ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

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

MINUTES OF MEETING
November 17, 2017
8:00 a.m.

Committee Members Present:
Jeffrey Demain, MD, Chair
Robert Carlson, MD (telephonic)
Denise Evey, PharmD
Vincent Greear, R.Ph. (telephonic)
Jenna Hiestand, MD
Charles Ryan, MD
Claudia Phillips, MD (telephonic)
John Riley, PA (telephonic)
Ryan Ruggles, PharmD

Committee Members Absent:
Diane Liljegren, MD (excused)
Trish White, R.Ph. (excused)

Others Present:
John McCall, R.Ph., Magellan Medicaid Administration
Erin Narus, PharmD, State of Alaska
Ladonna Lindley, Kron Associates

1. Call to Order – Chair

Dr. Demain called the meeting to order at 8:08 a.m. He noted that industry comments would be taken on red and blue classes only and were limited to three minutes. Two new board members, Dr. Charles Ryan and Dr. Denise Evey, were welcomed to the meeting.

2. Roll Call

The roll call was taken, and a quorum was present.

3. Public Comments - Local Public/Health Practitioners

There were no public comments.

4. Class Review, Discussion & Vote

4-A. Cystic Fibrosis: CFTR Potentiator Agents (Blue Class); Antibiotics, Inhaled (Green Class); Pancreatic Enzymes (Green Class)

Public Comments for Cystic Fibrosis: CFTR Potentiator Agents (Blue Class)

Lisa Allen, a representative of Vertex Medical Affairs, discussed Kalydeco and Orkambi. Kalydeco and Orkambi target the underlying cause of cystic fibrosis, which is a genetic defect in a cystic fibrosis transmembrane conductance regulator protein. Other therapies treat the symptoms or manifestations of the disease. In May 2017, the FDA expanded the indication for Kalydeco to include 23 Ivacaftor-responsive mutations. This precision medicine decision was based on invitro data and supported by safety and efficacy data from previously conducted clinical trials with up to 5 years of use in patients. Several trials and their outcomes were reviewed. Twenty-seven mutations that are not responsive to Kalydeco and are not indicated for treatment are listed in the USPI, Section 12.1. In July, the FDA further expanded Kalydeco's indication with an additional five Ivacaftor-responsive mutations called splice mutations. To study the clinical efficacy and safety in Kalydeco in people with these five mutations, a trial of patients with CF was completed. The trial and its outcomes were reviewed. The warnings and precautions associated with Kalydeco are in the prescribing information and should be reviewed. The recommended dosages for Kalydeco are contained in the product information. The PROGRESS study and its outcomes was reviewed. Warnings and precautions associated with Kalydeco included important information on its use in patients with advanced liver disease, liver-related events, respiratory events, effects on blood pressure, drug interactions and cataracts.

In response to Dr. Demain, Lisa Allen said Kalydeco has only been available since 2012 so there is no increased longevity of life shown for CF patients. However, one of the aspirational endpoints is change of lung function decline, which is believed to translate into prolonged survival. Quality of life is typically not captured in clinical trials, but there is health economic information and research. Therefore, there is no specific data for quality of life index improvements. There are over 3,000 CF mutations and Kalydeco is indicated for less than 10 percent of those.

In response to Dr. Demain, Dr. Narus said due to the cost of this class and the unique patient population, there is clinical criteria for use and a prior authorization requirement. Prior authorizations have been in place since 2012 and was developed in consultation with pediatric pulmonary specialists to ensure that it captured patient needs and we were identifying those individuals correctly. Updates will reflect the new FDA indications and will be discussed at the January Drug Utilization Review meeting. This class has been effectively managed through the prior authorization process. The only advantage of including this class on the PDL would be potential manufacturer's rebates, if they exist.

DR. RUGGLES MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO BE USED APPROPRIATELY. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Cystic Fibrosis: Antibiotics, Inhaled (Green Class)

Mr. McCall gave the Magellan presentation on Cystic Fibrosis: Antibiotics, Inhaled. According to the Cystic Fibrosis Pulmonary Care guidelines for patients 6 years of age or older with moderate to severe

lung disease and Pseudomonas present in the cultures of the airways, there are strong recommendations both for Aztreonam and Tobramycin, not the other inhaled antibiotics. At the last review the motion was therapeutic alternatives.

The committee discussed the utilization report. There were 50 prescriptions, all for non-preferred drugs. Erin Narus explained that sometimes when a new generic enters the marketplace, it is more expensive to the Medicaid program than the brand-name product. We have been working with the Pulmonary Group to make accommodations for this, which will be reflected on the updated PDL.

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

Cystic Fibrosis: Pancreatic Enzymes (Green Class)

Mr. McCall gave the Magellan presentation on Cystic Fibrosis: Pancreatic Enzymes. In cystic fibrosis, reduced pancreatic enzyme effects occur due to thickened secretions of the GI tract, specifically the pancreas. Pancreatic enzymes are unable to move into the duodenum, leading to malabsorption of nutrients and malnutrition. This relates to poor growth, fatty diarrhea, and deficiency in fat-soluble vitamins. For infants, capsule contents may be administered orally or with applesauce. At the last review the motion was class effect to include at least one pediatric preparation.

In response to Dr. Demain's question about whether this class was being utilized in the naturopathic world, Erin Narus said there was not a specific breakdown of the diagnoses for which these medications were being used. We can look at that from the drug utilization standpoint and identify individuals who might be using these products outside of the standards. Dr. Demain felt staff should ensure that this class was being utilized appropriately.

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

4-B. CENTRAL NERVOUS SYSTEM: Multiple Sclerosis Agents (Red Class); Stimulants and Related Agents (Red Class); Sedative Hypnotics (Blue Class); Anticonvulsants (Blue Class); Antipsychotics - Atypical (Blue Class); Antidepressants (Green Class); Alzheimer's Agents (Green Class)

Public Comments for Central Nervous System: Multiple Sclerosis Agents (Red Class)

Lynda Finch, a representative of Biogen, discussed Tecfidera. Multiple Sclerosis (MS) is a very heterogeneous disease. Multiple products should be available for these patients, who have unique MOAs, so they can receive optimal treatment for the course of their disease. Biogen makes multiple products for MS including Avonex, Tecfidera, Plegridy and Tysabri. Tecfidera is the most widely used oral MS medication. Several studies and their outcomes were reviewed. The combination of Tecfidera's unique MOA and well-defined safety and efficacy profiles support Tecfidera as a valuable long-term treatment option for patients with MS.

Margaret Olmon, a representative of AbbVie, discussed Zinbryta. Prescribing information can be found at www.zinbryta.com. MS is a very difficult disease to treat. It affects about 400,000 people in the United States. Women are two to three times more likely to have MS than men. MS patients usually present with symptoms between the ages of 20 and 40, so they may be on disease modifying therapy for many years. MS progresses differently for each patient and differently throughout their disease. Therefore, patients may need several distinctive treatments over the course of their disease. The unique mechanism by which Zinbryta exerts therapeutic affects makes it an important addition to the options of treatment. Cells that require high-affinity IL-2 receptor signaling, such as the activated T-cells that play a central role in MS pathology, are selectively inhibited. Zinbryta is indicated for the treatment of relapsing forms of Multiple Sclerosis in adults. Because of its safety profile, the use of Zinbryta should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for MS treatment. It is administered as a self-injected, subcutaneous, monthly injection. It is contraindicated in patients with preexisting hepatic disease or hepatic impairment. Zinbryta has a box warning for hepatic injury including autoimmune, hepatitis, and other autoimmune-related disorders. For that reason, Zinbryta is available only through its REMS program, which was described. Several trials and their outcomes were reviewed. We request Zinbryta be added to the PDL so patients and physicians in Alaska can have another treatment for relapsing forms of MS; one with a unique mechanism of action, proven efficacy over Avonex, and a monthly subcutaneous dosing.

Maria Agapova, a representative of Teva Neurosciences, discussed Copaxone, which is indicated for the treatment of patients with relapsing forms of MS. It is available in formulations of daily injections or injections three times a week. Its safety and efficacy are well established, expanding 20 years and over two million patient years of exposure. The GLACIER study and its outcomes was reviewed. Given the nature of this disease, we ask that Copaxone be available on the PDL.

Mary Kemhus, a representative of Novartis, discussed Gilenya. It is the first oral disease-modifying agent to be FDA approved for the treatment of relapsing forms of MS. Although it is difficult to predict when an MS relapse will occur and how severe it will be, the goal is early recognition and treatment adherence to prevent additional events and delay the onset of disability. The number of relapses experienced by an MS patient in the first two years of their diagnosis has been associated with a higher risk of disability progression and a greater risk of converting to secondary progressive MS. High-efficacy, disease-modifying therapy, such as Gilenya, should be considered early in the treatment algorithm. Several studies and their outcomes were reviewed. Gilenya has been on the market for over seven years and has extensive real-world experience with over 217,000 patients treated and over 480,000 patient years of exposure. There is no REMS program and the overall benefit profile remains positive. Gilenya has demonstrated sustained efficacy, an expected safety profile, and it has demonstrated superior efficacy to injectable therapy. For these reasons, we request that Gilenya be considered a preferred treatment for Alaska Medicaid patients.

Mr. McCall gave the Magellan presentation on Central Nervous System: Multiple Sclerosis Agents. Ocrevas is the first agent to be approved by the FDA for the treatment of primary progressive MS. Where 85 to 90 percent of MS patients start with relapsing MS, primary progressive MS affects about 10 percent of those patients. The ORATORIO study showed a significant reduction in disability progression, decreased volume of brain lesions, and decreased whole brain volume loss with Ocrevas. It was also approved for relapsing MS in the OPERA I and OPERA II trials.

In response to Dr. Demain, Erin Narus said there were no specific clinical criteria for the drugs in this class, except Lemtrada. This class contains many different products with different pharmacologic actions, which would be helpful to consider when making the motion.

In response to Dr. Demain, John McCall said a product on a REMS program does not necessarily have a prior authorization requirement. Prior authorization is based on whether the committee sets criteria for the specific class.

In response to Dr. Greear, Erin Narus said drugs that are infused in an outpatient setting are considered covered outpatient drugs under federal regulation. It is possible to have manufacturers offer supplemental rebates within this class. As pharmacy becomes more complex, we are starting to see an intermingling between drugs that used to be solely institutionally administered versus outpatient administered. MS is one of those areas that has melded these two worlds. We would consider all the agents in this class, including injectables. This is a very complex drug class.

Dr. Carlson felt it was impossible for a committee like this one to evaluate this class due to the number of products, the small number of patients, the variable clinical outcomes, and the large number of new medications. There is no real experience or understanding of the advantages of one medication versus another. He felt they should consider finding a consultant, with no industry ties, who could provide a better strategy than simply calling them therapeutic alternatives.

Erin Narus said local prescribers provided input on the challenges of this class in terms of access to medications and how to manage the class as it continues to expand. The committee can decide whether a specific class is appropriate for the PDL. If the committee is not comfortable reviewing a class, we can take that into consideration.

John McCall explained that as prescriptions for MS medications went through a call center, they would go to the state for prior authorization and would need to meet at least the criteria on the package insert.

Dr. Greear said that even though a prior authorization would be required, no one would be denied a claim when attempting to use these agents.

Erin Narus said the FDA label and the appropriateness of use for individual patients would be taken into consideration during the prior authorization process.

Dr. Demain felt Dr. Carlson's suggestion of utilizing a consultant in the more complicated classes that had multiple choices and multiple indications was a good idea and should be considered in the future. A motion of therapeutic alternatives would allow a case-by-case review and would be determined based on the criteria of use.

Dr. Carlson said his comment was for any chronic disease biologics, especially when there were two or three new biologic agents a year and a relatively small number of patients with the chronic disease that qualifies. You need a large population base to have a sense of the efficacy and side effects. At this point, the committee is probably stuck with therapeutic alternatives.

Dr. Demain said the industry representatives were talking about experience with 200,000 patients and large studies. He felt the data that was presented was sound. A strategy for moving forward can be discussed during executive committee.

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

Public Comments for Central Nervous System: Stimulants and Related Agents (Red Class)

There were no public comments.

Mr. McCall gave the Magellan presentation on Central Nervous System: Stimulants and Related Agents. ADHD is the most common neurobehavioral disorder in childhood. It is a chronic condition that affects 4 to 12 percent of school-aged children and about 4 percent of adults. It can detrimentally affect academic performance, social interactions, and general wellbeing. There are three main types: primary hyperactive, primary inattentive, and mixed. Treatment varies depending on age. Behavior therapy is first-line for children under 6 years of age. Stimulants are highly effectively for most children in reducing the core symptoms of ADHD. They are considered first-line therapy for patients 6 years of age or greater. Long-acting agents are useful and can be used adjunctively with short-acting agents. New agents in the class were reviewed. CotemplaXR-ODT is a methylphenidate extended-release orally-disintegrating tablet that has a 12-hour duration. Mydayis is mixed salts of a single-entity Amphetamine. It has three different releasing actions and a 16-hour duration. It is approved for patients 13 years of age and older. Vyvanse has a new generic formulation that is chewable. There is also a new generic formulation of Straterra. Non-stimulants can be used when people want to avoid stimulants. At the last review, the motion was therapeutic alternatives to include at least one oral preparation, at least one extended-release preparation, at least one non-stimulant preparation, at least one extended-alpha agonist, and at least one orally-disintegrating preparation or liquid.

Dr. Demain noted that narcolepsy was included in this class, although he felt they should be separate since narcolepsy was different than ADHD.

Mr. McCall said this class of drugs was also used to treat excessive sleepiness, which could be experienced by patients with narcolepsy or obstructive sleep apnea. There have been no new guidelines related to these indications for quite a while.

Dr. Demain noted that only 1 percent of the utilization for narcolepsy was for preferred agents. The committee needs to look at whether it is a matter of availability, cost or if the wrong products are being recommended. Erin Narus explained that this was primarily due to the brand-name product being less expensive than the generic, but most of the pharmacies carry the generic products.

Dr. Ruggles discussed the pharmacy software systems and pre-edits that stop certain Medicaid prescriptions from going through. He suggested incorporating a primary rejection for generics when the brand-name products are preferred. Erin Narus said pharmacies tend to order the less expensive products regardless of whether they are Medicaid preferred agents, which was taken into consideration for the upcoming PDL.

Dr. Carlson said the incidence of narcolepsy is 50 to 100 per 100,000 people. The number of people being supplied narcolepsy medicine is for a population many times the size of Alaska.

Dr. Greear said last year's motion included at least one long-acting alpha agonist, which did not seem to make it onto the PDL. Erin Narus said the PDL that included that motion was in the regulation process and would be coming out for public comment soon.

In response to Dr. Demain, Erin Narus said stimulants are a focus that the Drug Utilization Review Committee is starting to work on.

The committee discussed the narcolepsy agents. Dr. Ryan said narcolepsy agents were prescribed for a variety of hypersomnia that were not narcolepsy. Dr. Demain said they were also used for jet lag.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE ORAL PREPARATION, AT LEAST ONE EXTENDED-RELEASE PREPARATION, AT LEAST ONE NON-STIMULANT PREPARATION, AT LEAST ONE EXTENDED ALPHA AGONIST, AND AT LEAST ONE ORALLY DISINTEGRATING PREPARATION OR LIQUID. SECONDED BY DR. GREEAR. THE MOTION PASSED UNANIMOUSLY.

Dr. Hiestand arrived at 9:10 a.m.

Public Comments for Central Nervous System: Sedative Hypnotics (Blue Class)

There were no public comments.

Mr. McCall gave the Magellan presentation on Central Nervous System: Sedative Hypnotics. Insomnia is a symptom complex that comprises difficulties falling asleep, staying asleep, or a non-refreshing sleep. The American College of Physicians puts as first-line therapy cognitive behavioral therapy. They did not prefer one agent over another. The guidelines mention low-to-moderate data in support of Doxepin, Eszopiclone, Zolpidem, and Belsomra effectiveness. The American Academy of Sleep Medicine issued guidance on pharmacologic therapy of chronic insomnia in adults. They recommended eight drugs for sleep onset and/or maintenance including Doxepin, Eszopiclone, Ramelton, Suvorexant, Temazepam, Triazolam, Zaleplon and Zolpidem. In 2016, the FDA informed healthcare professionals that concurrent use of opioids and benzodiazepines has resulted in serious adverse reactions such as profound sedation, respiratory depression, coma, and death. Providers should avoid that interaction. Box warnings were added to the labeling of all prescription opioids, including those indicated for pain and cough, and benzodiazepines. The utilization report was reviewed. At the last review, the motion was therapeutic alternatives.

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

Public Comments for Central Nervous System: Anticonvulsants (Blue Class)

Kim Laubmeier, a representative of Sunovion, discussed Aptiom. Epilepsy is a serious and potentially fatal neurological condition. The American Epilepsy Society has stated that, "People with epilepsy must have access to, and insurance coverage for, all AAEDs and all their formulations without formulary restrictions." In 2017, Aptiom received FDA approval for an expanded indication to treat partial-onset seizures in patients 4 years of age and older. It is dosed once daily and may be taken crushed or whole, and with or without food. It is not a controlled substance, so drug monitoring is not required. Please see the full prescribing information for a complete list of warnings, precautions, and adverse events. Several studies and their outcomes were reviewed. Aptiom may help address an important need in adult and pediatric patients, 4 years of age and older, with partial onset seizures. We request that Aptiom be added to the PDL.

Mr. McCall gave the Magellan presentation on Central Nervous System: Anticonvulsants. The FDA has a new rule granting a monotherapy indication based solely on the results of randomized controlled trials of adjunctive therapy for partial or focal onset seizures. Therefore, more drugs are expanding their indications in that direction. Fycompa is now approved as monotherapy for patients 12 years of age and older who have partial onset seizures. Briviact is now FDA approved as monotherapy for partial-onset seizures in patients 16 years of age and older. Aptiom is now FDA approved for the treatment of partial-onset seizures in children and adolescents 4 to 17 years of age.

In response to Dr. Demain, Erin Narus explained that anticonvulsant drugs obtained additional FDA labeling as monotherapy. As far as the motion, the state does not need the committee to make specific recommendations to require monotherapy agents versus adjunctive therapy agents.

Mr. McCall continued his presentation on Central Nervous System: Anticonvulsants. Qudexy XR is now approved for migraine prophylaxis in adults and adolescents 12 years of age and older. Trokendi XR is now approved for the treatment of migraine headache in adults and adolescents 12 years of age and older. Other anticonvulsants indicated for migraine prophylaxis are Depakote and Topamax. The utilization reports were reviewed. At the last review, the motion was therapeutic alternatives.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RUGGLES. THE MOTION CARRIED UNANIMOUSLY.

Public Comments for Central Nervous System: Antipsychotics - Atypical (Blue Class)

Lyle Laird, a representative of Sunovion, discussed Lurasidone (Latuda). Lurasidone is indicated for the acute treatment of both schizophrenia and bipolar depression in adults. It is the only agent in this class with an indication in both monotherapy and adjunctive therapy, with Lithium or Valproate, for the acute treatment of bipolar depression. In 2017, Lurasidone received approval for the treatment of schizophrenia in adolescents age 13 to 17. The efficacy of Lurasidone in adolescent schizophrenia was established in a six-week, double-blind, placebo study, which was described. Please see the full prescribing information for a complete list of warnings, precautions, and adverse events.

Kim Laubmeier, a representative of Sunovion, discussed Lurasidone (Latuda). In addition to the clinical trial outcomes, Lurasidone has also consistently demonstrated favorable compared with health outcomes and cost effectiveness in adult patients with schizophrenia and bipolar disorder. Several trials and their outcomes were reviewed. Lurasidone addresses the need for safe and cost-effective agents to

manage adult and adolescent patients with schizophrenia and adult patients with bipolar depression. We request that Lurasidone be retained on the PDL.

Tim Birner, a representative of Alkermes, discussed Aripiprozole Lauroxil ER or Aristada. It is an extended release injectable. It is an atypical antipsychotic for IM use. Several trials and their outcomes were reviewed. The most common adverse events are insomnia, akathisia, and headache. It has a class box warning for increased mortality in elderly patients with dementia-related psychosis. Depending on an individual patient's needs, treatment with Aristada can be initiated at a dose of 441, 662, or 882 milligrams administered every month. A dose of 1,064 milligram, administered every two months, was recently approved. The dosage formulations of Aristada were reviewed. When making dosage adjustments, the pharmacokinetics and the prolonged release characteristics of Aristada should be considered. The proprietary technology utilized to develop Aristada allows for a controlled release after injection and extends exposure to the active molecule. Aristada is the first long-acting atypical antipsychotic with both once monthly, six weeks and every two-month dosing. These results support Aristada as an important treatment option for schizophrenia. We request that you consider adding Aristada to the Alaska PDL.

In response to Dr. Hiestand, Tim Birner explained how to transition from Aripiprozole to Aristada. When you start Aristada, you need 21 days of oral therapy. We are currently working on Initio, which is a short-acting drug that will be used instead of the 21 days of oral therapy.

In response to Dr. Demain, Tim Birner said the lowest dosage of Aristada could be administered in the shoulder, but the rest of the doses were gluteal and had to be administered by healthcare professionals. A large percentage of patients with schizophrenia are not capable of taking their medications daily, which is the main reason for relapses, and this is where long-acting injectable formulations are beneficial.

Malaak Brubaker, a representative of Otsuka, discussed Abilify Maintena. Please review the full prescribing information. Abilify Maintena, an extended-release injectable suspension, is an atypical antipsychotic indicated for the treatment of schizophrenia, and now for maintenance monotherapy treatment with bipolar I disorder in adults. It is an injection and should be administered by a healthcare professional. Several trials and their outcomes were reviewed. We request that Abilify Maintena continue to be available on the PDL.

Mr. McCall gave the Magellan presentation on Central Nervous System: Antipsychotics - Atypical. Asenapine has an expanded indication to include maintenance monotherapy in adults with bipolar 1 disorder. Ability Maintena is now indicated for maintenance monotherapy of bipolar 1 disorder in adults. We have migrated toward the second-generation antipsychotics to avoid extrapyramidal side effects, but there are metabolic side effects associated with them. At the last review, the motion was therapeutic alternatives to include at least one oral preparation, at least one intramuscular injection, and at least two long-acting intramuscular injectables, one of which has a duration of at least four weeks.

Dr. Phillips advocated for increasing the injectable formulations. A large market share is currently going to Invega Sustaina, which is a nonpreferred drug. Risperidone must be refrigerated, whereas Invega Sustaina does not. If we can maintain medications for these patients, especially in the first stages of schizophrenia, we will have better overall outcomes.

Dr. Hiestand agreed with Dr. Phillips that more options for long-acting injectables were needed. Patients might respond to one medication and not the other three, so it is important to have more options and find the right fit for this patient population.

The committee discussed the antipsychotic class. Dr. Demain said there has always been many preferred agents in this class. He noted that the medically necessary clause could always be utilized. In response to Dr. Demain, Dr. Phillips said she was not specifically advocating for the inclusion of Invega Sustaina, but we need to offer more options in this class. Erin Narus said the PDL currently in the regulation process is reflective of last year's motion to ensure that there is broader representation of long-acting injectables.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE ORAL PREPARATION, AT LEAST ONE INTRAMUSCULAR INJECTION, AND AT LEAST TWO LONG-ACTING INTRAMUSCULAR INJECTABLES, ONE OF WHICH WITH A DURATION OF AT LEAST FOUR WEEKS. SECONDED BY DR. RUGGLES.

The committee discussed the motion. Dr. Hiestand said she would like to have at least two drugs available with a duration of four weeks, which would include both Invega and Abilify. Dr. Phillips said the current motion does not exclude having two formulations with a duration of four weeks, but it leaves more room for financial negotiations. Dr. Demain noted that the medically necessary clause could always be utilized.

THE MOTION PASSED UNANIMOUSLY.

Break from 9:54 a.m. to 10:09 a.m.

Dr. Demain took the roll call and called the meeting back to order at 10:09 a.m.

4-B. CENTRAL NERVOUS SYSTEM (CONTINUED): Multiple Sclerosis Agents (Red Class); Stimulants and Related Agents (Red Class); Sedative Hypnotics (Blue Class); Anticonvulsants (Blue Class); Antipsychotics - Atypical (Blue Class); Antidepressants (Green Class); Alzheimer's Agents (Green Class)

Central Nervous Systems: Antidepressants (Green Class)

Dr. Demain noted that the committee would be addressing two classes in this category: SSRIs and Antidepressants - Others.

Mr. McCall gave the Magellan presentation on Central Nervous System: Antidepressants - SSRIs. Major depressive disorder is the most prevalent depressive disorder, with an estimated lifetime prevalence of 16 percent in the United States. The American Psychiatric Association defined MDD as depressed mood, or loss of pleasure or interest, along with the following symptoms: changes in appetite, sleep patterns, psychomotor activity, energy, concentration or decisiveness, inappropriate guilt and suicidal ideation. In 2016, the American College of Psychology issued guidelines on nonpharmacologic and pharmacologic treatment of adults with major depressive disorder. After a review of the literature, they found that cognitive behavior therapy and second-generation

antidepressants were similarly effective and had similar discontinuation rates. At the last review, the motion was therapeutic alternatives.

DR. HIESTAND MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

Mr. McCall gave the Magellan presentation on Central Nervous System: Antidepressants - Other. This group includes the SNRIs. The utilization report was reviewed. At the last review, the motion was therapeutic alternatives.

DR. RUGGLES MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. HIESTAND. THE MOTION PASSED UNANIMOUSLY.

Central Nervous System: Alzheimer's Agents (Green Class)

Mr. McCall gave the Magellan presentation on Central Nervous System: Alzheimer's Agents. Alzheimer's disease is the most common type of dementia, accounting for 60 to 80 percent of all dementia disorders. Symptoms include cognitive defects, memory impairment, deterioration of language, dysphagia, disorientation, and impaired judgment. Psychiatric symptoms include depression, delusions or hallucinations, physical or verbal aggression, wandering, and repetitive mannerisms. There are two classes: acetylcholinesterase inhibitors and NMDA receptor antagonists. Each can be used as monotherapy or as a combination. At the last review, the motion was therapeutic alternatives.

Dr. Demain said he recently attended a summit in Washington, D.C., where Alzheimer's funding received the largest increase in federal funding, an increase of about 23 percent.

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

4-C. ANALGESICS: NSAIDS (Red Class); Analgesics, Opioid - Short-Acting (Red Class); Analgesics, Opioid - Long-Acting (Red Class); Neuropathic Pain (Green Class); Antimigraine Agents (Green Class); Skeletal Muscle Relaxants (Green Class); Restless Leg Syndrome (RLS) (Green Class)

Public Comments for Analgesics: NSAIDS (Blue Class)

Mr. McCall explained that this class was originally categorized as a red class, but the new medication in the class did not seek federal rebates, so it will be a blue class.

There were no public comments.

Mr. McCall gave the Magellan presentation Analgesics: NSAIDS. The CDC guidelines have had an influence on the other guidelines. They have come out with the "WHO's Cancer Pain Ladder" for adults. They recommend non-opioids as a first step, making sure that the pain is addressed by the clock, and then moving up toward opioids. For the management of chronic pain in survivors of adult

cancer, they had the same recommendations. The American Academy or Orthopedics also recommended other agents besides opioids as first-line therapy. The newest guidelines for noninvasive treatment for acute, subacute and chronic low back pain includes non-pharmacologic treatment as first-line therapy with NSAIDs or skeletal muscle relaxants as the initial drugs of choice. Duloxetine or Tramadol as second-line therapy. Clinicians should reassure patients that acute or subacute low back pain usually improves over time, regardless of the treatment. NSAIDs are commonly used to treat rheumatoid arthritis and osteoarthritis. NSAIDs are the most widely used drugs in the U.S., accounting for about 4.5 percent of all prescriptions. They are associated with GI bleeds. There is a black box warning related to MI and stroke. The utilization report was reviewed. At the last review, the motion was therapeutic alternatives.

The committee discussed NSAIDs. Dr. Demain said Meloxicam was considered a COX-2 and should be moved to the appropriate category in the materials. For topical NSAIDs, 54 percent of the prescriptions were for the nonpreferred agent, Diclofenac gel. Erin Narus explained that there were three product types: branded products with a brand name; authorized generics with specific agreements, which are generally less expensive but have the branded name; and true generics. We start seeing a shift with the authorized generics, such as Diclofenac gel, because it is technically a branded product, but it looks like a generic and is generally less expensive than the branded products. Dr. Demain noted the only changes in the class were in guideline utilization and black box warnings.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. EVEY. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Analgesics: Analgesics, Opioid - Short-Acting (Red Class)

There were no public comments.

Mr. McCall gave the Magellan presentation on Analgesics: Analgesics, Opioid - Short-Acting. RoxyBond is a new agent that is not yet in the marketplace. It is an Oxycodone Hydrochloride formulation and will be the first short-acting, abuse-deterrent formulation of Oxycodone. FDA indications and warnings include the use of Codeine in children younger than 12 years of age, the use of Tramadol in children younger than 12 years of age, and the use of Tramadol in children younger than 18 years of age after surgery to remove tonsils and/or adenoids. Codeine and Tramadol have product label warnings stating they are not recommended for adolescents between the ages of 12 and 18 who are obese or have conditions of obstructive sleep apnea or severe lung disease.

Erin Narus said that due to the safety concerns, an edit was added to the pharmacy system to flag those prescriptions and notify the pharmacists that those were not recommended for the pediatric population.

Mr. McCall continued his presentation on Analgesics: Analgesics, Opioid - Short-Acting. At the last review, the motion was therapeutic alternatives.

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

The committee discussed the opioids class. Dr. Carlson felt the committee needed to address the large number of prescriptions in this class due to the deaths in Alaska and around the country. Erin Narus

said the Drug Utilization Review Committee would be addressing the utilization of opioids, trends in the class, and prescribing pattern maps to increase provider-level education in opioid utilization at their next meeting. There have been additional efforts by the state and significant legislation in that regard as well. Erin Narus said the Drug Utilization Committee would be talking about improving the education at the point-of-sale level to ensure that there is a robust system in place to identify situations where opioids are a less favorable option and to ensure appropriate access for individuals who have legitimate prescriptions. Dr. Demain discussed a recent study that indicated the appropriate use of NSAIDs was as effective as Oxycodone in post-operative orthopedic cases.

SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.

The committee discussed RoxyBond. Erin Narus said RoxyBond was classified as an abuse-deterrent drug because it uses physical and chemical barriers that make it more difficult to manipulate and inject. Dr. Carlson said the idea of abuse deterrence is great, but there are no studies showing any real-life differences in outcomes. Dr. Demain said RoxyBond appeared to be a deterrent for inappropriate modes of administration, but it still had abuse risks.

Public Comments for Analgesics: Analgesics, Opioid - Long-Acting (Red Class)

There were no public comments.

Mr. McCall gave the Magellan presentation on Analgesics: Analgesics, Opioid - Long-Acting. The new agents in this class were reviewed. The utilization report, which is 56 percent for preferred products, was reviewed.

In response to Dr. Demain, Erin Narus said between September 2016 and September 2017, there appeared to be a smaller portion of the Medicaid population utilizing opioids on a per-member basis. However, it is too early to see the overall changes in the shortening of duration. One of the challenges for Alaska Medicaid has been prescribers who prescribe within the Medicaid limits and then encourage their patients to fill a second prescription and pay for it in cash. We are working with PDMP to identify those types of situations. We continue to work with our pharmacies and prescribers to promote good practices in prescribing opioids.

Mr. McCall continued his presentation on Analgesics: Analgesics, Opioid - Long-Acting. At the last review, the motion was therapeutic alternatives to include at least one oral preparation, at least one transdermal preparation, and at least one abuse-deterrent preparation. The only generic abuse-deterrent preparation available is for OxyContin.

In response to Dr. Ryan, Erin Narus explained why Methadone was not a preferred agent on the PDL. Methadone has some significant safety concerns, such as cardiac risks. There has been a significant push, especially within Medicaid programs, to move away from Methadone as being a preferred agent for pain management. Specific open access to Methadone has been viewed unfavorably nationally. Two or three years ago, Alaska Medicaid placed Methadone on the PDL, but required a prior authorization.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE ORAL PREPARATION, ONE TRANSDERMAL

PREPARATION, AND AT LEAST ONE ABUSE-DETERRENT PREPARATION. SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.

Analgesics: Neuropathic Pain (Green Class)

Mr. McCall gave the Magellan presentation on Analgesics: Neuropathic Pain. Neuropathic pain can be caused by several different diseases (diabetes mellitus, herpes zoster, human immunodeficiency virus), medical interventions (chemotherapy and surgery), and injuries. It has recently been defined as the pain that evolves because of direct injury or disease to the nervous system. According to the 2015 peripheral neuropathy review by the Mayo Clinic, first-line treatment is Neurontin, Gabapentin, or Pregabalin. According to the 2011 American Academy of Neurology Guidelines for the management of diabetic neuropathic pain, treatments include Pregabalin, Gabapentin and other agents from other classes. At the last review, the motion was therapeutic alternatives.

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

In response to Dr. Demain, Erin Narus discussed the utilization report, which indicates only 2 percent of the prescriptions were for the preferred agent. This is again a generic-versus-brand situation, which has been taken into consideration.

THE MOTION PASSED UNANIMOUSLY.

Analgesics: Antimigraine Agents (Green Class)

Mr. McCall gave the Magellan presentation on Analgesics: Antimigraine Agents. Headache is one of the most common complaints by patients when presenting to a physician. Migraines account for 10 to 20 percent of all headaches in adults and affects over 38 million men, women, and children in the United States. The American Academy of Family Physicians and the American College of Physicians have recognized that the Triptans are effective agents for the acute treatment of migraine. Data reviewed for the guidelines did not demonstrate that any one Triptan was superior. At the last review, the motion was therapeutic alternatives to include multiple administration groups.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. HIESTAND. THE MOTION PASSED UNANIMOUSLY.

Analgesics: Skeletal Muscle Relaxants (Green Class)

Mr. McCall gave the Magellan presentation on Analgesics: Skeletal Muscle Relaxants. Skeletal muscle relaxants consist of antispasticity and antispasmodic agents. The antispasticity agents, such as Baclofen, Tizanidine, and Dantrelene, aid in reducing muscle hypertonicity and involuntary jerks. Antispasmodic agents, such as Carisoprodol, Cyclobenzaprine, Metaxalone, and Methocarbamol, are primarily used to treat musculoskeletal conditions. Very few comparative studies are available for the skeletal muscle relaxants. At the last review, the motion was therapeutic alternatives.

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

Analgesics: Restless Leg Syndrome (RLS) (Green Class)

Mr. McCall gave the Magellan presentation on Analgesics: Restless Leg Syndrome (RLS). Restless Leg Syndrome is a neurological sensory disorder in which patients experience irrepressible sensations in the legs and arms while sitting or lying still that causes them to move their arms or legs. Prior to 2000, Levodopa was the dopaminergic agent most studied for RLS. Pramipexole, Ropinirole, and Rotigotine are now approved for RLS and there has been increased focus on their use. The American Journal of Medicine's 2007 review of guidelines and standards of practice for RLS report that dopaminergic therapy appears to be the most effective and relieves symptoms rapidly. At the last review, the motion was class effect.

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

4-D. SUBSTANCE DEPENDENCE: Smoking Cessation Products (Green Class); Opioid Dependence (Green Class); Opioid Reversal Agents (Green Class)

Substance Dependence: Smoking Cessation Products (Green Class)

Mr. McCall gave the Magellan presentation on Substance Dependence: Smoking Cessation Products. Cigarette smoking is the leading preventable cause of death and is responsible for about one in five deaths annually, or about 480,000 deaths per year in the United States. The 2008 Clinical Practice Guidelines for Treating Tobacco Use and Dependence from the Agency for Healthcare Research and Quality states that all smokers who are trying to quit should be offered medication, except when contraindicated or for specific populations for which there is insufficient evidence of effectiveness. Recommendations include Chantix and a combination (nicotine patch plus a rapid-onset NRT) as being more effective than NRT monotherapy or Bupropion. However, Bupropion seems to be as effective as an NRT. With Chantix there have been reports of neuropsychiatric symptoms. With Bupropion, physicians should worry about seizures in patients with a history of seizures. At the last review, the motion was therapeutic alternatives.

The committee discussed the smoking cessation products. Dr. Demain noted that Chantix, which accounted for 86 percent of the prescriptions, was not a preferred agent on the Alaska PDL. The committee discussed why Nicoderm CQ had a 31 percent utilization as compared to 38 percent for the approved generic nicotine patch. Dr. Evey said her pharmacy did not carry the branded product, and Dr. Ruggles said his pharmacy had access to the generic product, so they were not sure why the utilization was so close. Dr. Demain felt the products dispensed should not be at the retailer's discretion, because the branded product was significantly more expensive. He suggested issuing a letter to pharmacies regarding the dispensing of smoking cessation products.

The committee discussed whether Chantix, which accounted for 86 percent of the prescriptions, should be specifically included in the motion.

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

The committee further discussed whether Chantix should be included on the PDL. Dr. Phillips said the motion stated that Chantix was a therapeutic alternative, which physicians could take into consideration when prescribing to their patients. Dr. Demain noted there was clear data that Chantix is the most effective therapy and has been shown to be superior to the other options. Erin Narus said the committee's discussion would be taken into consideration, but she supported the idea of the committee including Chantix in the motion if they felt it should be included on the PDL.

DR. GREEAR AMENDED THE MOTION TO INCLUDE CHANTIX. DR. PHILLIPS ACCEPTED THE AMENDMENT.

SECONDED BY DR. GREEAR. THE MOTION PASSED UNANIMOUSLY.

Dr. Demain noted that this motion was a good example of where the committee wanted to include a specific therapy on the PDL because there was clear evidence that the therapy was superior to the others in the class in terms of efficacy.

Substance Dependence: Opioid Dependence (Green Class)

Mr. McCall gave the Magellan presentation on Substance Dependence: Opioid Dependence. Under the Drug Addiction Treatment Act of 2000, to become a qualified practitioner, physicians must be licensed under state law to practice medicine, obtain a waiver from the U.S. Substance Abuse and Mental Health Services Administration, and notify the Secretary of Health and Human Service of their intention of prescribing or dispensing Buprenorphine. Buprenorphine is a Schedule III controlled substance and has the same potential for abuse as other opioids. Both Buprenorphine and Buprenorphine/Naloxone can be used for office-based detoxification by specially-trained and registered physicians. Buprenorphine can suppress opiate withdrawal symptoms and block the effect of other opiates. There is also an implantable Buprenorphine product, Probuphine, for patients stabilized on low-to-moderate doses of transmucosal Buprenorphine for a minimum of three months. Oral Naltrexone is approved for the adjuvant treatment of patients who are dependent on opiate agonists. Naltrexone is also approved for the treatment of alcoholism. Vivitrol is a once-monthly intramuscular Naltrexone formulation indicated for alcohol dependence. Methadone, which is not reviewed in this class, is used for opioid dependence. At the last review, the motion was therapeutic alternatives to include Vivitrol.

MR. RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE VIVITROL. SECONDED BY DR. RUGGLES.

In response to Dr. Hiestand, Erin Narus said the Buprenorphine implant would fall under medical, rather than pharmacy, because it would have to be done in a medical setting.

THE MOTION PASSED UNANIMOUSLY.

Substance Dependence: Opioid Reversal Agents (Green Class)

Mr. McCall gave the Magellan presentation on Substance Dependence: Opioid Reversal Agents. Naloxone Hydrochloride injection have been utilized in the treatment for the complete or partial reversal of opioids and the treatment of known or suspected opioid overdose. Naloxone Hydrochloride injection (Evzio) offers a unique delivery device with a pre-filled auto-injector and electronic voice instruction for emergency use while awaiting emergency medical assistance. Naloxone nasal spray (Narcan) is also indicated for use for emergency treatment of opioid overdose. The nasal formulation offers an alternative to the Naloxone auto-injector for treatment outside of healthcare settings. Neither of these formulations should be considered substitutes for emergency medical care. At the last review, the motion was therapeutic alternative to include Vivitrol.

Dr. Phillips noted that 95 percent of the prescriptions were for Narcan nasal spray, which was a life saver. She questioned if Narcan would be available on the PDL if the committee determined the drugs in the class were therapeutic alternatives. Erin Narus said Alaska Medicaid has placed Narcan nasal spray, through the Drug Utilization Review Committee, on the PDL as a preferred agent and we do not anticipate any changes to this category. There is also a safety net that alerts pharmacists when an individual is filling their third dose within a one-year period. In response to Dr. Demain, Dr. Ruggles said that third parties and pharmacists in Alaska who have the necessary education can prescribe and dispense Narcan. While it is not directly over-the-counter, it can be available through a pharmacist.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE NARCAN. SECONDED BY DR. EVEY. THE MOTION PASSED UNANIMOUSLY.

The committed moved into executive session at 11:11 a.m.

5. Review Minutes from September 2017 Meeting

This item was addressed in executive session.

6. Comments from Committee Members or Chair

This item was addressed in executive session.

7. Adjourn

The meeting adjourned at 11:37 a.m.