ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

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

MINUTES OF MEETING
November 16, 2018
8:00 a.m.

Committee Members Present:
John Riley, PA, Chairman
Sarah Doran Atchison, PharmD
Robert Carlson, MD (telephonic)
Vincent Greear, MD (telephonic)
Claudia Phillips, MD (telephonic)
Ryan Ruggles, PharmD
Charles Ryan, MD
Trish White, MD (telephonic)

Committee Members Absent:
Jenna Hiestand, MD

Others Present:
Chuck Semling, PharmD, RPh, State of Alaska
Erin Narus, PharmD, State of Alaska
Elaine Edwards, RPh, Magellan Medicaid Administration
Umang Patel, PharmD, RPh, Magellan Medicaid Administration
Colette Grower, Kron Associates

1. Call to Order – Chairman

Chairman Riley called the meeting to order at 8:00 a.m.

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. Central Nervous System: Alzheimer's Agents (Green Class); Anticonvulsants (Red Class); Antidepressants (Blue Class); Antipsychotics - Atypical (Red Class); Multiple Sclerosis Agents (Red Class); Sedative Hypnotics (Green Class); Stimulants and Related Agents (Red Class)

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

Dr. Umang Patel gave the Magellan presentation on Central Nervous System: Alzheimer's Agents. Approximately 5.7 million Americans suffer from Alzheimer's disease (AD), of which 5.5 million are age 65 and older. It is the most common type of dementia, accounting for 60 to 80 percent of dementia disorders in the elderly and is the sixth leading cause of death in the United States. It is characterized by irreversible loss of, or decline in, memory and other cognitive abilities. It is characterized by progressive cognitive decline associated with impairment of activities of daily living and behavioral disturbances. Other types of dementia include vascular dementia, dementia with Lewy bodies, mixed dementia, and frontotemporal dementia. Patients with this may eventually lose all cognitive, analytical, and physical functioning. In addition, there are seven stages of AD over the course of the disease and individuals may not experience the same symptoms or rate of disease progression.

Guidelines from the American Academy of Family Physicians and the American Psychiatric Association was reviewed. At the last review, a motion for therapeutic alternatives passed unanimously.

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

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

Dr. Umang Patel read a letter Dr. Kristen Jessen from Central Peninsula Neurology advocating for the inclusion of Vimpat on the Alaska PDL.

ELAINE MORLOCK, a representative of UCB, discussed Vimpat. Despite the availability of over 25 antiepileptic drugs, unmet treatment needs remain. More than 30 percent of patients continue to experience seizures and are considered refractory to therapy. Vimpat oral solution and tablets are indicated for the treatment of partial onset seizures in patients 4 years of age and older. As the safety of Vimpat injection has not been studied in pediatric patients, Vimpat injection is indicated for the treatment of partial onset seizures in patients 17 years of age and older. It is a schedule V controlled substance. It can be initiated as a single loading dose in patients who require immediate antiseizure medication, such as those experiencing breakthrough partial onset seizures. In such cases, patients can achieve a therapeutic dose more quickly than with a standard titration. The use of a loading dose in pediatric patients has not been studied. The primary mechanism of action of Vimpat is believed to be selective enhancement of slow inactivation of sodium channels. Conversely, the majority of sodium channel blocking antiepileptic drugs effect fast inactivation. The precise mechanism by which Vimpat exerts its effects in humans is unknown. Several trials and their outcomes demonstrating the efficacy of Vimpat in reducing seizure frequency were reviewed. Vimpat is associated with warnings and precautions including suicidal behavior and ideation, dizziness and ataxia, cardiac rhythm and

conduction abnormalities, and multi-organ hypersensitivity reactions. The adult clinical trials, the most common adverse reactions were dizziness, headache, and nausea. Adverse reactions reported in the monotherapy and pediatric trials were similar to those seen in adult patients. Vimpat is available in multiple formulations including tablets, oral solution, and intravenous injection. No dosage adjustments are necessary when switching between formulations, allowing for uninterrupted therapy between outpatient and inpatient care settings. We respectfully request that you add Vimpat and Briviact to the PDL for Alaska Medicaid patients.

ADAN SOSA, a representative Sunovion Pharmaceuticals, discussed Aptiom. Aptiom is indicated for the treatment of partial onset seizures for patients 4 years of age and older. Some key differentiating features about our product is that Aptiom is not a controlled substance. It is dosed once a day, taken whole or crushed, with or without food. Please refer to the full prescribing information for a complete list of warnings, precautions, and other safety topics. The American Epilepsy Society has stated that people with epilepsy must have access to all antiepileptic drugs in all formulations and without formulary restrictions. A retrospective study looked at the impact of treatment restrictions and concluded that restrictions on access to all formulations of newer antiepileptic drugs (AEDs) resulted in an increased number of emergency room visits and hospitalizations with no reduction in health care costs. Several studies and their outcomes were reviewed. Aptiom has demonstrated clinical and economic value in patients with partial onset seizures in real-world clinical practice. We respectfully request that Aptiom be added to the PDL without restriction.

Dr. Umang Patel gave the Magellan presentation on Central Nervous System: Anticonvulsants. Epilepsy is one of the most common disorders of the central nervous system. It is defined when a person has two or more seizures. It affects 2.2 million Americans with approximately 150,000 new cases diagnosed each year. The risk is estimated to be 1 percent from birth to age 20 years of age, and then it increases to 3 percent at age 75 years. Isolated seizures may also occur during a febrile illness, after head trauma, or as a result of withdrawal from alcohol or sedative and hypnotics. A seizure is traceable to an unstable cell membrane or cluster of cells. Excessive excitability spreads either locally (partial seizure) or more widely (generalized seizure). Partial seizures begin in one hemisphere of the brain and, unless they become secondarily generalized, they can cause alterations in motor functions, sensory symptoms, or automatisms. If there is no loss of consciousness, they are called simple partial. If there is loss or impairment of consciousness, they are called complex partial. About 70 percent of patients with epilepsy can be maintained on one drug. Noncompliance and evolving refractory epilepsy are common reasons for treatment failure. If control is not achieved with one drug, an alternative medication should be attempted before others are added to the current therapy.

Lennox-Gastaut syndrome is one of the most severe forms of childhood epilepsy and is one of the hardest forms to treat. It is characterized by mental retardation and multiple seizure types. Patients have seizures daily, sometimes experiencing several seizures within a day. Patients may also experience “drop attacks” which are defined as a loss of muscle control causing the patient to fall abruptly to the floor.

Infantile spasm primarily consists of a sudden bending forward of the body with stiffening of the arms and legs. West syndrome is characterized by infantile spasms, developmental regression, and a specific pattern on electroencephalography (EEG) testing called hypsarrhythmia (chaotic brain waves). The onset of infantile spasms is usually in the first year of life, typically between 4 and 8 months and usually stop by the age of 5, but they may be replaced by other seizure types.

The goals of treating epilepsy are to reduce the frequency of seizure occurrence along with providing the best possible quality of life for the patient. Ideally, this would be achieved using a medication with minimal adverse effects and drug interactions. Treatment will depend on the type of seizure. Many different classes of drugs are available to treat the different forms of seizures. Some patients will require more than one drug to control their seizures.

Guidelines from the American Epilepsy Society (AES) and the American Academy of Neurology (AAN) were reviewed.

The new medications in the class were reviewed. Epidiolex is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. It has a high risk of increased seizure frequency and status epilepticus if discontinued abruptly. Recommended dosing was reviewed. It is available in an oral solution. Diacomit is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older taking Clobazam. It has a risk of increased seizure frequency and status epilepticus if discontinued abruptly. Recommended dosing was reviewed. It is available as a capsule and powder for oral suspension. Briviact has an FDA expanded indication for the treatment of partial onset seizures to include patients 4 to 15 years of age. Briviact IV is still only approved for patients 16 years of age and older. Sabril received an expanded indication for a generic powder formulation. However, the indications, limitations, dosing and availability remain the same.

There is a hemophagocytic lymph histiocytosis warning, which is a life-threatening syndrome of immune activation characterized by extreme systemic inflammation that has occurred in patients taking Lamotrigine. Common symptoms include fever, hepatosplenomegaly, rash, lymphadenopathy, neurologic symptoms, cytopenia, abnormal liver functions, and coagulopathies. These symptoms have been reported within 8 to 24 days following the initiation of Lamotrigine, which should not be restarted if an alternative source for the symptoms cannot be determined.

The utilization report was reviewed: 96.1 percent of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

Dr. Carlson felt it was difficult to make a motion because all the drugs in this class treated very different conditions. The only logical solution would be therapeutic alternatives, but the grouping does not seem logical. Dr. Phillips noted that according to the utilization report, 96.1 percent of the prescriptions were for preferred products. Dr. Semling noted the medically necessary clause could be utilized.

DR. PHILLIPS MOVED THE DRUGS INT EH CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

4B. Cystic Fibrosis: CFTR Potentiator Agents (Red Class); Antibiotics, Inhaled (Green Class); Pancreatic Enzymes (Green Class)

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

DR. ROBERTS stated two disclosures. The Cystic Fibrosis Foundation asked him to attend the meeting because there was concern that there were no chloride channel potentiators on the PDL. He is the coordinator of the Cystic Fibrosis clinic and the director for the Therapeutics Development Network and his salary is paid by Providence Hospital, which conducts and pays for clinic drug trials. We have done studies for two of the companies involved in the development of chloride channel potentiators including Novartis. We understand the resistance to excluding very expensive drugs from the formulary and the requirement for due diligence before they are approved. We appreciate the fact that patients needing these drugs have not been turned down. The problem is the process after that. Once a prescription is approved, we have to get it reapproved over and over again. Each time we have to get it reapproved, there is a lapse in treatment. Data suggests that these patients are at a higher risk for pulmonary exacerbation and hospitalization when the reauthorization process interrupts their drugs. I would encourage the committee to reconsider the need for authorization of these drugs.

Dr. Erin Narus clarified that the PDL is not the full formulary for Alaska Medicaid, which has created some confusion. CFTR drugs are part of the Alaska formulary and are available via the prior authorization process. We understand that this group of patients is very fragile in terms of health care needs, and we want to ensure that any barriers from the administrative process are minimized. We have been working with Magellan on automatic renewal authorizations, which should be coming online in the next few months.

Dr. Umang Patel read a letter from Dr. Bruce Marshall and Dr. Lisa Feng advocating for the inclusion of Kalydeco, Orkambi, and Symdeko on the PDL.

DR. LISA ALLEN, a representative of Vertex Medical Affairs, discussed Symdeko, Orkambi, and Kalydeco. Symdeko is indicated for the treatment of patients with cystic fibrosis, ages 12 and older. Several trials and their outcomes were reviewed. Baseline and follow-up examinations are recommended in pediatric patients initiated on Symdeko. On August 7, 2018, the FDA expanded the indication for Orkambi to include children when cystic fibrosis, 2 years of age and older, who are homogenous for the F508del gene mutation based on clinical data. Several studies and their outcomes were reviewed. The efficacy and safety of Orkambi has not been established in patients with CF, other than those who are homozygous for the F508del mutation. On August 16, 2018, the FDA expanded the indication for Kalydeco to include children with cystic fibrosis, 12 months or older, who have one mutation in the CFTC regulator gene that is responsive to Ivacaftor based on clinical and/or in vitro assay data. Several studies and their outcomes were reviewed. Please review the prescribing information for additional information, including a complete list of warnings and precautions.

The committee discussed the CFTC agents. Chairman Ryan said CFTC drugs were on the PDL, but they required prior authorization due to their cost. Dr. Semling said any drugs that exceeds $7,500 per month automatically requires prior authorization.

Dr. Umang Patel gave the Magellan presentation on Cystic Fibrosis: CFTR Potentiator Agents. The medications in the class were reviewed. Symdeko, approved in February 2018, is indicated for the treatment of patients with cystic fibrosis, 12 years of age or greater, who are homozygous for the F508del mutation or who have at least one mutation of the CFTR gene that is responsive to Symdeko based on in vitro data and/or clinical evidence. There have been elevated transaminases observed in patients with cystic fibrosis treated with Symdeko. ALT and AST should be assessed at baseline every three months during the first year of treatment and annually thereafter. A dosing adjustment for

Symdeko is required in patients using concomitant strong CYP3A inhibitors. Recommending dosing was reviewed. It is available as a tablet. The mechanism of action of Symdeko was reviewed. Kalydeco has an FDA expanded indication to include patients from 12 to 24 months. It is indicated for the treatment of cystic fibrosis in patients ages 12 months and older who have one mutation in the CFTR gene that is responsive to Ivacaftor. There were no changes in its limitations. Recommended dosing was reviewed. It is available in tablets and oral granules in unit-dose packets. Orkambi has an FDA expanded indication for patients 2 years of age or greater. There is a new unit-dose packet of oral granules for use in this expanded population. It is indicated for the treatment of cystic fibrosis in patients age 2 years or greater who are homozygous for the F508del mutation in the CFTR gene. The limitations have not changed. Recommending dosing was reviewed. It is available as tablets and oral granules in unit-dose packets.

The utilization report was reviewed: 91.7 percent of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives, to be used appropriately, passed unanimously.

DR. RYAN 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)

Dr. Umang Patel gave the Magellan presentation on Cystic Fibrosis: Antibiotics, Inhaled. Cystic fibrosis is a serious autosomal recessive multiorgan disorder that affects approximately 30,000 children and adults in the United States and is the most common fatal genetic disease in Caucasians. The median expected survival age of patients born between 1992 and 1996 is 31 years, and those born between 2012 and 2016 is 43 years. Mutations lead to the disease of the exocrine gland function, resulting in the formation of thick mucus that builds up in the lungs, digestive tract, and other parts of the body. CFTR functions as a chloride channel. Mutations in CFTR can result in abnormalities of chloride transport across epithelial cells on mucosal surfaces. The goals of cystic fibrosis treatment include maintaining lung function by controlling infection and clearing mucus in the airway, maintaining appropriate growth by providing nutritional support, and managing disease complications. CFTR modulators are the newest class of medications available for this disease and improve chloride ion transport abnormalities. The guidelines from the Cystic Fibrosis Foundation and the Clinical Pharmacogenetics Implementation Consortium were reviewed. Orkambi and Symdeko, which were not approved in 2013/2014, were not addressed in the guidelines.

The utilization report was reviewed: 0 percent of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

Cystic Fibrosis: Pancreatic Enzymes (Green Class)

Dr. Umang Patel gave the Magellan presentation on Cystic Fibrosis: Pancreatic Enzymes. The utilization report was reviewed: 96.6 percent of the prescriptions were for preferred products. At the last review a motion of therapeutic alternatives passed unanimously.

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

4E. Antiviral Monoclonal Antibodies: Respiratory Syncytial Virus (Red Class)

There were no public testimonies.

Dr. Umang Patel gave the Magellan presentation on Antiviral Monoclonal Antibodies: Respiratory Syncytial Virus. Respiratory syncytial virus (RSV) was discovered in 1956 and has since been recognized as one of the most common causes of childhood illnesses. It causes annual outbreaks of respiratory illnesses in all age groups. In most regions of the United States, RSV usually circulates during the fall, winter and spring, but the timing and severity of the RSV season in a given community can vary from year to year. Scientists are developing several vaccines, monoclonal antibodies, and antiviral therapies to help protect infants and young children, pregnant women's unborn babies, and older adults from severe RSV infections. Healthcare professionals should consider RSV in patients with severe respiratory illnesses, particularly during the season. Palivizumab is a monoclonal antibody recommended by the American Academy of Pediatrics to be administered to high-risk infants and young children likely to benefit from immunoprophylaxis based on gestational age and certain underly medical conditions. It is given in a monthly intramuscular injection during the RSV season.

The new drug in the class was reviewed. Synagis is indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease. Its safety and efficacy were established in children with bronchopulmonary dysplasia, infants with a history of premature birth, and children with hemodynamically significant congenital heart disease. The safety and efficacy in children greater than 24 months of age at the start of dosing has not been established. The safety and efficacy of Synagis has not been established for the treatment of RSV disease, only for prevention. Recommended dosing was reviewed. It is available in a single-dose liquid solution vial. The mechanism of action of Synagis was reviewed.

There is no utilization or previous motion for this class as this is its first review.

Erin Narus, explained that this was the first time Synagis was being reviewed for the PDL. Synagis and the criteria surrounding the utilization of Synagis was reviewed by the Statewide Workgroup to set season on/off dates. The committee has been meeting throughout the fall, as the RSV virus circulation has increased over the past several weeks. The current criteria for the use of Synagis is based on previous Red Book recommendations, which were updated in 2014. As mentioned earlier, the PDL is a subset of the overall Alaska Medicaid formulary. Alaska Medicaid provides Synagis to approximately 100 individuals within a given season.

In response to Dr. Ryan, Erin Naris said including Synagis on the PDL would not open the drugs up to prescribing outside of the guidelines recommended by the Statewide Workgroup. The clinical

recommendations of the workgroup would still be utilized, and they would review any specific changes to the criteria. Synagis would still require prior authorization.

DR. CARLSON MOVED TO ADD SYNAGIS TO THE FORMULARY AS A CLASS EFFECT. SECONDED BY RYAN. THE MOTION PASSED UNANIMOUSLY.

4-A. Central Nervous System (Continued): Alzheimer's Agents (Green Class); Anticonvulsants (Red Class); Antidepressants (Blue Class); Antipsychotics - Atypical (Red Class); Multiple Sclerosis Agents (Red Class); Sedative Hypnotics (Green Class); Stimulants and Related Agents (Red Class)

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

There were no public testimonies.

Dr. Umang Patel gave the Magellan presentation on Central Nervous System: Antidepressants. The prevalence of 12-month and lifetime major depressive disorder (MDD) is approximately 16.1 million American adults or 6.7 percent of the American population. The lifetime incidence of MDD is 12 percent in men and 20 percent in women. In addition, the incidence of depression has been reported to occur in approximately 12.5 percent of adolescents, ages 12 to 17. With appropriate treatment, 70 to 80 percent of patients experiencing MDD achieve response. However, as many as one-half of all patients do not experience sufficient symptom improvement with initial treatment. Among patients who remit, residual symptoms are common and associated with impaired psychosocial functioning and increased relapse rates. Until recently, known differences among antidepressant drugs were generally limited to safety and tolerability issues. Over the past few years, a number of studies have emerged to evaluate possible differences among antidepressant classes and their ability to resolve specific symptoms of depression. Each of the groups of drugs in this class has a potential role in the treatment of MDD, primarily as a result to their heterogeneous spectrums of activity. As with many psychotropic drugs, patients failing to respond to one type of antidepressant may respond to a switch to, or augmentation with, an antidepressant with another mechanism of action.

Within the antidepressant group, there are subclasses of different behavioral disease states. Generalized anxiety disorder (GAD) affects about 6.8 million adult Americans and about twice as many women as men. The disorder develops gradually and can begin across the life cycle, though the risk is highest between childhood and middle age. GAD is diagnosed when a person worries excessively about a variety of everyday problems for at least six months or are unable to get rid of their concerns, even though they usually realize that their anxiety is more intense than the situation. Physical symptoms that generally accompany GAD are fatigue, headaches, muscle tension, muscle aches, difficulty swallowing, trembling, twitching, irritability, sweating, nausea, and hot flashes. Social anxiety disorder (SAD) is the most common anxiety disorder in the U.S., affecting approximately 5.3 million people per year. It is the third most common psychiatric disorder after depression and alcohol abuse. It is characterized by a marked and persistent fear of social or performance situations in which embarrassment may occur. Women and men are equally likely to develop the disorder, which usually beings in childhood or early adolescence. SAD is often accompanied by other anxiety disorders or depression, and substance abuse may develop if people try to self-medicate their anxiety. Panic disorder is a severe, chronic anxiety disorder characterized by recurrent episodes of panic and the development of fear or anxiety regarding the possibility of future panic attacks. The incidence ranges

between 3 to 6 million people per year with one-half to two-thirds of those affected being female. Up to 15 percent of the general population experiences isolated panic attacks, whereas up to 3.5 percent develop full panic disorder during their lifetime.

The guidelines from the American Psychiatric Association, the American College of Physicians, the National Institute of Mental Health, the American College of Physicians, the American Psychiatric Association, and the American Academy of Pediatrics were reviewed.

For GAD, the International Consensus Group on Depression and Anxiety (ICGDA) recommends SSRIs, SNRIs, TCAs, and CBT as first-line treatments. For SAD, the ICGDA expert panel guidelines recommend SSRIs as first-line therapy. For panic disorder, the 2009 APA treatment guidelines state SSRIs, SNRIs, TCAs, and Benzodiazepines are roughly comparable in efficacy. SSRIs and SNRIs are frequently preferred as initial therapy due to their favorable safety and adverse effect profile. The APA does not distinguish a particular SSRI amongst those approved by the FDA for panic disorder. For OCD, SSRIs are preferred as a first medication trail. All SSRIs appear to be equally effective; however, individual patients may respond well to one and not to another. For PTSD, SSRIs are the recommended first-line treatment medications.

The guideline update for the American Academy of Pediatrics and the North American Menopause Society and National Network on Depression Centers in 2018 was reviewed.

The utilization report was reviewed. For SSRIs: 97.1 percent of the prescriptions were for preferred products. For Antidepressants, Others: 93.7 percent of the prescriptions were for preferred drugs.

At the last review, a motion for therapeutic alternatives for Antidepressants, SSRIs passed unanimously and a motion for therapeutic alternatives for Antidepressants, Other, passed unanimously.

ANTIDEPRESSANTS, SSRI: DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY RUGGLES. THE MOTION PASSED UNANIMOUSLY.

ANTIDEPRESSANTS, OTHER: DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

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

TIM BIRNER, a representative of Alkermes, discussed Aristada. It is an atypical antipsychotic indicated for the treatment of schizophrenia. Several studies and their outcomes were reviewed. Depending on an individual patient's need, treatment with Aristada can be initiated at various dosage forms: once a month, once every six weeks, or once every eight weeks. The new addition to the family is Aristada Initio. It is indicated for the initiation of Aristada when used for the treatment of schizophrenia in adults. It is part of a one-day initiation regiment combined with a single 30mg Aripiprazole oral dose. The half-life of oral Aripiprazole is two days whereas the half-life of Aristada Initio is two weeks and the half-life of Aristada is two months. By combining all three of these doses on day one, the patient is covered for two months if that 1064 dose is used. The formulation difference between Aristada and Aristada Initio is the particle size of the Aripiprazole crystals. Aristada Initio is

an alternative to 21 days of oral medication. Aristada is the first long-acting atypical antipsychotic with dosing once a month, once every six weeks, or once every two months. These results support Aristada and Aristada Initio as an important treatment option for schizophrenia.

In response to Dr. Phillips, Mr. Birner said the 1064 formulation was dosed every two months and the 882 formulation could be dosed every month or every six weeks. By providing different formulations, Aristada provides physicians with the flexibility to individualize their patient's treatment.

VALERIA NG, a representative of Indivior, discussed Perseris, an extended-release injectable suspension of Risperidone for subcutaneous use. Perseris is indicated for the treatment of schizophrenia in adults. It is to be administered by a healthcare professional in the abdominal area, subcutaneously, and should not be administered by any other route. It is initiated at a dose of 90 milligrams or 120 milligrams, once a month and should not exceed more than one dose per month. Neither a loading dose nor a supplemental oral Risperidone dose is recommended. The most common adverse reactions were increased weight, sedation, and musculoskeletal pain, all of which were consistent with that of the systemic safety profile of oral Risperidone. For complete safety information and boxed warnings, please refer to the full prescribing information. Several studies and their outcomes were reviewed. We request that Perseris be added to the PDL as an additional option for the treatment of schizophrenia in adults.

In response to Dr. Phillips, Ms. Ng agreed that the doses of 90 and 120 milligrams of Perseris were somewhat limiting, but there were ongoing studies to formulate higher doses of Perseris for more severely ill patients.

In response to Dr. Ruggles, Ms. Ng discussed the differences between the subcutaneous route and the intermuscular route. There are no head-to-head trials comparing the pain scale, but the subcutaneous injection is significantly smaller than the intermuscular injection. The volume of the 90 milligrams is 0.6 ml and the volume of the 120 milligrams is 0.8 ml. The amount of pain was included in the study using a scale of 0 to 100 with 100 being the most painful. Immediately after the dose, Perseris was rated 27, but was reduced to 3-5 within 30 minutes to an hour. Perseris is the first and only subcutaneous injection of long-acting antipsychotics in the marketplace.

ADAM SOSU, a representative of Sunovion, discussed Latuda (Lurasidone). Lurasidone is indicated for the treatment of adult and adolescent patients, age 13 to 17, for schizophrenia and for major depressive episodes associated with bipolar I disorder, otherwise known as bipolar depression. It is also indicated as monotherapy in adults. In 2018, it was approved for pediatric patients, ages 10 to 17. In addition, Lurasidone is approved as adjunctive therapy with Lithium or Valproate in adults with major depressive episodes associated with bipolar I disorder. Please refer to the full prescribing information for a complete list of warnings, precautions, and adverse events. An evidenced-based guideline from the 2018 Canadian Network for Mood and Anxiety Treatments, along with the International Society for Bipolar Disorders released treatment recommendations, which lists Lurasidone among first-line agents for the treatment as monotherapy or adjunctive therapy with Lithium or Valproate for acute bipolar depression in adults. Lurasidone is the only first-line agent recommended in children and adolescents with acute bipolar depression. Lurasidone has consistently demonstrated favorable, comparable health outcomes in cost effectiveness in adults with both schizophrenia and bipolar depression. Several analyses and their outcomes were reviewed. Lurasidone addresses the need for well-tolerated and cost-effective treatments for patients with schizophrenia and

bipolar depression. We request that Lurasidone be included on the PDL, without restrictions, which would not include the requirement of failure or previous treatment of another product.

Dr. Umang Patel gave the Magellan presentation on Central Nervous System: Antipsychotics - Atypical. Schizophrenia is the most common psychotic illness, which affects 1 percent of the population. Between 25 and 50 percent of schizophrenic patients attempt suicide, and 10 percent of patients succeed in their attempts. Symptoms include delusions, hallucinations, disorganized speech, disorganized or catatonic behavior, and negative symptoms, and at least one of these should be delusions, hallucinations, or disorganized speech. The guidelines from the American Academy of Child and Adolescent Psychiatry was reviewed. For bipolar disorder, the lifelong prevalence estimates bipolar disorder ranges between 0.9 to 2.1 percent of the population. It is characterized by episodes of mania, depression, or a mixed state. Criterion used to diagnose bipolar I disorder is the presence of a manic episode or a mixed features specifier and three or more other characteristic symptoms. These symptoms include inflated self-esteem or grandiosity, decreased need for sleep, more talkative than usual or pressured speech, flight of ideas or feelings of racing thoughts, distractibility, increase in goal-directed activity or psychomotor agitation, and excessive involvement in risky, pleasurable activities. The guidelines from the American Psychiatric Association were reviewed.

The new drugs in the class were reviewed. Perseris is indicated for the treatment of schizophrenia in adults. Healthcare providers are encouraged to register pregnant women in the pregnancy exposure registry. Patients prescribed Perseris who have hepatic and renal impairment should be carefully titrated with oral Risperidone, up to at least 3 milligrams, prior to starting SC Risperidone at a dose of 90 milligrams. Prior to initiating therapy with long-acting intermuscular antipsychotics, patients should be previously stabilized on short-acting formulations and should have tolerability established with oral agents. Recommended dosages were reviewed. It is available as an abdominal subcutaneous injection by a healthcare provider. Latuda is indicated for the treatment of schizophrenia in adults and adolescents (13 to 17 years), depressive episodes associated with bipolar I disorder in adults and pediatric patients (10 to 17 years) as monotherapy, and depressive episodes associated with bipolar I disorder in adults as adjunctive therapy with Lithium or Valproate. Healthcare providers are encouraged to register pregnant women in the pregnancy exposure registry. Prior to initiating therapy with long-acting intramuscular antipsychotics, patients should be previously stabilized on short-acting formulations and should have tolerability established with oral agents. Boxed warnings include elderly patients with dementia-related psychosis treatment with antipsychotic drugs are at an increase risk of death, and it can increase the risk of suicidal thoughts and behaviors in pediatric and young adult patients. Recommended dosages were reviewed. It is available as a tablet. Abilify Maintena was reviewed. In November 2017, the FDA approved the first oral tablet with a digital ingestible tracking system, which was an Aripiprozole tablet with a sensor. It is indicated for the treatment of adults with schizophrenia, bipolar 1 disorder, or major depressive disorders. Tolerability to oral Aripiprozole should be estimated prior to initiating Ability Maintena. It should only be administered by intramuscular injection in the deltoid or gluteal muscle by a healthcare professional. For patients naïve to Aripiprazole, tolerability with oral Aripiprazole should be established prior to initiation. In conjunction with the first dose, take 14 consecutive days of concurrent oral Aripiprazole or current oral antipsychotic. In 2016, the FDA issued a drug safety communication regarding impulsive or uncontrollable problems associated with Aripiprazole-containing products (Ability, Abilify Maintena and Aristada), including compulsive or uncontrollable urges related to gambling, shopping/spending money, binge eating, and sexual behavior. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Recommendations for dosing were reviewed.

It is available as an extended-release suspension in syringes and lyophilized powder in vials for injection. Aristada Initio is indicated in combination with oral Aripiprazole for the initiation of Aristada when used for the treatment of schizophrenia in adults. It should be administered by a healthcare professional in combination with a single 30-milligram dose of oral Aripiprazole. The first Aristada dose may be administered on the same day as Aristada Initio or up to 10 days thereafter. Aristada Initio is not interchangeable with the original Aristada due to differing pharmacokinetics. Elderly patients with dementia-related psychosis treatment with antipsychotic drugs are at an increased risk of death. Recommended dosages were reviewed. It is available in an extended-release suspension for injection in syringes.

The utilization report was reviewed: 97.5 percent of the prescriptions were for preferred products. At the last review, a motion for 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, passed.

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 HAS A DURATION OF AT LEAST FOUR WEEKS. SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.

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

LYNDA FINCH, a representative of Biogen, discussed Tecfidera. Tecfidera is the most prescribed MS medication in the United States. It has been used by over 300,000 patients worldwide and is the most prescribed disease-modifying therapy for MS by Medicaid patients in the in state of Alaska. It is currently in a preferred drug on the formulary, and we request that it remain a preferred agent so patients who are newly diagnosed can use Tecfidera as a first-line agent. Several studies and their outcomes were reviewed. Tecfidera has shown a very consistent efficacy and safety profile that has been characterized in over 300,000 patients worldwide and over 3,000 clinical trial patients. It is a combination of its unique mechanism of action and its consistent safety and efficacy profile that makes it an ideal product for preferred placement on the PDL.

Dr. Umang Patel gave the Magellan presentation on Central Nervous System: Multiple Sclerosis Agents. Multiple Sclerosis (MS) is a complex human autoimmune-type inflammatory disease of the central nervous system. More than 2.3 million people worldwide have MS. It occurs most commonly in Caucasians, with rare cases in African-Americans and Asian-Americans. Although the etiology is predominantly unknown, MS is characterized pathologically by demyelination and subsequent axonal degeneration. The nerve degeneration associated with MS can result in a wide variety of symptoms including sensory disturbances resulting in numbness, paresthesia, burning, and pain in the limbs, optic nerve dysfunction, ataxia, fatigue, and bladder, bowel, and sexual dysfunction. Severe cases may result in partial or complete paralysis. While cognitive impairment occurs in approximately 50 percent of people with MS, only 10 percent experience serious intellectual deterioration. MS can be categorized as either relapsing-remitting MS, which is observed in 85 to 90 percent of patients, or primary progressive MS, which is observed in 10 percent of patients. Relapses or attacks typically present subacutely, with symptoms developing over hours to several days, persisting for several days or weeks, and then gradually dissipating. The clinical course of MS falls into one of the following categories:

relapsing-remitting, primary progressive, secondary progressive, progressive-relapsing, or clinically isolated syndromes. The guidelines from the American Academy of Neurology and the International Pediatric MS Study Group and American Academy of Neurology were reviewed.

Drugs in the class were reviewed. Gilenya has expanded approval and is now for patients 10 years of age and older. It is indicated for relapsing forms of MS in patients 10 years of age and older. Patients taking class Ia or III antiarrhythmics, beta-blockers, and calcium channel blockers are at increased risk of developing bradycardia or heart blocks while on Fingolimod. Serous adverse events described for Fingolimod include bradyarrhythmia and atrioventricular blocks, infections, macular edema, respiratory effects, and cutaneous malignancies. It is a pregnancy category C drug. Recommended dosages were reviewed. It is available as a capsule. On March 2, 2018, Abbvie/Biogen announced a voluntary global withdrawal of the interleukin-2 blocking antibody Zinbryta following seven reports of serious inflammatory encephalitis and meningoencephalitis. Glatopa is a branded generic of Copaxone that was approved via an abbreviated new drug application. It is indicated for relapsing forms of MS. warnings associated with Glatiramer include post-injection reaction, chest pain, lipoatrophy and skin necrosis, and effects on the immune system. Recommended dosing was reviewed. It is available in single-dose prefilled syringes.

The utilization report was reviewed: 73.3 percent of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

Central Nervous System: Sedative Hypnotics (Green Class)

Dr. Umang Patel gave the Magellan presentation on Central Nervous System: Sedative Hypnotics. The utilization report was reviewed: 62.1 percent of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

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

There were no public testimonies.

Dr. Umang Patel gave the Magellan presentation on Central Nervous System: Stimulants and Related Agents. Attention deficit hyperactivity disorder (ADHD) has been diagnosed in approximately 11 percent of children 4 to 17 years of age and about 4 percent of adults. It is a chronic condition with core symptoms of inattention, hyperactivity, and difficulty controlling behavior. It may also be accompanied by internalized disorders, such as sadness and anxiety, as well as aggressive and oppositional disorders. The three main types of ADHD are primary hyperactive, primary inattentive, and mixed.

The guidelines from the American Academy of Pediatrics and the Medical Letter were reviewed.

Drugs in the class were reviewed. Jornay PM is indicated for the treatment of ADHD in patients greater than 6 years of age. It is not substitutable for other methylphenidate products on a milligram to milligram basis. Recommended dosages were reviewed. It is available as a capsule. This medication has not launched and is anticipate in early 2019. Adzenys ER is a new formulation indicated for the treatment of ADHD in patients greater than 6 years of age. Cases of intestinal necrosis, resulting in some deaths, have been reported with the concomitant use of sodium polystyrene sulfonate and sorbitol, inactive ingredients found in Adzenys ER. Recommended dosages were reviewed. It is available in an orally disintegrating tablet or a suspension.

The utilization report was reviewed: 98.1 percent of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include at least one oral preparation, one extended-release preparation, one non-stimulant preparation, one alpha agonist, and one orally disintegrating preparation or liquid passed unanimously.

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

Erin Narus noted the guidelines were from 2011 and asked the committee if they were seeing any changes in terms of transitioning away from stimulants to more non-stimulants in initiating therapy due to the risk of abuse.

Dr. Phillips said parents prefer stimulant medications primarily because it is active on the day it is used, and they do not have to use it on days that they do not want their child to be on the medication. Dr. Ryan said the abuse potential of stimulants, as defined by the FDA, is people using the medication when it was not prescribed to them, such as college students studying for exams. He has never seen anyone become addicted to stimulants. Dr. Phillips agreed that she has never had to stop a medication for an ADHD patient because it was being abused.

THE MOTION PASSED UNANIMOUSLY.

Dr. Phillips excused herself for the remainder of the meeting.

4D. Substance Dependence: Opioid Dependence (Red Class); Opioid Reversal Agents (Green Class); Smoking Cessation Products (Green Class)

Public Comments for Substance Dependence: Opioid Dependence (Red Class)

TIM BIRNER, a representative of Alkermes, discussed Vivitrol. It is indicated for the treatment of alcohol dependence as well as the prevention of relapsed opioid dependence following opioid detoxification. Treatment with Vivitrol for either indication should be part of a comprehensive program that includes psychosocial support. It is not an opioid replacement therapy, but an opioid antagonist. It is not a controlled substance or associated with the development of tolerance or

dependence. There is no potential for abuse and no diversion issues. Several studies and their outcomes were reviewed. We appreciate the availability of Vivitrol on the PDL and request that it be maintained in that position.

VALERIE NG, a representative of Indivior, discussed Sublocade. Sublocade injection for subcutaneous use is an extended-release formulation of Buprenorphine, which is a mu-opioid partial agonist. It is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with an oral or transmucosal Buprenorphine-containing product, followed by a dose adjustment for a minimum of seven days. It should be used as a part of a complete treatment plan that includes counseling and psychosocial support. It should only be administered subcutaneously in the abdominal region, once a month, as serious harm may occur if administered intravenously. It comes in 100- and 300-milligram prefilled syringes and is provided to a Data 2000 Waivered healthcare professional. The recommended dosages were reviewed. Several studies and their outcomes were reviewed. Sublocade is physician-administered injection that forms a depot after subcutaneous administration. It is distributed through a closed distribution system and is subject to Risk Evaluation and Mitigation Strategy (REMS). We request that you consider the coverage of Sublocade as an additional treatment option for patients who are suffering from moderate to severe opioid use disorder.

Erin Narus read a letter from Jyll Green, a family nurse practitioner with Alaska Regional myHealth Clinic, advocating for the inclusion of Vivitrol on the Alaska PDL.

Dr. Umang Patel gave the Magellan presentation on Substance Dependence: Opioid Dependence. There is an estimated 28.6 million Americans, ages 12 years and older, who were current illicit drug users. There were approximately 11.8 million people, ages 12 and older, in the United States who misused opioids between 2016 and 2017. Approximately 20.1 million people, ages 12 and older, in 2016 were considered to have a substance use disorder, including 15.1 million people with an alcohol use disorder, 7.4 million people with an illicit drug use disorder, and 2.1 million had an opioid use disorder. Under the Drug Addiction Treatment Act of 2000, in order 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 Services of their intention of prescribing or dispensing Buprenorphine. Such practitioners hold a modified Drug Enforcement Administration registration in which they are designated by a unique identifier and must include it on each prescription written. Prescribers are limited in the number of patients they may treat under a waiver, but they may request approval to treat additional patients.

The guidelines from the American Society of Addiction Medicine, the Centers for Disease Control and Prevention, and the Surgeon General of the United States were reviewed.

Drugs in the class were reviewed. Cassipa is a new FDA-approved medication. It should be used as part of a complete treatment plan to include counseling and psychological support. It is indicated for the maintenance treatment of opioid dependence. Patients should only be started after induction and stabilization of the patient and the patient has been titrated to a dose of 16 milligrams of Buprenorphine using another marketed product. Recommended dosages were reviewed. It is available as a sublingual film. Lucemyra is FDA approved as the first non-opioid agent to mitigate opioid withdrawal symptoms. It is indicated in the reduction of opioid withdrawal symptoms in adults following abrupt discontinuation of opioids. It may decrease blood pressure, pulse, and syncope. Vital signs should be monitored before the dose of Lofexidine, and ongoing monitoring for bradycardia,

hypotension, and orthostasis is recommended. It is known to prolong the QT interval and should be avoided in patients with congenital long QT syndrome. It may potentiate the CNS depressive effects of alcohol, barbiturates, and other sedating drugs including benzodiazepines. Patients who have discontinued opioids during initial treatment with Lofexidine are at increased risk of fatal overdose if opioids are resumes. The recommended dosages were reviewed. It is available as a tablet. Sublocade is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treated with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of seven days. It should be used as part of a complete treatment plan that includes counseling and psychosocial support. There are boxed warnings for serious harm or death if the injection is administered intravenously. There is a REMS program to ensure the healthcare setting and pharmacy is certified and that the injection is dispensed directly from the pharmacy to a healthcare provider to avoid the risk of serious harm or death due to intravenous administration. The recommended dosages were reviewed. It is available in prefilled syringes with safety needles.

The utilization was reviewed: 85.1 percent of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include Vivitrol passed unanimously.

In response to Dr. Ryan, Erin Narus explained how prices for covered outpatient drugs were negotiated.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE VIVITROL AND A SUBCUTANEOUSLY-ADMINISTERED ALTERNATIVE.

DR. RUGGLES OFFERED A FRIENDLY AMENDMENT TO STATE THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE LONG-ACTING INJECTABLE PRODUCT.

In response to Dr. Ryan, Dr. Ruggles explained the friendly amendment. Instead of mandating both Vivitrol and a subcutaneous-administered alternative, he suggested including at least one long-acting injectable. This would not exclude Medicaid from including both agents, but it would provide them with some flexibility.

DR. RYAN ACCEPTED THE FRIENDLY AMENDMENT. SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.

Substance Dependence: Opioid Reversal Agents (Green Class)

Dr. Umang Patel gave the Magellan presentation on Substance Dependence: Opioid Reversal Agents. The utilization report was reviewed: 0 percent of the 207 prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include Narcan passed unanimously.

After discussion, it was determined the utilization report was incorrect and 100 percent of the prescriptions were for Narcan, which is an approved drug on the PDL.

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

Substance Dependence: Smoking Cessation Agents (Green Class)

Dr. Umang Patel gave the Magellan presentation on Substance Dependence: Smoking Cessation Agents. 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. Approximately 70 percent of smokers have a desire to quit completely, and 55 percent have made a quit attempt in the past year. Discontinuing smoking often requires multiple attempts. Relapse is often caused by stress, weight gain, and withdrawal symptoms. Examples of common nicotine withdrawal symptoms include irritability, anxiety difficulty concentrating, and increased appetite.

The guidelines from the Clinical Practice Guidelines for Treating Tobacco Use and Dependence were reviewed. All smokers who are trying to quit should be offered medication except when contraindicated for specific populations or if there is insufficient evidence. All seven of the approved medications for treating tobacco use are recommended as first-line therapy.

The utilization report was reviewed: 97.3 percent of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include Chantix passed unanimously.

DR. RUGGLES MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVE TO INCLUDE CHANTIX. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

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

Public Comments for Analgesics: Antimigraine Agents (Red Class)

SYLVIA CHURCHILL, a representative of Amgen, discussed Aimovig, which is indicated for the preventative treatment of migraine. This new group of drugs is taken to prevent migraines or to decrease the number of migraines that a patient experiences, which is different than drugs that are taken to treat an acute migraine. The American Academy of Neurology recommends that patients who suffer from four or more migraines per month should consider preventive therapy. Before this new class of drugs was approved this year, the available agents to try and prevent migraines included certain oral beta-blockers, certain antiseizure medications, and certain antidepressants. None of these are specifically formulated for migraine prevention. They are effective in some patients, but not in others. The older oral agents have significant side effects that often lead to discontinuation due to intolerability. Aimovig is the first fully-human monoclonal antibody that targets the CGRP receptor. CGRP is the neuropeptide that is implicated in migraine headaches when levels are elevated. By inhibiting CGRP, you can decrease the number of migraines that patients experience. The recommended dosages were reviewed. This is a self-administered medication that is a monthly subcutaneous injection and it is supplied as a sure-click autoinjector. The full prescribing information is available online. Several studies and their outcomes were reviewed. If patients are managing their migraines successfully on oral therapy, they should continue to do so. Aimovig is intended for those patients who have tried oral preventive therapy and have had an insufficient response to experienced

poor tolerability. Migraine is a very difficult disease and significantly impacts a patient's quality of life and ability to perform work. We request that Aimovig be included on the Alaska PDL.

Dr. Umang Patel gave the Magellan presentation on Analgesics: Antimigraine Agents. Migraine accounts for 10 to 20 percent of all headaches in adults and affects over 39 million men, women, and children in the U.S. It is one of the most common complaints by patients when presenting to a physician. Sixty-four percent of physician-diagnosed patients who experience migraines and 41 percent of undiagnosed migraine sufferers reported severe impairment or the need for bed rest due to their symptoms. In addition, 18 percent of women, 6 percent of men, and 10 percent of children experience migraine. Approximately 85 percent of patients with migraine headaches suffer less than three to four attacks per month. The median frequency of a migraine attack among migraine suffers is 1.5 per month. Migraine headaches must be differentiated from tension-type headaches. The key criteria for the diagnosis of migraine headache includes an episodic headache lasting four to 72 hours with at least two of the following symptoms: unilateral pain, throbbing, aggravated by routine physical activity, pain of moderate to severe intensity. During the headache at least one of the following are present: nausea and/or vomiting, or photophobia and phonophobia.

The guidelines from the American Academy of Neurology and the American Headache Society were reviewed.

Drugs in the class were reviewed. Aimovig is indicated for the preventative treatment of migraine in adults. There is no adequate data in pregnant, pediatric or geriatric patients. The recommended dosages were reviewed. It is available as a solution in a single-dose prefilled syringe or auto-injector. Endo Pharmaceuticals has announced they will discontinue Sumavel DosePro 6-milligram injection for reasons that are not related to quality, safety, or efficacy of the product. The FDA indicates that the end market date for both strengths is April 30, 2019. The 4-milligram formulation was discontinued in 2016. Treximet was FDA approved as first generic. It is indicated for acute treatment of migraine attacks with or without aura in those 12 years of age and older. It is pregnancy category C. Products containing NSAIDs should not be used in pregnant women during the third trimester due to risk of premature closure of the ductus arteriosus, which makes it category X. Treximet should not be used in patients with advanced renal disease. Recommended dosages were reviewed. It is available as tablets.

The utilization report was reviewed. Antimigraine Agents, Triptans: 94.2 percent of the prescriptions were for preferred products. Antimigraine Agents, Other: 0 percent of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

MARIE AGAPOVA, a representative of Teva Pharmaceuticals, discussed Ajovy. It is a fully-humanized monoclonal antibody. (Indiscernible -- telephonic.) Ajovy is an injectable formulation that can be administered both by a healthcare professional, patients, and caregivers. It offers both monthly and three-month dosing regimen. The exposure to this drug has been well established. The most prevalent adverse event is injection site reaction in about 1 percent of the patients.

DR. CARLSON MOVED THE ANTIMIGRAINE AGENTS, TRIPTANS DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

The committee discussed the Antimigraine Agents, Other class. Dr. Umang Patel referenced the guidelines from the American Academy of Neurology and the American Headache Society. An updated guideline was anticipated for mid-2018 but has not yet been released. Dr. Semling said these products were new to the marketplace so there is very little utilization information. The committee discussed possible motions for this class.

DR. RUGGLES MOVED THE ANTIMIGRAINE AGENTS, OTHER, DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE INJECTION AND AT LEAST ONE ORAL PREPARATION.

Erin Narus said the Antimigraine, Other, class would include ergots and the new biologics. Preventative medications are not incapsulated within this group based on the market basket. Page 28 of the utilization report includes the products the motion would apply. The medically necessary clause could always be utilized. You could also request that the Drug Utilization Review Committee look at the clinical appropriateness of the various products.

The committee continued to discuss the Antimigraine Agents, Other, class. A question was raised as to whether it was appropriate to include drugs that prevent acute migraines with preventative drugs, because they could not be deemed therapeutic alternatives. Dr. Umang Patel said did not know the answer, but he could research it. Erin Narus said class effect might be something more similar to an ACE inhibitor. Therapeutic alternatives recognize that there are different mechanisms of action. With a mixed class like this, we can entertain a motion that would consider the mix of mechanisms and indications.

THE MOTION FAILED DUE TO LACK OF A SECOND.

DR. RUGGLES MOVED THE ANTIMIGRAINE AGENTS, OTHER, DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO BOTH TREATMENT AND PREVENTION OF MIGRAINES. SECONDED BY DR. RYAN. THE MOTION PASSED.

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

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Analgesics: Opioid, Long-Acting. While definitions vary, chronic pain is generally defined as pain lasting more than three months or past the time required for normal tissue healing. It has various etiologies, including injury, inflammation, and underlying medical conditions. Approximately 11.2 percent of adults report daily pain, which is greatly misunderstood. Historically, data has suggested that pain may be undertreated, but newer estimates imply that opioid treatment for pain may be overutilized. An estimated 20 percent of patients presenting to outpatient providers with noncancer pain or pain-related diagnoses, whether acute or chronic, receive an opioid prescription. Per capita, opioid prescriptions increased by 7.3 percent from 2007 to 2012 with prescribers writing 66.5 opioid prescriptions for every 100 Americans in 2016. Unfortunately, approximately 165,000 people have died from overdoses related to opioid pain medications in the U.S. from 1999 to 2004. Drug-related deaths have tripled from 1999 to 2015. During 2015 alone, 33,091 people in the U.S. died from opioid-related overdoses. Opioid-related overdose was higher among males in comparison to females. Despite this, persistent pain that is

uncontrolled may have clinical, psychological, and social consequences; thus, it is critical to weight the risks and benefits of opioid use and reevaluate routinely for appropriate dose, duration, and treatment choice, including both pharmacologic and nonpharmacologic modalities.

The guidelines from the Centers for Disease Control and Preventions, the HIV Medicine Association of the Infectious Disease Society of America, and the American Association of Oral and Maxillofacial Surgeons were reviewed.

The utilization report was reviewed: 65.2 percent of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include at least one oral preparation, one transdermal preparation, and at least one abuse-deterrent preparation passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE ORAL PREPARATION, ONE TRANSDERMAL PREPARATION AND ONE ABUSE-DETERRENT PREPARATION. SECONDED BY DR. RUGGLES. THE MOTION PASSED UNANIMOUSLY.

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

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Analgesics: Opioid, Short-Acting. The guidelines from the American College of Obstetrics and Gynecology were reviewed.

Drugs in the class were reviewed. Apadaz is indicated for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. It exposes patients and other users to the risk of opioid addiction, abuse, and misuse, which can lead to overdose and death. Access each patient's risk prior to prescribing benzhydrocodone/acetaminophen and monitor all patients regularly for the development of these behaviors and conditions. To ensure that the benefits of opioid analgesics outweigh the risk of addiction, abuse and misuse, the FDA has required a REMS for these products. Prolonged use of Apadaz during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. The recommending dosages were reviewed. It is available as immediate-release tablets. Abstral is FDA approved first generic. It is indicated for breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain for patients 18 years of age and older. To ensure that the benefits of opioid analgesics outweigh the risk of addiction, abuse, and misuse, the FDA has required a REMS for these products. The recommended dosages were reviewed. It is available in tablets of various micrograms.

The utilization report was reviewed: 25.1 percent of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

Public Comments for Analgesics: Neuropathic Pain (Red Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Analgesics: Neuropathic Pain. Neuropath pain has recently been defined as the pain that evolves as a result of direct injury or disease to the nervous system, specifically the somatosensory system. It can be caused by a number of different diseases, such as diabetes mellitus, herpes zoster, HIV infection, and medical interventions.

The guidelines from the Mayo Clinic, the American Academy of Neurology for Management of Diabetic Neuropathic Pain, and the American Academy of Neurology for Treatment of Postherpetic Neuralgia were reviewed.

Drugs in the class were reviewed. Ztlido is indicated for the relief of pain associated with post-herpetic neuralgia. It is contraindicated in patients with a known history of sensitivity to local amide anesthetics, or to any other component of the product. Patients with severe hepatic disease are at greater risk of developing toxic blood concentrations of Lidocaine because of their inability to metabolize Lidocaine normally. The recommended dosages were reviewed. It is available as a patch as a single-use topical system. Lyrica CR is FDA approved as an ER formulation of Lyrica for the treatment of neuropathic pain associated with diabetic peripheral neuropathy and postherpetic neuralgia. It is not approved for fibromyalgia or seizures. It is a schedule V controlled substance. Gabapentin and Pregabalin should be gradually withdrawn over at least a one-week period to minimize the potential of increased seizure frequency. The recommended dosages were reviewed. It is available as extended-release tablets.

The utilization report was reviewed: 98.9 percent of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

Analgesics: NSAIDs (Green Class)

Dr. Umang Patel gave the Magellan presentation on Analgesics: NSAIDs. NSAIDs are commonly used to treat a variety of diseases including rheumatoid arthritis, osteoarthritis, and pain from various etiologies. It is the most widely used drug in the U.S. with approximately 80 million prescriptions. It is estimated that over-the-counter NSAIDs are used five to seven times more often than prescription NSAIDs. NSAIDs are associated with adverse effects including gastrointestinal bleeding, peptic ulcer disease, hypertension, edema, and renal disease. They have also been linked with an increased risk of myocardial infarction which is reflected in the boxed warning for all NSAIDs. In July 2015, the FDA issued a safety alert strengthening the existing warning on the increased risk of heart attack and stroke risk association with NSAIDs.

The utilization report was reviewed: 99.7 of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

Public Comments for Analgesics: Restless Leg Syndrome (Blue Class)

There were no public comments.

Dr. Umang Patel gave the Magellan presentation on Analgesics: Restless Leg Syndrome (RLS). RLS is a neurological sensory disorder in which patients experience irrepressible sensations in the legs or arms while sitting or lying still to cause them to move their arms or legs. Studies suggest the RLS is associated with the dopamine system and depletion of iron stores. Providers will need to rule out other movement disorders with similar symptoms such as periodic limb movement disorder, antipsychotic drug adverse effects, and dyskinesis to correctly diagnose and treat these symptoms. Historically, RLS has been treated with opioids, benzodiazepines, anticonvulsants, iron replacement, and dopaminergic agents. Mirapex, Requip, Neupro, and Horizant are approved for patients with RLS.

The guidelines from the Scientific and Medical Advisory Board of the Restless Legs Syndrome Foundation and the American academy of Neurology were reviewed.

The utilization report was reviewed: 97.8 percent of the prescriptions were for preferred products. At the last review, a motion of class effect passed unanimously.

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

Analgesics: Skeletal Muscle Relaxants (Green Class)

Dr. Umang Patel gave the Magellan presentation on Analgesics: Skeletal Muscle Relaxants. Skeletal muscle relaxants are FDA-approved to treat two types of conditions: muscular pain or spasms from peripheral musculoskeletal conditions and spasticity from upper motor neuron syndromes. Both conditions affect a patient's mobility and independence in activities of daily living and work. Spasticity is a condition in which muscles are continuously contracted causing stiffness or tightness, which may interfere with movement and speech. It is usually caused by damage to the portion of the brain or spinal cord that controls voluntary movement. It is a major health concern and can be associated with a number of disease entities such as spinal cord injury, multiple sclerosis, traumatic brain injury, cerebral palsy, and stroke. Common musculoskeletal conditions associated with muscle spasms include low back pain, neck pain, tension headaches, and myofascial pain syndrome. Hypertonicity and hyperreflexia are not present as with upper motor neuron syndromes. These conditions can cause significant disability and pain.

The guidelines from the Multiple Sclerosis Council for Clinical Practice Guidelines for Spasticity Management were reviewed.

The utilization report was reviewed: 70.8 percent of the prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

Erin Narus noted this concluded the public portion of the meeting. She thanked everyone who attended. The next meeting is scheduled for Friday, January 18, 2019, at 8:00 a.m.

5. Review of Minutes from September 2018

The committee reviewed the meeting minutes of September 2018.

DR. (UNIDENTIFIED) MOVED TO APPROVE THE MEETING MINUTES FROM SEPTEMBER 2018. SECONDED BY DR. (UNIDENTIFIED). THE MOTION PASSED UNANIMOUSLY.

6. Comments from Committee Members or Chair

This issue was discussed off the record.

7. Adjournment

The next meeting is scheduled for January 18, 2019.

The meeting adjourned at 11:56 a.m.