and pulmonary embolism in patients using testosterone products. All gel and solution products carry a boxed warning of virilization of children following secondary exposure. The boxed warning does not presently include testosterone patches, although women and children are cautioned to avoid exposure. Androderm transdermal testosterone has been reconfigured by the manufacturer with a 20% lower dose of testosterone and a smaller patch than the previous formulation. At the last review, a motion for class effect passed unanimously.

MR. RILEY MOVED A CLASS EFFECT. SECONDED BY DR. PHILLIPS.

In response to Dr. Demain, Dr. Hope said the utilization statistics only included items for which there were claims. If a drug is not included in a bid category then it will not be part of the review packet, whether or not it is a related agent.

THE MOTION PASSED UNANIMOUSLY.

7. Re-Review of Antihistamines, Minimally Sedating (Red Class)

There were no public testimonies.

Dr. Balogun gave the Magellan presentation on Antihistamines, Minimally Sedating. This class was previously reviewed as low-sedating antihistamines. The agents are selective, competitive, peripherally acting H_1-receptor antagonists with little or no central or autonomic nervous system activity. All agents in the category have similar efficacy. Some studies indicate Cetirizine may be more effective than Loratadine at providing systematic relief. However, Cetirizine causes significantly more sedation in medications. Although first-generation antihistamines are clinically effective, the rationale for using second-generation antihistamines is that they control allergic rhinitis symptoms with less sedation and anticholinergic. Allegra appears to cause the fewest CNS effects because its absorption into the brain is minimal. Xyzal should be used with caution in patients at greater risk of urinary retention, such as those with spinal cord injuries and prostatic hyperplasia. If urinary retention is discovered, Xyzal should be discontinued immediately. In January 2015, there were 548 claims. At the last review, a motion for class effect passed unanimously.

Dr. Hope noted that Dr. Bergeson suggested adding coverage for Zyrtec and Allegra OTC several years ago. As of May 18, 2014, we were able to do that. We have CMS approval and they are now in the regulations. Know that committee members' ideas are heard, but the process can be slow.

In response to Dr. Demain, Dr. Hope explained why Certirizine tablets appeared to be so expensive on the utilization list. It is a relative scale. If Loratadine tablets are one cent per tablet and Certirizine tablets are five cents per table. Certirizine, which is still inexpensive, would be five times more expensive than the relative comparator.

DR. SEMLING MOVED A CLASS EFFECT, TO INCLUDE A CHILDREN'S SYRUP. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

8. Re-Review of Epinephrine, Self-Injected Agents (Red Class)

DR. PATEL, a representative Mylan Pharmaceuticals, discussed Epi Pen and Epi Pen Jr. Both injectors are indicated for emergency treatment of Type I allergic reaction, including anaphylaxis sustained in biting insects, allergen immunotherapy, foods, drugs, diagnostic testing substances, and other allergens. It is also used for the treatment of idiopathic anaphylaxis or exercise induced anaphylaxis. According to the NIAID Guidelines, Epinephrine is the first line treatment for anaphylaxis reaction. The pharmacological actions of this agent address the pathological changes that occur in anaphylaxis better than any other single agent drug. Failure to administer Epinephrine early in the course of treatment has been repeatedly implicated in anaphylaxis fatalities. Epi Pen is available in two dose strengths, .3 milligrams for patients weighing more than 30 milligrams and .15 milligrams for patients weighting between 15 and 30 milligrams. Epi Pen has been the number one prescribed Epinephrine auto injector for over 25 years, with 16 million prescriptions from 1981 to 2014. Every

Epi Pen auto injector comes with a hard plastic carrying case and offers a built-in needle protection to increase the safety of its after use. Epi Pen is easy and straightforward to use. It has one dose per syringe with a clear and simple three-step administration process to facilitate prompt administration. Patients are able to learn how to administer Epi Pen through the patient insert as well as the training device that is included with every two-pack. We request that Epi Pen and Epi Pen Jr. be retained on the PDL.

Dr. Demain talked about a recent study that looked at the Epi Pen utilization in northern altitudes. The higher the altitude, the more frequently the Epi Pen was prescribed per capita for this disease state, as well as respiratory problems, which could be due to lack of sunlight and vitamin D. Three guidelines state that if a patient ingests or is subjected to a known allergen that causes anaphylaxis, every second counts and the Epi Pen should be used as soon as possible.

Dr. Balogun gave the Magellan presentation on Epinephrine, Self-Injected Agents. According to the 2010 National Institute of Allergy and Infectious Diseases Guidelines, intramuscular Epinephrine is the treatment of choice for all instances of anaphylaxis resulting from food or any other cause. It should be administered immediately at first signs of anaphylaxis. Although Epinephrine has a rapid onset of action, it is also quickly metabolized. It acts on both alpha- and beta-adrenergic receptors, resulting in alleviation of intravascular fluid volume and hypotension, as well as bronchospasm, wheezing, and dyspnea. Epinephrine may also be useful in reducing symptoms due to its relaxing effects on the smooth muscle of the stomach, intestines, uterus, and urinary bladder. In January 2015, there were 103 claims. Since the last review, Adrenaclick was re-launched in June 2013 and Auvi-Q was approved. Adrenaclick auto injectors each contain 1.1 mL of Epinephrine solution, delivering either 0.15 milligrams or 0.3 milligrams of Epinephrine in a single administration. Auvi-Q, the 0.3 milligrams and 0.15 milligrams, each contain 0.76 mL of Epinephrine solution. These devices include visual cues through LED lights, audible beeps, and electronic voice instructions for use. At the last review, this class was not voted on due to the prevalence of drug discontinuation at that time.

Dr. Hope explained that this class was not voted on at the last review because there had only been one product in the class, but now there are three.

Dr. Demain felt this class was unique in that the drugs were identical. The only difference is the device. Samples of an Epi Pen, Auvi-Q, and Adrenaclick were distributed so the committee could see the devices.

Dr. Carlson felt that patient training was an issue. If we decide the drugs are therapeutic equivalents then a grandfathering clause would be important. Many children being labeled as allergic to this or that, but have never had anaphylaxis, so the training they received does not have much effect three or four years later when they need to use their Epinephrine. Someone who has had anaphylaxis and is using this on a regular basis, changing their delivery system could be a big problem.

Dr. Demain noted that Epinephrine starts to lose its potency very rapidly after its expiration date, which is 12 to 18 months.

Dr. Hope noted that there had been a grandfathering clause for Epinephrine in the past. The committee discussed how a grandfathering clause could be included in the motion.

MR. RILEY MOVED A CLASS EFFECT TO INCLUDE A GRANDFATHERING CLAUSE. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

9. Re-review of Glucocorticoids, Inhaled (Red Class)

There were no public testimonies.

Dr. Balogun gave the Magellan presentation on Glucocorticoids, Inhaled. The 2014 GINA Guidelines states that inhaled corticosteroids are currently the most effective anti-inflammatory medications for the treatment of persistent asthma. These guidelines also states that daily treatment with low dose inhaled Glucocorticoids are very effective in reducing asthma symptoms, risks of asthma-related exacerbations, hospitalizations, and death. If asthma is not controlled on the patient's current regimen then treatment should be stepped up until control is achieved. Once control has been maintained for at least three months, treatment can be stepped down at that point. The agents in this class have demonstrated efficacy in improving lung function, reducing symptoms, reducing frequency, severity of exacerbations, and improving quality of life. In January 2015, there were 974 claims. Since the last the review, Arnuity Ellipta and Asmanex HFA have been added to the class. Both agents are indicated for the maintenance treatment of asthma as prophylaxis therapy. Starting dose is based on prior asthma therapy. These two agents are indicated for patients 12 years of age and older. They are both Pregnancy Category C. Arnuity Ellipta is dosed once daily and is available in 100 and 200 microgram strip of inhalation powder. Asmanex HFA is dosed twice daily and is available as a pressurized meter dosed inhaler that delivers 100 and 200 micrograms per actuation. At the last review, a motion to include one high-potency product, one low- to medium-potency product, one combination product, and a nebulized Budesonide passed unanimously.

Dr. Demain noted that Budesonide was the only Pregnancy Category B drug in the class, which we use. The guidelines say if a patient is stable on a medication then you do not need to change them. We usually change them and put patients on Budesonide during pregnancy.

In response to MR. RILEY, Dr. Demain said the new agents were dosed once daily and are approved for patients 12 years of age and older.

In response to Dr. Carlson, Dr. Demain discussed several head-to-head trials on Glucocorticoids and their outcomes.

The committee discussed the possible language of the motion in relation to whether there was greater patient compliance with the once daily formulations. Dr. Hope said the motion should include what the committee wants, but he advocated for flexibility for potential savings. Dr. Carlson said there were huge compliance issues on almost all pharmaceuticals. The biggest issue with compliance is cost of the patient, which we do not have to consider.

DR. GREEAR MOVED TO INCLUDE ONE-HIGH POTENCY PRODUCT, ONE LOW- TO MEDIUM-POTENCY PRODUCT, ONE COMBINATION PRODUCT, AND A NEUBULIZED BUDESONIDE. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

10. Re-review of Beta$_2$ Adrenergic Agonists - Short-Acting (Red Class)

There were no public testimonies.

Dr. Balogun gave the Magellan presentation on $Beta_2$ Adrenergic Agonists - Short-Acting. The indications for the agents in this class are including treatment of reversible bronchospasm and prevention of exercise-induced bronchospasm in adults and children. These products have a rapid onset of action and are useful for the temporary relief of bronchoconstriction with acute symptoms such as wheezing, chest tightness, and cough. The agents in this class are also used in the treatment of COPD. In January 2015, there were 2,428 claims. Since the last review, the GOLD Guidelines have been updated. The classification system was modified and now uses a grading system of airflow limitations based on the ratio of FEV_1 to FVC. The GOLD grade classifications, which are divided into four groups, were reviewed. At the last review, a motion for class effect, to include at least one Albuterol inhaled product and a nebulizer solution, passed unanimously.

DR. RADER MOVED A CLASS EFFECT, TO INCLUDE AT LEAST ONE ALBUTEROL INHALED PRODUCT AND A NEUBULIZER SOLUTION. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

11. Re-Review of $Beta_2$ Adrenergic Agents - Long-Acting (Red Class)

CHRISTI BRONSON, a representative of AstraZeneca, discussed Symbicort, which was reviewed earlier in the meeting with the Glucocorticoids class. The GOLD Guidelines recommend treatment with ICS/LAVA combination therapy. The first choice option for symptomatic patients with GOLD Group C and D, COPD, Symbicort 164.5 is approved for the twice-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and emphysema. AstraZeneca does not recommend the use of its products in any other manner than as described in the full prescribing information. Several studies and their outcomes were reviewed. The prescribing information contains a boxed warning stating long-acting $beta_2$ agonists, such as Formoterol, one of the active ingredients in Symbicort, increases the risk of asthma related death. The most common adverse reactions were reviewed. Please refer to the Symbicort PI for complete product information. Based on today's testimony, AstraZeneca requests that Symbicort be maintained on the PDL for the Alaska Medicaid Program.

STEVE HALL, a representative of Boehringer Ingelheim, discussed Striverdi Respimat, an Olodaterol inhalation spray. This is a long-acting $beta_2$ agonist indicated for long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with COPD, which includes chronic bronchitis and/or emphysema. It is not indicated to treat of acute deteriorations of COPD or asthma. Several trials and their outcomes were reviewed. From a safety standpoint, Striverdi Respimat contains a black boxed warning of asthma related deaths so it is not indicated for the treatment of asthma. Adverse reactions were reviewed. The Respimat inhaler is a hand-held pocket-sized device that uses mechanical energy to generate a slow moving aerosol cloud of medication of a meter volume, but the drug solution is a fine mist. This inhaler is a unique delivery mechanism and is propellant free.

Dr. Balogun gave the Magellan presentation on $Beta_2$, Adrenergic Agents - Long-Acting. The agents in this class lead to improvements in lung function symptoms and reduce the need for short-acting beta agonists for quick relief. Long-acting beta agonists are not to be used as monotherapy for controlling asthma and should not be initiated in patients who are acutely deteriorating with COPD. Long-acting beta agonists should be used with caution in patients with cardiovascular or convulsive disorders or with sensitivity to sympathomimetic drugs. In January 2015, there were 3 claims. Since the last review, Striverdi was added to this class. This agent is only indicated for use in adults. The recommended

dosage is three inhalations that deliver 2.7 micrograms per inhalation. It is classified as Pregnancy Category C. At the last review, a motion for class effect passed unanimously.

In response to Dr. Demain, Dr. Hope said that motions have not specified hand-held versus nebulized devices in the past.

In response to MR. RILEY, Dr. Demain said the Respimat device did not need a spacer. It is a soft puff, activated release.

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

12. Re-Review of COPD Agents (Red Class)

STEVE HALL, a representative of Boehringer Ingelheim, discussed Spiriva Respimat. It is an inhalation spray of Tiotropium Bromide. It is indicated for the long-term, once-daily maintenance treatment of bronchospasm associated with COPD. It is also indicated for reducing COPD exacerbations. Several trials, their outcomes and safety profiles were reviewed. The most commonly reported adverse reactions were pharyngitis, cough, and sinusitis. The Respimat inhaler device, which was described earlier in the meeting, is the new device being used with Spiriva Respimat.

Dr. Balogun gave the Magellan presentation on COPD Agents. COPD is characterized by the presence of airflow obstruction due to chronic bronchitis or emphysema. It is progressive, may be accompanied by airway hyper reactivity, and may be partially reversible. Drugs in this class work to improve emptying of the lungs, reduced dynamic hyperinflation at rest and during exercise, and improve exercise performance. The agents are used as needed for symptom relief or scheduled to prevent symptoms. The GOLD Guidelines do not recommend one agent over another. Therapy should be individualized based on the patient's limitation of airflow symptoms, exacerbations, and co morbidity. In January 2015, there were 428 claims. Since the last review, Spiriva Respimat and Incruse Ellipta have been added to the class. Incruse Ellipta is indicated for the long-term, once-daily maintenance treatment of airflow obstruction in COPD patients. It is an inhalation powder available in blisters. Each blister contains 62.5 micrograms. Dosage is one inhalation, once daily. It is Pregnancy Category C. Spiriva Respimat is indicated for the long-term, once-daily maintenance treatment of bronchospasm associated with COPD and for reducing COPD exacerbations. It is formulated in an inhalation spray that delivers 2.5 micrograms per actuation. The recommended dosage is two inhalations, once daily. It is also Pregnancy Category C. At the last review, a motion for therapeutic alternatives, to include at least one long-acting, one combination, and one oral agent, passed unanimously.

Dr. Demain noted that Albuterol/Ipratropium is listed as a preferred agent, but there is a generic available.

The committee discussed how it came about that an oral agent was included in the last motion. Daliresp, which is very different from the other products, is the only oral agent available. Dr. Hope said there had been a little feedback on why there was an oral agent on the PDL, but it was minimal.

MR. RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE AT LEAST ONE LONG-ACTING, ONE COMBINATION,

AND ONE ORAL AGENT. SECONDED BY DR. PHILLIPS. THE MOTION PASSED WITH ONE OPPOSED.

13. Re-Review of Hepatitis C Agents (Red Class)

DR. HOLTZER, a representative of Abbvie, discussed Viekira Pak. Viekira Pak, with or without Ribavirin, is indicated for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis, HIV co-infection, and liver transplant recipients. It is not recommended for use in patients with decompensated liver disease. Viekira Pak does not require dose adjustments in patients with mild, moderate, or severe renal impairment. For patients who require Ribavirin, further Ribavirin prescribing information is available. Viekira Pak can be administered with a proton pump inhibitor Omeprazole. Any HCV/HIV-1 co-injected patients treated with Viekira Pak should also be on a suppressive antiretroviral drug regimen to reduce the risk of HIV-1 protease inhibitor drug resistance. All direct-acting antivirals have drug-drug interactions and those should be assessed before starting treatment. Several trials and their outcomes were reviewed. For patients receiving Viekira Pak with Ribavirin, the most common adverse events included fatigue, nausea, pruritus, insomnia, asthenia, and other skin reactions. Patients receiving Viekira Pak without Ribavirin, the most common adverse events included nausea, pruritus, and insomnia. Comprehensive safety and efficacy data for Vierkira Pak is found at rxabbvie.com. We request Vierkira Pak be included on the PDL.

In response to Dr. Carlson, Dr. Holtzer said the longest duration of follow-up of patients who have been cleared is about two years, but no data has been published. The relapse rate of patients who have been cleared, not taking into account re-injections, is less than 1%.

STUART O'BROCHTA, a representative of Gilead, discussed Harvoni. Harvoni is a combination of two direct acting agents, NS5A and NS5B inhibitors that are direct acting agents, Sofosbuvir and Ledipasvir. These agents have been combined in a single tablet, all oral, once a day regimen. No interferon and no Ribavirin required. Harvoni offers the shortest course of therapy, down to eight weeks, in a significant number of HCV infected patients who are treatment-naïve without cirrhosis and have pre-treatment HCV RNA less than 6 million. There is no distinction with genotype 1A or 1B, nor any historic negative predictors of response to therapy that changes the SVR rates with Harvoni. It has a limited number of drug-drug interactions. It does not affect the CYP3A system. The concomitant use of Harvoni and P-gp inducers, such as Rifampin or St. John's wort, may significantly decrease Ledipasvir and Sofosbuvir plasma concentrations and may lead to a reduced therapeutic effect. Therefore, the use of Harvoni with P-gp inducers is not recommended. There are no absolute contraindications to either drug. There has been no treatment failure on our resistance identified on treatment. All failure has been directly related to relapse only. Several trials and their outcomes were reviewed. Considering the safety, tolerability, high efficacy rates, and low discontinuation rates, we request Harvoni be placed on the PDL as there are very few patients who cannot be successfully treatment with this therapy.

ROD GORDON, a local community pharmacist representing himself, discussed the hepatitis B agents. He has been in practice for 34 years and most recently has worked with a pharmacy that manages HIV, oncology, and hepatitis C patients. He has worked with seven GI doctors in Anchorage and would like to speak on their behalf as well. It is important for physicians of genotype 1 patients to have the ability to choose the product that they feel is appropriate for their patients. Every patient is unique and have different issues related to what they are able to do. The ability to manage a 10-pill per

day regimen can be difficult for these patients. Patients are better able to tolerate and adhere to a once-daily formulation. The same is true of HIV patients. If you can simplify the regimen, you get much better adherence and better outcomes. For the benefit of these patients, he asked the committee to consider the one pill, once a day formulations for the PDL.

Dr. Balogun gave the Magellan presentation on Hepatitis B Agents. Hepatitis C virus is an infectious, single-stranded enveloped RNA virus. There are six HCV genotypes and more than 50 subtypes. Genotype 1 accounts for about 70 to 75% of HCV cases in the United States, while 2 and 3 account for the majority of the other 25 to 30 percent. The primary goal of treatment is to reduce all cause mortality and liver related health adverse consequences by the achievement of virologic cure as evidenced by an SVR. The agents in this class are divided into subgroups that include interferons, Ribavirin, oral protease inhibitors, oral NS5B polymerase inhibitors, and oral combination products. Dual therapy with interferons and Ribavirin was the standard of care for many years. However, this regimen was not well tolerated, as interferon therapies were associated with severe adverse effects. Hence, tripe therapy with the first generation protease inhibitors, Peginterferon, and Ribavirin were introduced and resulted in higher SVR rates in genotype 1 patients. Patients with HIV and Hep C co-infection should be treated the same as patients without HIV infections, after recognizing and managing interactions with antiviral medications. In January 2015, there were 6 claims. Since the last review, Sofosbuvir, Moderiba, Harvoni, and Viekira Pak were approved by the FDA. Each of the drugs formulations, therapy recommendations, and adverse effects were reviewed. Sofosbuvir, Harvoni, and Viekira Pak are Pregnancy Category B. Olysio is Pregnancy Category C. Merck has announced plans to voluntarily discontinue the manufacture and distribution of Victrelis in the United States by December 2015. As of March 31, 2014, the manufacturing of Infergen was discontinued. At the last review, a motion for therapeutic alternatives for each subclass passed unanimously.

Dr. Carlson noted that there was a new class of agents that were effective in genotype 1, but every newspaper in the world is commenting on the costs. With the complicated list, he felt deeming the drugs in the class as therapeutic alternatives would be very challenging.

Dr. Hope suggested that if the committee was uncomfortable with a motion of therapeutic alternatives the then management of the genotype 1 drugs could be handled by the DUR Committee. The DUR Committee has spent many hours discussing and researching these agents. This is one of the hottest topics in health care and the outcome of the motion will be very significant.

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

Break from 9:35 a.m. to 9:53 a.m.

14. Re-Review of Hepatitis B Agents (Green Class)

Dr. Balogun gave the Magellan presentation on Hepatitis B Agents. The agents in this class are indicated for the treatment of chronic hepatitis B infection. The goal of antiviral therapy is to eliminate and suppress the replication of the virus and to decrease the risk of progression to cirrhosis, hepatocellular carcinoma, or liver failure, which may eventually lead to death or liver transplantation. The American Association for the Study of Liver Diseases guidelines lists the first-line therapy for the treatment of chronic hepatitis B was reviewed. Baraclude and Epivir are approved for use in children 2

years and older. In January 2015, there were 4 claims. At the last review, a motion for therapeutic alternatives passed unanimously.

Dr. Carlson felt the incidence of people needing treatment for hepatitis B had decreased significantly in light of the 25 years of immunizations. Dr. Hope said hepatitis B has taken a back seat to hepatitis C due to the availability of immunizations for hepatitis B.

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

15. Re-Review of Cyclosporine Ophthalmic 0.05% Emulsion (Restasis) (Green Class)

Dr. Balogun gave the Magellan presentation on Cyclosporine Ophthalmic 0.05% Emulsion (Restasis). This class was previously reviewed as anti-inflammatory immunomodulators. Restasis is the only agent in this class. It is indicated to treat keratoconjunctivitis sicca, a dry eye disease related to either aqueous tear deficiency or evaporative tear deficiency due to poor tear quality. Restasis is a cyclosporine ophthalmic emulsion. The exact mechanism of action of this agent to treat this eye disease is unknown. However, the immunomodulating activity of cyclosporine is thought to reduce ocular inflammation. In January 2015, there were 33 claims. At the last review, a motion for class effect passed unanimously.

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

16. Re-Review of Ophthalmic Anti-Inflammatories (Green Class)

Dr. Balogun gave the Magellan presentation of Ophthalmic Anti-Inflammatories. Ophthalmic anti-inflammatories include corticosteroids and non-steroidal anti-inflammatory drugs (NSAIDs). The main use of ophthalmic NSAIDs is for ophthalmic surgery. These agents reduce inflammation in the cornea and conjunctiva in refractive surgery and are effective at reducing pain both during and after the procedure. Ophthalmic NSAIDs also control inflammation during the first few days following the procedure. Topical corticosteroids are effective in acute ocular inflammatory and allergic conditions. In ocular disease, route of administration depends on the site and extent of the condition being treated. Products with invasive administration are typically administered when topical therapy fails. In January 2015, there were 69 claims. At the last review, a motion for class effect passed unanimously.

DR. CARLSON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE AT LEAST ONE DRUG FROM EACH SUBGROUP. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

17. Re-Review of Ophthalmics for Allergic Conjunctivitis (Green Class)

Dr. Balogun gave the Magellan presentation on Ophthalmics for Allergic Conjunctivitis. Conjunctivitis may occur secondary to infectious or non-infectious stimuli. Seasonal and perennial allergic conjunctivitis are non-infectious types of conjunctivitis and are among the most common ophthalmic problems. The agents in this class are divided into antihistamines, mast cell stabilizers, and anti-inflammatory agents. These agents all work to relieve symptoms like itching, redness, swelling, and

mucous discharge. For persistent or frequent symptoms, a mass cell stabilizer may be used. Short courses of ophthalmic corticosteroids may be used to treat disease flares or severe symptoms. In January 2015, there were 83 claims. At the last review, a motion for therapeutic alternatives passed unanimously.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES.

In response to Dr. Carlson, Dr. Hope said the outcome would likely be the same with a motion of class effect to include at least one drug from each subgroup or therapeutic alternatives. The committee discussed the wording of the proposed motion.

SECONDED BY DR. PAPPENHEIM. THE MOTION PASSED UNANIMOUSLY.

Dr. Demain recognized Bill Burkhortz (ph), who has been with Pfizer for 35 years and has attended almost every meeting of the P&T Committee.

18. Re-Review of Ophthalmic Antibiotic Steroid Combinations (Green Class)

Dr. Balogun gave the Magellan presentation on Ophthalmic Antibiotic Steroid Combinations. The agents in this class are indicated for corticosteroid responsive inflammatory ophthalmic conditions for which corticosteroids are indicated and where bacterial infection or risk of bacterial infection exists. Infections of the eye can rapidly damage important functional structures and lead to permanent vision loss or blindness. A corticosteroid will reduce inflammation. And when combined with an antibiotic, the antibiotic treats or prevents an infection, which may be associated with the inflammation. A wide variety of combinations of corticosteroids and antibiotics are available in this class. Several of these are available as ointments and suspensions. In January 2015, there were 31 claims. At the last review, a motion for class effect, including one product that is Erythromycin based, passed unanimously.

The committee discussed by an Erythromycin based product was included in last year's motion. Dr. Demain said there were more problems with Erythromycin than any other drug. He thought that maybe the motion was supposed to exclude Erythromycin. Dr. Carlson noted that many patients purchased over-the-counter products with Erythromycin and generally did not have problems with it.

Dr. Love pointed out that 93 percent of the usage in this category was for non-preferred agents.

Dr. Hope explained that the new PDL became effective in March 2015 and the utilization data is reflective of the prior PDL. One of the downsides to the medically necessary clause is that you are not able to shift utilizations to the products on the PDL.

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

19. Re-Review of Ophthalmic Antibiotics (Green Class)

Dr. Balogun gave the Magellan presentation on Ophthalmic Antibiotics. This class was previously reviewed as subgroups of Quinolones, Macrolides, and Ointments. The agents in this class are divided into Aminoglycosides, Fluoroquinolones, Macrolides, and Other. The indications are varied and

include treatment of superficial ocular infections. A wide variety of ophthalmic antimicrobials is available and many of these antibiotics exhibit a broad spectrum of activity. Many agents used to treat acute bacterial conjunctivitis are available as generic products, including second-generation Fluoroquinolones and certain Macrolides. In January 2015, there were 519 claims. At the last review, a motion for class effect for each subclass passed unanimously.

In response to Mr. Riley, Dr. Hope said Ofloxacin was added to the PDL after the last review. Alaska's large tribal health network often has drugs on their formulary that may be different from what is in the open market. Dr. Carlson thought the tribal pharmacies got a better deal on the VA formulary medications. Ofloxacin may be on the PDL because it was on the VA formulary.

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

20. Re-Review of Immunomodulators, Atopic Dermatitis (Green Class)

Dr. Balogun gave the Magellan presentation on Immunomodulators, Atopic Dermatitis. Atopic dermatitis, often referred to as eczema, is a chronic non-contagious, inflammatory disease of the skin resulting from a combination of generic and environmental factors. There are two agents in this class: Elidel and Protopic. Both are indicated for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in immunocompromised patients who are 2 years of age and older and have failed to respond to other topical prescription products or when those treatments are not advisable. Protopic 0.1% ointment is only approved for use in adults. Elidel and Protopic are calcineurin inhibitors that act locally on T-cells resulting in the suppression of cytokine transcription, which in turn reduces the extent, severity, and symptoms of atopic dermatitis. In January 2015, there were 35 claims. At the last review, a motion for therapeutic alternatives passed unanimously.

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

21. Re-Review of Leukotriene Modifiers (Green Class)

Dr. Balogun gave the Magellan presentation on Leukotriene Modifiers. The agents in this class are used as add-on therapy in patients for the prophylaxis and treatment of asthma. They can also be used in patients utilizing inhaled Glucocorticoids to reduce the steroid dose. Leukotriene radiated effects include airway edema, smooth muscle contraction, mucous secretion, and micro vascular permeability. Safety and efficacy of the Zileuton and Zileuton ER in children under 12 years of age has not been established. Singular is indicated for prophylaxis and chronic treatment of asthma in children 1 year of age and older, relief of symptoms of seasonal allergic rhinitis in children 2 years of age and older, and relief of symptoms of perennial allergic rhinitis in children 6 months of age and older. Accolate is indicated for prophylaxis and treatment of asthma in children 5 years of age and older. In January 2015, there were 782 claims. At the last review, a motion for therapeutic alternatives, to include all forms of Montelukast passed unanimously.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTNERATIVES, TO INCLUDE ALL FORMS OF MONTELUKAST. SECONDED BY DR. GREEAR. THE MOTION PASSED UNANIMOUSLY.

22. Re-Review of Intranasal Rhinitis Agents (Green Class)

Dr. Balogun gave the Magellan presentation on Intranasal Rhinitis Agents. Allergic rhinitis is a constellation of symptoms characterized by sneezing; itchy eyes, nose, and palate; rhinorrhea; and nasal obstruction. It is also often associated with postnasal drip, cough, fatigue, and irritability. The agents in this class consist of nasal corticosteroids, intranasal antihistamines, intranasal corticosteroids, antihistamine combinations, and anticholinergic. Flonase became available over-the-counter in February 2015. In January 2015, there were 636 claims. At the last review, a motion for therapeutic alternatives, to include one agent from the antihistamine, anticholinergic, and corticosteroid subclasses, passed unanimously.

Dr. Demain noted that the products in this class were distinctly different as far as topical antihistamines, topical anticholinergic, and corticosteroids. He felt those three categories needed to be kept separate.

Dr. Hope discussed the utilization of Fluticasone, which is still an Rx product and does not require any changes to the regulations or the CMS plan to continue covering the product. When the generic manufacturers stop making the Rx version of Flonase then we would have to seek additional regulatory and CMS approval. If no prescription Flonase was available, based on federal and state rules then that product could no longer be billed to Medicaid and those prescriptions would have to be changed.

DR. SEMLING MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE ONE AGENT FROM THE ANTIHISTAMINE, ANTICOLONERGIC, AND CORTICOSTEROID SUBCLASSES. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

23. Re-Review of Smoking Cessation Agents (Green Class)

Dr. Balogun gave the Magellan presentation on Smoking Cessation Agents. The agents in this class are divided into nicotine replacement products and non-nicotine replacement products. The nicotine replacement products come in a variety of dosage forms, which were reviewed. The non-nicotine replacement products include two agents: Zyban and Chantix. Zyban is contraindicated in patients with severe seizure disorder and should not be initiated in a patient who is being treatment with reversible MAOIs. Chantix is associated with an increased risk of certain cardiovascular adverse effects in patients who have cardiovascular disease. There have been reports to seizures in patients treated with Chantix. Potential risks and benefits should be considered in patients with a history of seizure disorder before prescribing. You should also discontinue immediately if a seizure occurs. In January 2015, there were 163. At the last review, a motion for therapeutic alternatives passed unanimously.

Dr. Hope discussed the utilization of Bupropion, or Zyban. The utilization is much higher, because reporting on Wellbutrin, which is the exact same drug, has a different drug code and is in the antidepressant category.

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

In responses to Mr. Riley, Dr. Hope said whether Chantix was included on the PDL would be up to the manufacturer’s bid. Dr. Pappenheim said the medically necessary clause could always be utilized.

THE MOTION PASSED UNANIMOUSLY.

24. REVIEW MINUTES FROM JANUARY 16, 2015 MEETING

DR. BERGESON MOVED TO APPROVE THE MEETING MINUTES OF JANUARY 16, 2015. SECONDED BY DR. COOKE. THE MOTION PASSED UNANIMOUSLY.

25. Comments from Committee Member or Chair

Dr. Hope said this would be last meeting and thanked everyone for being so easy to work with.

The committee thanked Dr. Hope for his service and they have enjoyed working with him.

Dr. Hope said staff explored using WebEx or Go To Meeting in place of the current format, but found they have just as many problems so it would not be beneficial at this time. Staff will continue to keep their eyes open for a better format.

22. Adjourn

DR. DEMAIN DEFERED THE ABILITY TO ADJOURN THE MEETING TO DR. HOPE, WHO ADJOURN THE MEETING.

The meeting adjourned at 10:30 a.m.

Minutes approved 11/20/2015.