ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

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

MINUTES OF MEETING
November 15, 2013
8:00 a.m.

Committee Members Present:
Dharma Begich, Pharm.D.
Marvin Bergeson, MD
Robert Carlson, MD
Jeffrey Demain, MD
Vincent Greear, R.Ph.
Jenny Love, MD
Claudia Phillips, MD
John Riley, PA-C
Chuck Semling, Pharm.D.
Jill Reid, R.Ph (telephonic)
Trish White, R.Ph. (telephonic)
Greg Salard, MD

Committee Members Absent:
Diane Liljegren, MD
John Pappenheim, MD
Maggi Rader, CNM

Others Present:
Chad Hope, Pharm.D.
Erin Narus, Pharm.D., Magellan Medicaid Administration
CJ Kim, R.Ph.

Due to the need for extensive revisions the approved minutes for this meeting is limited to the summary of the motions below. The draft minutes follow for historical reference.

Review of Vaginal Antibiotics (Red Category):
MR. GREEAR MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILIPS. THE MOTION PASSED UNANIMOUSLY.

Re-review of Multiple Sclerosis Agents (Red Category):
DR. SEMLING MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE INJECTABLE AND ONE ORAL. SECONDED BY DR. PHILLIPS. THE MOTION PASSES UNANIMOUSLY.

Re-review of Antihyperuricemics (Blue Class):
DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE ZANTHINE OXIDASE INHIBITOR, ONE COLCHICINE PRODUCT, AND ONE URICOSURIC PRODUCT. SECONDED BY DR. LOVE. THE MOTION PASSED UNANIMOUSLY.

Re-review of Alzheimer's Agents (Blue Class):
MR. RILEY MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY MR. GREEAR. THE MOTION PASSED UNANIMOUSLY.

Re-review of 2nd Generation Antipsychotics – Injectable (Blue Class):
DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE AGENT THAT IS ABLE TO BE DOSED MONTHLY TO EXCLUDE ZYPREXA RELPREVV. MOTION FAILS DUE TO LACK OF A SECOND.

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

Re-review of Stimulants and Related Agents (Blue Class):
DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE IMMEDIATE RELEASE, ONE EXTENDED RELEASE, AND ONE NON-STIMULANT FORMULATION. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

Re-review of Long-Acting Narcotic Analgesics (Green Class):
DR. LOVE MOVED DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE TRANSDERMAL PREPARATION. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

Re-review of Antimigraine Agents (Green Class):
DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

Re-review of NSAIDs (Green Class):
DR. CARLSON MOVED A CLASS EFFECT AND ALSO INCLUDES A COX-2 AND A TOPICAL. SECONDED BY DR. BERGESON. THE MOTION PASSED WITH ONE OPPOSED.

Re-review of Opiate Dependence Treatments (Green Class):
DR SEMLING MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES AND TO INCLUDE AN INJECTABLE AND ONE ORAL. SECONDED BY DR. SALARD. MOTION FAILS BY A VOTE OF 7 NAYS TO 5 AYES.

MR. GREEAR MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. LOVE. MOTION PASSED WITH 2 OPPOSED.

Re-review of GI Antibiotics (Green Class):
DR. LOVE MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Re-review of Hepatitis B Agents (Green Class):
DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. CARLSON. THE MOTION PASSED UNANIMOUSLY.

Re-review of Hepatitis C Agents – Ribavirins (Green Class):
DR. LOVE MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

Re-review of Hepatitis C Agents – Interferons (Green Class):
DR BERGESEN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. LOVE. THE MOTION PASSED UNANIMOUSLY.

Re-review of Hepatitis C Agents – Oral Protease Inhibitors (Green Class):
DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. SEMLING. THE MOTION PASSED UNANIMOUSLY.

Re-review of Erythropoiesis Stimulating Agents (Green Class):
DR BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. LOVE. THE MOTION PASSED UNANIMOUSLY.

Re-review of Phosphate Binders (Green Class):
DR. LOVE MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

Re-review of 2nd Generation Antipsychotics – Oral (Green Class):
DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

Review minutes from April 19, 2013 meeting: DR. LOVE MOVED TO ACCEPT THE MINUTES AS AMENDED, WITH THE CORRECTIONS BY DR. DEMAIN. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

End of approved minutes

1. Call to Order – Chair

Dr. Dermain called the meeting to order at 8:00 a.m.

2. Roll Call

A quorum was present.

3. Public Comments – Local Public/Health Practitioners

Jannette Grastone, NAMI, requested that the committee keep open access to all potentially effective FDA approved anti-psychotics, because we will never know which one will work for each individual person.

4. Review of Vaginal Antibiotics (Red Category)

There were no public testimonies.

Ms. Narus gave the Magellan presentation of Vaginal Antibiotics. All products within this class are indicated for the intervaginal treatment of bacterial vaginosis, resulting from Gardnerella Vaginalis and Mycoplasma hominis in non-pregnant women. Clindamycin cream is also FDA approved for treatment in pregnant women in their second and third trimesters. Bacterial vaginosis has been associated with adverse pregnancy outcomes including premature rupture of membrane, preterm labor, intraamniotic infections, and postpartum endometritus. All women, regardless of pregnancy status, who have symptomatic disease, require treatment. CDC guidelines recommend oral metronidazole or oral clindamycin for pregnant women with bacterial vaginosis. Oral therapy is preferred in pregnant women because of the possibility of a clinical upper genital tract infection. There is currently no existing data to support the use of topical agents during pregnancy. Further, the CDC does not support the use of intervaginal metronidazole to treat pregnant women. Oral based products, such as clindamycin cream may weaken latex condoms and diaphragms. Metronidazole gel products are _____. Other pathogens commonly associated with vaginitis include Trichomonas, Chlamydia, Gonorrhea, Candida albicans, and Herpes simplex, and those agents should be ruled out.

This is a new class utilization within the month of September for this class. There were 35 claims for Metronidazole, accounting for approximately 79.5%. Clindamycin crème at 9.1%, and Cleocin ovules at 4.5%. As this is a new class, there is no previous discussion. Significant changes in the past year include

Clendes, which had been removed from the market in 2009 due to noncompliance with CGMP or Good Manufacturing Processes and reentered the market in August 2013.

Ms. Narus stated that the majority of pregnant women are treated orally; the topical route is the acceptable route for non-pregnant women. Mr. Hope explained there is low utilization, approximately 60 claims a month, but one where there was potential so wanted to add this.

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

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

Public testimony: Dr. Deborah Profant, medical science liaison for TelePharmaceutical, testified that a NAH funded study has evaluated the combination of Copaxone with Avonex in MS patients compared to a Copaxone alone arm, and also to an Avonex alone arm. This was a double blind, randomized, controlled study. The primary endpoint was annualized relapse rate. Both the combination arm with Copaxone and Avonex together had a similar relapse rate to the Copaxone single agent arm. The relapses in those groups were significantly lower than the relapse rate in the Avonex alone arm. No agent was better or no arm of the study was better at change in disability, and the adverse event profiles in the study were similar to the published adverse events for these agents. There were no new significant safety signals and the most common side effect attributed to Copaxone continues to be injection site reaction. Copaxone remains the only agent with Pregnancy Category B, even in light of the more recently approved agents for relapsing remitting MS.

Public Testimony: Dr. Deborah Crawford, Acorda, testified providing new information for Ampyra extended release tablets, which has become available since the last review of Amprya. Amprya is a potassium channel blocker indicated to improve walking in patients with multiple sclerosis. This was demonstrated with an increase in walking speed. A recently published analysis utilizing the dalfampridine pivotal trial data further evaluated the clinically meaningful changes in a timed 25 foot walk and the 12 item multiple sclerosis walking scale, a patient reported outcome. Across nine groups, with a total range in walking speed change from greater than 20% slower to greater than 40% faster, results showed a relationship between the timed 25 foot walk and the MSWS 12. There was an indication that as walking speed improves or worsens, self reported walking ability improves or worsens. Additionally, there was notable MSWS 12 change score variability in all nine of the walking speed groups. This finding is expected when instruments measure different aspects, speed and ability in this study of a common variable walking from different perspectives, that of a clinician and patient. This highlights the complexity and diversity of walking and the challenges associated with walking measurement. This finding also highlights concerns about extrapolating group based clinical trial results and the individual patient clinical decision making need arise in routine clinical practice. The post marketing safety data on safety experience available from the clinical trials and from the exposure of approximately 62,400 patients in the United States since launch through March 2012 were presented at Ectrins in October 2012, and were similar to previous reported data after one year post marketing use. The most commonly adverse

events at two years were those already described in the US product labeling. In the United States, cases of seizures and convulsions are expected events and additional information on seizures was actively sought as part of the REMS commitment making significant under-reporting of this event unlikely. Seizures were reported at a rate of 4.6% per 1,000 patient years after two year post marketing use, which is consistent with the reported rate after one year post marketing use. Amprya is contraindicated in patients with a history of seizures and patients with moderate or severe renal impairment, and in patients with a hypersensitivity to dalfampridine or 4AP. Additionally, on June 18, 2013, Acorda received a letter from the FDA informing Acorda that they had been granted approval to remove the REMS program. The decision by the FDA to remove the REMS was based on the Agency's assessment that Acorda had successfully completed the communication goals of the REMS program, and that the communication plan was no longer required to insure that the benefits of the drug outweigh the risks. Acorda will continue to abide by its obligation to inform patients and health care professionals about the risk and benefits of Ampyra. The medication guide will continue to be provided as part of the package insert, which accompanies every prescription of Ampyra.

Dr. Phillips asked if this prevents relapse. Dr. Crawford replied no, this is for symptom management.

Dr. Carlson said he could see the length of the trial quoted, and asked how long do the effects persist in real life. Dr. Crawford replied that it depends. Because it is symptom management, we are not doing anything to prevent the progression of the disease, so it will vary with individuals depending on how their disease progresses. In the extension trials, patients did remain on for up to five years. It was an open label extension trial, so patients were allowed to continue for the entire length of the trial. For patients that did continue, it did remain effective. Typically, we see a response within six weeks.

Public Testimony: Dr. Mary Kennus, pharmacist with Narvartis Pharmaceuticals, provided a clinical update on Gilenya, the first oral disease modifying therapy approved to treat patients with relapsing forms of MS. Gilenya is approved to reduce both the frequency of clinical relapses and to delay the accumulation of disability. To date, it's the only oral disease modifying therapy that has shown significant reduction in annualized relapse rate versus an active comparator in the label. Gilenya has been on the market for three years and has a demonstrated safety profile established in both clinical trials and real world use in over 71,000 patients world wide. Some of these patients are in their 7th year of therapy. Gilenya has proven consistent advocacy from two pivotal trials and is the only MS disease modifying therapy with superior head to head clinical trial data. In the transforms trial, Gilenya demonstrated superior advocacy when directly compared to Avonex, showing a reduction in relapses by 52% at one year. In our FREEDOMS 2 year placebo controlled trial, Gilenya showed a 30% reduction in the risk of 3 month confirmed disability compared to placebo. We have had some recent updates to Gilenya's clinical data. These updates include continued long term extension safety and advocacy data from both of our pivotal trials. The Phase 3 extension of our placebo controlled study shows that patients receiving Gilenya for over 4 years were demonstrated sustained reduction in annualized relapse rate and remained relapse free over patients who were initially placed on placebo and switched to Gilenya. In addition, our 4.5 year results of our Phase 3 head to head study versus Avonex showed sustained reductions in annualized relapse rate, and also a greater number of Gilenya patients remaining relapse free versus those

on Avonex. The data also showed an additional reduction of 29% in annualized relapse rate in patients who switched from Avonex to Gilenya. Our long term extension and post marketing safety studies continue to show well characterized and manageable safety profile consistent with its known mechanism of action. With a label that aids prescribers in identifying the proper patients for Gilenya, there is little doubt which patients can safely use it. In closing, we request the Committee add Gilenya to the PDL.

Public testimony: Dr. Linda Finch, Biogen, testified that Biogen has three drugs for MS, Avonex, Tycabreon, Tecfidera. I'm going to primarily address Tecfidera today since that is our new agent that was approved in March this year. The CombiRx trial was a failed trial. It didn't meet its primary or secondary endpoints, but the data that was presented about superiority in terms of the relapse rate from Copazone versus the Avonex alone arm was a post talk analysis, which showed a small but significant difference of annualized relapse rate of .05, which equates to one relapse in 20 years. I wanted to let the Committee know about that data. It's not consistent with any other data outcomes in the trial. The mechanism by which this drug works is not well understood yet. It does work through activation of an indigenous antioxidant pathway, called interiv two pathway. That is involved in the cellular response to oxidated stress, which is the mechanism of damage in MS. The efficacy has been well established in two phase III trials with over 2,600 participants. These were published in the New England Journal in 2012. DEFINE, was a placebo controlled study, and CONFIRM, was placebo controlled and also contained an active comparative arm of Copaxone. Treatment with Tecfidera significantly decreased the annualized relapse rate in this trial, with a relative reduction of 53% versus placebo in the first study and 44% in the second study. In that study, Copaxone had a rate of reduction of 28.6%. Improvements were also demonstrated on measures of disability in neurologic outcomes relative to placebo with a 38% statistically significant relative rate of reduction versus placebo in Study 1. The other outcomes were significant for all parameters for MRI. Atifiter has no contraindications; however it may decrease lymphocyte counts. Patients experience approximately 30% reduction in lymphocyte counts, staying within normal levels, but there is a 6% incidence of lymphopenia that we saw in the clinical trials. Importantly, there were no serious infections in the patients who experience lymphopenia. But, we do recommend a CBC prior to initiating therapy as well as annually or as clinically indicated. The most common adverse events with this drug are flushing and GI events which occur predominately in the first month of treatment, and resolve or decrease significantly thereafter. In summary, Ticfidera offers a twice daily oral administration, demonstrated clinical efficacy with statistically significantly reductions in annualized relapse rate. From personal patients relapsing and a statistically significant reduction, the risk of sustained disability progression in our first study, and statistically significant effects on MRI endpoints in both studies, I respectfully request the Committee consider adding oral Ticfidera to the _____ preferred position for the treatment of multiple sclerosis.

Ms. Narus gave the Magellan presentation on multiple sclerosis agents. Multiple sclerosis is an autoimmune type inflammatory disease that can result in sensory disturbances, ataxia, fatigue, partial or full paralysis, and cognitive impairments. It is divided into four clinical courses, relapsing- remitting, primary progressive, secondary progressive, and progressive-relapsing. There are a number of different agents in this class. There are injectible agents, which include the interferons Avonex, Rebif, Betaseron, Extavia, and Copaxone, which has a alternative mechanism of action which is through the T suppressor

cell pathway. Oral agents within this class have expanded in the last couple of years, and include Aubagio – teriflunomide, which arrived on the market approximately September 2012, Tecfidera, which was discussed earlier and arrived this year, Gilenya, which came on the market approximately three years ago back in 2010, and the non-disease modifying agent Ampyra, which we heard about earlier also. Since Aubagio had not been discussed previously with the previous speakers, a few items will be highlighted. This agent does carry a risk of liver complications including death, and also carries a significant risk of birth defects with this particular agent. Women of child bearing age are required to be on contraception while on Aubagio, and individuals who do become pregnant during this time, are candidates for an accelerated elimination procedure using coal staraline or activated charcoal. Other conditions or situations warranting accelerated elimination of this product from the body includes skin reactions, leucopenia, peripheral neuropathy, and respiratory effects. The reason for the accelerated elimination procedure is that the drug can dwell in the body for up to eight months following the last dosage due to its large volume of distribution. Live vaccines are not advised during usage of this medication and for the eight month elimination period thereafter. Aubagio may decrease the white blood cell count, and so monitoring of CBCs are advised, as well as signs and symptoms of infection. As mentioned, there are significant pregnancy risks with this particular medication. It is labeled as Pregnancy Category X, and there is a pregnancy register available to document cases surrounding that. Long term safety of co-administration of Aubagio with other MS agents has not been established. Several of the other oral agents have pregnancy registries. Tecfidera is Pregnancy Category C, but does have a pregnancy registry available to monitor fetal outcomes. Gilenya is Pregnancy Category C. Significant changes include in August 2013, there was a case of progressive multi-focal leukocyte leukoencepholophy or PML for a patient who had been treated with Gilenya for 8 months, and at that time FDA was looking into that. February 2013, Robados, a single use auto injector, had been launched and there were 17 claims in August 2013 for this drug class and 14 claims in September. It's well spread across the preferred agents, Avonex, Betaseron, the interferons account for 21.4% within both of those agents. Copaxone accounted for 14.3% of that drug class, Rebif accounted for 28.6%, and Gilenya 14.3% in September. Last year's previous discussions within this drug class included therapeutic alternatives to include at least one drug other than Ampyra and there was one opposed.

Dr. Carlson stated he would open the discussion to make them therapeutic alternatives again. This is a very serious illness, and no single drug stands out as an answer. Think the patients and doctors need alternatives more than our pointing in one direction. This is an illness where you can't predict when there will be a relapse or progression. It is hard to tell if in one patient whether the medicine is working or not. If someone is seemingly not responding, trying something different makes sense. Our locking everyone into a narrow choice would not be the best thing.

Dr. Demain stated he was incorrect and Copaxone is Category B. Multiple Sclerosis is a condition or disease that effects females more. Are there any others that are Category B?

Ms. Narus responded that it is the only one she has in Category B. The interferons are Category C.

Dr. Semling stated agreement with the therapeutic alternatives, but maybe we should add one injectable and one oral this time to the list.

Ms. Narus repeated the motion from last year "therapeutic alternatives to include at least one drug other than Ampyra".

DR. SEMLING MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE INJECTABLE AND ONE ORAL. SECONDED BY DR. PHILLIPS. THE MOTION PASSES UNANIMOUSLY.

6. Re-review of Antihyperuricemics (Blue Class)

There were no public testimonies.

Ms. Narus gave the Magellan presentation on Antihyperuricemics. Gout is managed in three states: acute treatment, prophylaxis to prevent acute flares, and lowering excess stores of urate to prevent flares of gouty arthritis and prevent tissue deposition of urate crystals. Colcrys is the only FDA approved brand colchicine. It is indicated for both treatment and prevention of gout flares. Inhibitor therapy should not be initiated until 4-6 weeks after an acute episode. Patients using Uloric or allopurinol should not stop therapy. After starting Uloric or Krystexxa, an increase in gout flares is common due to mobilization of uric from the tissues. Patients started on Uloric or feboxostat must be monitored for hepatic injury. Krystexxa, which is indicated for the treatment of chronic gout in adult patients, has been known to cause delayed hypersensitivity reactions, including up to one hour post infusion. Therefore, observation is recommended and caution is advised when using this agent in individuals with CHF. Krystexxa is not indicated for the treatment of asymptomatic hyperuricemia and should not be used in patients with G6PD deficiency due to the increased risk of hemolysis and methemoglobinemia. Therefore, patients of Mediterranean or African ancestry should be screened for this deficiency before initiation, and administration should occur in a health care setting. There are several agents within this class which we've mentioned in the paragraph above. Uloric, or feboxostat, is an oral zanthine oxidase inhibitor which is indicated for the chronic management of hyperuricemia. Krystexxa is the only IV agent in this class and it's indicated for the treatment of chronic gout refractory to other treatment. Allopurinol is also available as a generic and is a xanthine oxidase inhibitor. Probenecid is indicated for prophylaxis and treatment of hyperuricemia and has also been used as an adjunctive therapy with antibiotics. Colcrys or colchicine is indicated for gout flares and also treatment of Familial Mediterranean Fever in individuals over 4 years of age. There is a combination of product, probenecid-colchicine, which is available as a generic. Utilization statistics for this class: 244 claims in September 2013. Allopurinol topped the list at 82.8% of claims. Colcrys at 10.3%, and Uloric at 7%. Agents not listed did not have any utilization within that month. Previous discussion on the subject include therapeutic alternatives to include at least one xanthine oxidase inhibitor, one colchicine product, and one uricosuric product and it passed unanimously.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE ZANTHINE OXIDASE INHIBITOR, ONE COLCHICINE PRODUCT, AND ONE URICOSURIC PRODUCT. SECONDED BY DR. LOVE. THE MOTION PASSED UNANIMOUSLY.

7. Re-review of Alzheimer's Agents (Blue Class)

Public Testimony: Dr. Mary Kennus, pharmacist with Narvartis Pharmaceuticals, testified focusing on the Exelon Patch and what is new with it this year. Exelon patch 13.3 mg is the new higher strength which was FDA approved in 2012. Our registration trial OPTIMA looked at the 13.3 mg strength and it demonstrated significantly improvement in overall function as measured by IADO and cognition as measured to ASCOG. Patients that were exhibiting cognitive and functional decline were on the lower 9.5 mg patch. There were no unexpected safety effects of treatment with either of the Exelon patch doses used in the trial, and the most commonly observed adverse events occurring in greater than 3% of the patients with the 13.3 mg strength were nausea/vomiting and increase in erythema. Exelon patch 13.3 mg also received FDA approval for all phases and severities of Alzheimer's disease in June 2013. We can now offer medication that can be initiated in the early phases of Alzheimers, and then use consistently for symptoms as the disease progresses. What makes the patch unique is, unlike other cholinesterase inhibitors, Exelon is indicated for both Alzheimers and Parkinsons disease dementia, and it is the only cholinesterase inhibitor that is available as a patch. With formulations of both the 9.5 mg and 13.3 mg doses, the clinician has flexibility and can titrate to elevated concentrations when medically appropriate. The Exelon patch formulation also provides a smooth and continuous delivery of rivastigmine at 9.5 mg doses. The patch was associated with 2/3 fewer GI adverse events than the capsule. GI intolerance is often a dose limiting side effect to using the capsules. The patch can be applied to the back in an out of reach, out of sight location for patients who are combative and try to remove it, and provides visual reassurance of medication delivery. It reduces the burden for patients and provides an alternative for patients who cannot take oral medications. In conclusion, I request that the Committee look to preserve Exelon patches status on the preferred drug list, providing clinicians with an additional treatment option for patients with Alzheimers and Parkinsons dementia.

Ms. Narus gave the Magellan presentation on Alzheimer's Agents. There are two sub-sections, acetylcholinesterase inhibitors and NMDA receptor antagonist. NMDA has a unique mechanism of action at the NMDA receptor antagonist. There have been medication errors that have resulted from not removing the old Exelon patches however, patients should be and caregivers can be educated on the proper dose and administration. Cholinesterase inhibitors have the potential for GI adverse effects by stimulating gastric acid secretion and monitoring for occult bleeding is advised. Within the acetylcholinesterase inhibitor class, we have Aricept which is in tablet and ODT form, Razadyne, Razadyne ER, and Exelon oral or patch. The NMDA receptor antagonist is Namenda, available also as Namenda XR, which has been made available in the past year. Significant changes include the change in indication for the Exelon patch, as well as the release of the Namenda XR. The utilization statistics for September 2013 were 115 claims of which the donepezil tablet topped at 51.3%, followed by the Namenda tablet at 36.5%. Then the dissolving tablet for the donepezil at 3.5%, and the non-preferred as

well as the Exelon patch came in at 1.7%. Previous discussions on the topic from last year's meeting were for therapeutic alternatives and that motion passed unanimously.

Dr. Solar asked how the patch compares to the pill form. Mr. Hope replied that being that the capsules are generic, the difference is significant. There has never been anyone from industry testify on generics.

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

8. Re-review of 2nd Generation Antipsychotics – Injectable (Blue Class)

Public testimony: Dr. Amy Everett, MSL America Pharmaceutical, testified on Abilify Maintena. The indications, the unique pharmacological profile, exceed safety, and real world impact on switching to Abilify Maintena on rates of psychiatric hospitalization based on interim study data. Brofimine tenaxidid released injectable suspension is an atypical antipsychotic for the treatment of schizophrenia. The mechanism of action in Abilify is unknown. It is proposed that it is mediated through a combination of activity at the D2 and 5HT1A receptors. Abilify Maintena is the first approved D2 partial agonist and a once monthly extended release injectable suspension. The efficacy of Abilify Maintena in adults with schizophrenia is demonstrated in a randomized, placebo-controlled trial in adults. Abilify Maintena treated patients showed a statistically significantly longer time to relapse which was the primary endpoint. Secondary endpoint was to set limitations meeting the exacerbation of psychotic symptoms/relapse criteria was also significantly lower in patients randomized to Abilify Maintena than in the placebo group. The safety profile of Abilify Maintena is expected to be similar to aripiprazole, based on a ___ with American Control Trials in oral-aripiprazole. In adults with schizophrenia, a dose ranging from 2-30 mg a day was given. Discontinuation due to adverse reaction was 7% in oral-aripiprazole, and 9% in placebo treated patients. Adverse reactions that led to discontinuation were similar for the two groups. The only common adverse reaction associated with the use of oral-aripiprazole in patients with schizophrenia was akathisia. The boxed warning for Abilfy Maintena is increased mortality in elderly with dementia psychosis. For a complete box warning and additional information, I have some PI's with me today. Turning to real world data in an actualistic setting, a multi-centered, open label mirror image study in patients with schizophrenia was conducted to compare total psychiatric hospitalization rates between retrospective treatment with oral standard of care in psychotics and perspective treatment with Abilify Maintena. The following results represent preliminary data based on 183 patients entering the prospective phase. After switching to Abilify Maintena, total psychiatric hospitalization rates for a six month prospective period was significantly lower compared to the retrospective six month period when the same patients received standard oral care and psychotics. 14.2% versus 41.5%. Common adverse events were psychotic disorder, akathisia, and insomnia. All cause discontinuation during the prospective phase was 44.8%. Final results are expected in 2014. In closing, respectfully request that Abilify Maintena be included on the preferred drug list in the State of Alaska.

Mr. Hope explained that this tab includes both injectable and non-injectable, but they are different discussions. This discussion is just on the injectable.

Ms. Narus gave the Magellan presentation on 2nd Generation Antipsychotics. The long acting injectable antipsychotics have indications varying from maintenance treatment of schizophrenia to bipolar disorder. These are 2nd generation agents that are serotonin-dopamine antagonists. These atypical antipsychotics show having increased efficacy for negative symptoms over their first generation counterparts. Abilify Maintena and Risperdal Consta both have active metabolites. Abilify Maintena is advised to be administered by health care professionals and should be administered no sooner than 26 days after the previous injection. This medication was released earlier this year. Zyprexa Relprevv is administered every 2 or 4 weeks. In addition to a medication guide, an injectable Zyprexa Relprevv requires the prescriber, pharmacy and patient to be enrolled in the Zyprexa Relprevv Patient Care Program. Invega Sustenna is administered monthly and Risperdal Consta is administered every 2 weeks. There is generally low utilization within this class. There were 45 claims for September 2013. Risperdal Consta accounted for approximately 89% of those claims, and Invega Sustenna accounted for 11%. There was no utilization record for that month for Abilify Maintena or Zyprexa Relprevv. Due to this class previously being looked at with the orals and injectables, the prior motion was for therapeutic alternatives with one oral preparation and one injectable. However, you can take that into context with the new split.

Dr. Phillips stated her understanding was that Relprevv was part of the REMS process and requires monitoring 3 hours after medication. Ms. Narus explained that there is a requirement for monitoring during that post injection phase due to the risks associated with it. Back in June 2013, the FDA was looking into two unexplained deaths after receiving an inappropriate dose. Dr. Phillips stated she would hope the Committee considers decreasing the amount of injections that patients have to get and that may help with compliance, possibly decreasing to a monthly injection. Don't want to take away Consta as they have a medication for bipolar.

Dr. Carlson stated that the Committee has always been non-restrictive on psychiatric medications. Don't know if we need to be protective of one over the other, as our pattern over the years has been to be permissive. If something happened to that pattern, there is always the therapeutic alternative. Mr. Hope responded that in general, the more broad a motion is, from a contracting standpoint, the more advantage exists for the State to generate the supplemental rebates. The narrower a motion is, or more specific it is, it ties our hands to be able to generate the supplemental rebates. If by chance, a product was listed as preferred, where others were not, we would have that medically necessary override.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE AGENT THAT IS ABLE TO BE DOSED MONTHLY TO EXCLUDE ZYPREXA RELPREVV. MOTION FAILS DUE TO LACK OF A SECOND.

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

9. Re-review of Stimulants and Related Agents (Blue Class)

Public testimony: Dr. David Gross, Pfizer, discussed Quillivant XR. It was released in December last year. Quillivant XR is an essential nervous system stimulant indicated for the treatment of Attention-deficit/Hyperactivity Disorder. It is the first and only extended release methylphenidate oral suspension for ADHD treatment. It is intended to address the unmet need for an oral extended release stimulant formulation that can be taken by patients that prefer the liquid dosage form. Extended release stimulant tablets and capsules cannot be crushed, and those that can be sprinkled on applesauce or something similar, or dissolved in water, could be potentially cumbersome to administer and may be rejected by patients where the flavor is not masked. The efficacy and safety for Quillivant XR was evaluated in a single, randomized, double blind, placebo controlled, crossover multi-center laboratory classroom study of 45 children between the age of 6 and 12 years old with ADHD. The subjects completed an open label dose optimization period from 4-6 weeks, followed by a 2 week double blind cross over treatment of the individually optimized dose between 20-50 mg per day versus placebo. At the end of each week, in the double blind treatment phase, there were trained observers that evaluated the attention and behavior of subjects in a laboratory classroom using the SKAMP scale. At 4 hours post dose, which was the primary efficacy endpoint, SKAMP combined scores were statistically significantly lower during treatment with Quillivant XR than during treatment with placebos. Results indicated that Quillivant XR provided a rapid onset within 45 minutes and was maintained throughout the entire 12 hour study period. As far as safety, based on accumulated data from other methylphendidate ER products, the most common adverse event is appetite decrease, insomnia, nausea, vomiting, abdominal pain, weight decrease, anxiety, tachycardia, and increase in blood pressure. Based on limited experience with Quillivant XR in controlled trials, the adverse reaction profile appears similar to other extended release methylphendidate products. As with other rmethylphendidate containing products and amphetamines, there is a black warning that there is a high potential for abusive and dependence, hence these products are controlled substances and Class II. The risk of abuse should be assessed prior to prescribing and monitoring for signs of abuse and dependence while on therapy is recommended. Quillivant XR is contraindicated in patients with known hypersensitivity to methylphenidate or other components of Quillivant. It is contraindicated during treatment with MAOI's and within 14 days of discontinuing MAOI's due to risk of hypertensive crisis. Ask your consideration.

Ms. Narus gave the Magellan presentation on Stimulants and Related Agents. This class is used to treat ADHD, Hypersomnolence, and Obesity – specifically Desoxyn. Stimulants act by blocking the reuptake of norepinephrine and dopamine into the presynaptic neuron. Amphetamines tend to release newly synthesized dopamine while methylphenidate causes the release of stored dopamine. Both types are available as racemic or single isomer products. Kapvay and Intuniv are non-stimulants and act as alpha-2A-adrenergic receptor agonists. Kapvay and Intuniv have FDA indication for the treatment of ADHD as an adjunct to stimulants. Both have dose dependent decreases in blood pressure and heart rate. Caution should be taken so patients don't become dehydrated or overheated. These products must not be abruptly discontinued but tapered down to avoid affects on blood pressure. Strattera is also a non-stimulant, and increases norepinephrine and dopamine in the prefrontal cortex. It is a longer duration of action than the stimulants, but a slower onset of action, generally one week after initiation. Strattera providual and individual require dosage estimates in cases of hympatic impairment. Strattera is contraindicated in

patients with cardiac or vascular disorders. Intuniv doses of 4 mg have not been systemically studied in controlled trials. According to their 2011 ADHD guidelines, the American Academy of Pediatrics recommends parents and/or teachers administer behavior therapy as first line treatment for children ages 4-5. In 2011, the FDA published a safety communication based on studies that evaluated heart attacks and sudden deaths, including children, adolescents and adults treated with ADHD medications. In a study that assessed strokes in these adults, the FDA concluded that no increase in risk of serious adverse cardiovascular disease in patients treated with ADHD medications was found. The medication study included stimulants, anomoxitine and pemoline, which are no longer marketed. Significant changes include a new warning for ADHD stimulants, in April 2013, indicating that there is an association between stimulant use and peripheral vasculopathy including Raynaud's phenomenon. It is best to monitor for the general changes during treatment with ADHD stimulants. In August 2013, Strattera issued a new contraindication specifically severe cardiovascular disorder that might deteriorate with clinically important increases in heart rate and blood pressure. They caution patients with hypertension, tachycardia, and/or cardiovascular or cerebrovascular disease to be monitored as a result. In May 2013, Vyvanse was approved for ages 6-17 years. Utilization for September 2013 included 2,653 claims. Of these, Concerta topped the list at 19.2%, Intuniv at 17%. Amphetamine salts combined to approximately 20%, and remainder of medications had less than 10%. Previous discussion on this class included therapeutic alternatives to include at least one extended-release and one non-stimulant formulation, and the motion passed unanimously.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE IMMEDIATE RELEASE, ONE EXTENDED RELEASE, AND ONE NON-STIMULANT FORMULATION. SECONDED BY DR. CARLSON.

Ms. Narus will provide information on the age breakdown for usage to the Committee. If a medication is not on the list, it has not had any utilization in the last 2 months or is not in the Magellan basket for approval reasons.

THE MOTION PASSED UNANIMOUSLY.

Break from 9:19 a.m. to 9:33 a.m.

10. Re-review of Long-Acting Narcotic Analgesics (Green Class)

Ms. Narus gave the Magellan presentation on Long-Acting Narcotic Analgesics. When properly used, long-acting opiates can decrease dosing frequency, decrease adverse affects, and increase consistent pain control. Agents in this class are the drugs of choice for moderate to severe pain, and FDA has moved to change that more severe pain. Serious respiratory depression can occur at any time during use of these medications, but usually occurs within the first 24-72 hours after initiation or increase in dose. Doses should be tapered gradually to prevent withdrawal signs and symptoms. Utilization within this class was 863 claims within September 2013. Majority of the claims came from morphine ER tablet, followed by OxyContin, and then the fentanyl transdermal patch at 17.2%, followed by the methadone tablet at 11.2%.

Within the past year, the prior authorization that used to be required on the extended release generic morphine and generic fentanyl transdermal had been removed. Significant changes as of September 2013, the FDA required color changes to the writing on the fentanyl patches, so they can be seen more easily to prevent accidental exposure. That same month, class wide safety labeling changes for all extended release and long acting opiate analgesics were proposed to curb prescription drug abuse, and specifically, it is now indicated that these products are indicated for severe pain, and are not indicated for PRN use. New box warnings have been developed on abuse in pregnancy. It is a contribution to neonatal opiate withdrawal syndrome. In May 2013, Providence ER added new information to their oncology; chronic use of opioids may influence hypothalamic pituitary ___ access leading to hormonal changes that manifest the symptoms of hypog_____, and should be monitored. The modification to the REMS program occurred in April 2013. This REMS uses a single shared system for the elements to ensure safe use of these medications. Previous discussions were for therapeutic alternatives to include at least one non-class, non-scheduled 2 preparation, and one extended release preparation. That motion failed and was followed by a motion for therapeutic alternatives to include at one transdermal preparation and that passed unanimously.

Dr. Demain stated that there is a proposal in front of the FDA now for most of these drugs to become a Schedule II for stricter regulation because the use has tripled over a period of time. Mr. Hope clarified that it is only for hydrocodone, and don't know how this issue will play out.

Dr. Carlson said that there is a national epidemic with poisoning gas, including Alaska, and is exceeding traffic deaths. Within the guidelines of this Committee, are we doing everything we can to play the proper role to try to diminish the problem. Mr. Hope responded that within the context of DUR and the PNT Committee, we have done a good job in Alaska. We have not fixed anything nor have the answers, but some of the edicts we use up here are superior to those of our counterparts in the Lower 48.

Ms. Narus stated last year's motion which was for therapeutic alternatives to include at least one transdermal preparation.

DR. LOVE MOVED DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE TRANSDERMAL PREPARATION. SECONDED BY DR. BERGESEN. THE MOTION PASSED UNANIMOUSLY.

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

Ms. Narus gave the Magellan presentation on Antimigraine Agents. The antimigraine agents in this class are in a variety of forms: tablets, injections, nasal spray, and powder packets. Triptan products issue warning for the possibility of serotonin syndrome when used in conjunction with SSRI's. Diclofenac can be a combo product with sumatriptan/naproxen. There was also a box warning for the possibility for gastric ulceration, perforation, and inflammation. Each drug is a defined maximum 24 hour dosage and should not be exceeded. Overuse of these agents may result in medication overuse and headaches in susceptible patients, which are characterized by migraine like daily headaches or an increase in migraine

attack frequency. Utilization within this class for September 2013, there were 162 claims. Majority of the claims at 53.1%, were for sumatriptan oral followed by Maxalt MLT at 12.4%, followed by sumatriptan nasal at 8.6%. Previous discussions on this class earlier this year was a motion for a class effect and it passed unanimously. There were no significant changes.

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

12. Re-review of NSAIDs (Green Class)

Ms. Narus gave the Magellan presentation on NSAIDs. NSAIDs are commonly used to treat rheumatoid arthritis, osteoarthritis and pain from various etiologies. Was unable to decipher what Ms. Narus was saying in this area. ....thru the COX-2 pathway. Despite the selective focus of the COX-2 inhibitors, this year, the cardiovascular concerns were with the non-selective products. In 2005, the FDA asked manufacturers of all marketed prescription NSAIDs to revise the labeling for the products to include a black box warning stating the risk of NSAIDs and potentially fatal cardiovascular thrombotic events, myocardial infarction, and stroke. All NSAIDs may have a similar risk, which increases with longer duration of use. Patients with cardiovascular disease or cardiovascular risk may be at greater risk. Indecipherable..... Topical NSAIDs are indicated specifically for the treatment of acute pain conditions including strains and sprains as well as chronic pain conditions, including osteoarthritis. For patients with administration of diclofenac, it's the Flector patch, a topical solution gel that provides an alternative method of drug delivery. Utilization within the class for September 2013 includes 472 claims. This class is based on the PDL that was out in December 2012, and not the proposed PDL which we are waiting signature.

Mr. Hope reported that the preferred drug list that we do our updates on is put out for comment and adopted into regulations. The part of the package that was put out for comment had an extra piece attached to it that didn't have anything to do with the drug list. It then had to be put out for comment again. The 472 claims are based on the current PDL, and not the proposed PDL that is awaiting signature.

Ms. Narus continued with the presentation. The meloxicam tablet accounted for 48.7% of claims, Voltaren topical 19.5%, Celebrex oral 17.8%, Flector topical 9.8%. Previous discussion on this topic in November 2012, it was moved that these were therapeutic alternatives to include one COX-2 inhibitor, and it passed with one opposed. Significant changes in June 2013 include updated knee osteoarthritis guidelines for the American Academy of Orthopedic Surgeons and NSAIDs, oral and topical or tramodol, is recommended for symptomatic osteoarthritis of the knee.

Dr. Demain stated that today we will assume naproxen and ibuprofen are in the grouping, as it includes NSAIDs in general. Celebrex is the only true COX-2 inhibitor. Mobic has the selectivity, but is not considered specific.

DR. CARLSON MOVED A CLASS EFFECT AND ALSO INCLUDES A COX-2 AND A TOPICAL. SECONDED BY DR. BERGESEN.

Dr. Riley inquired if this includes topical. Can we end up without a topical on the list? Mr. Hope responded that could be a possibility based on the motion. It's topicals, orals, COX-2 and non COX-2. Dr. Riley stated that the topicals are a great alternative and would not like to see them disappear.

THE MOTION PASSED WITH ONE OPPOSED.

13. Re-review of Opiate Dependence Treatments (Green Class)

Ms. Narus gave the Magellan presentation on Opiate Dependence Treatments. For opiate abuse, the available agents for detoxification include buprenorphine, naloxone, and naltrexone. All are actions at the mu-opiod receptor. Buprenorpine is an agorist and the other two are antagonists. Both the combination products, Suboxone and Vivitrol, participate in the REMS with medication guides to begin at the time of dispensing and all three agents are Pregnancy Category C. Previous utilization for September 2013, there were 390 claims of which the Suboxone film accounted for 68.5%. The buprenorphine generic sublingual at 27.2%, and the Vivitrol intramuscular at 4.4%. Significant changes this year was naltrexone did list an increase risk of hepatic toxicity. Previous discussion on the topic from last November meeting was moved that these were therapeutic alternatives and it passed unanimously.

Dr. Carlson asked to separate the numbers on the claim buprenorphine from the film that has the naloxone in it. It's listed on the sheet at 2.5:1 ratio.

DR SEMLING MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES AND TO INCLUDE AN INJECTABLE AND ONE ORAL. SECONDED BY DR. SALARD.

Mr. Hope explained that naltrexone is highly abused. It is one of the biggest drug spent categories. Every state is struggling primarily from the questions of what is the appropriate dose, what is the appropriate taper regime, how long should someone be on this. Our experience is that we notice people are being started on high doses and remaining there indefinitely. The buprenorphine products all require prior authorization. The Vivitrol product does not.

Dr. Love inquired about including the injectable, will that limit the State's ability to negotiate. Mr. Hope responded that it could potentially limit, as any time a specific drug is preferentially included, it can impact whether a supplemental rebate is available.

MOTION FAILS BY A VOTE OF 7 NAYS TO 5 AYES.

DR. GREEAR MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. LOVE. MOTION PASSED WITH 2 OPPOSED.

14. Re-review of GI Antibiotics (Green Class)

Ms Narus gave the Magellan presentation on GI Antibiotics. Antibiotics in this category have varied indications and mechanism of action. CDAD diarrhea, suppression of bowel flora, adjunctive hepatic encephalopathy therapy, and pseudomembranous colitis. Metronidazole has black box warning related to carcinogenicity. Tinidazole has a similar warning. Alcohol needs to be avoided during therapy. Nausea is fairly common when on these agents; however, nitazoxanide and tinidazole have lower rates of nausea than others in this group. Utilization statistics for September 2013, there were 399 claims. Metronidazole tablets accounted for 92.5% of the claims. Xifaxan followed with 6.3%. Previous discussion in April of this year, it was moved that these were therapeutic alternatives and that motion passed unanimously.

Mr. Hope explained that this item is being discussed again due to trying to expand and narrow different categories. Some items were moved for when their annual review will come up being operating within the State's fiscal year of July to June.

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

15. Re-review of Hepatitis B Agents (Green Class)

Ms. Narus gave the Magellan presentation on Hepatitus B Agents. All four products within this category are indicated for patients with chronic Hepatitis B infection. ____anti- viral therapy is needed for suppression of the infection. Epivir HBV can be used in individuals older than 2 years of age, and is a second line in compensated liver disease. Telbivudine is indicated for compensated liver disease when blood parameters are met. Hepsera is indicated for those ages 12 and older. Baraclude and Tyzeka are indicated for ages 16 and older. Utilization statistics for September 2013, there were 22 claims for this class. Baraclude topped the list at 54.6 %. Hepsera at 36.4%, followed by Epiver HBV at 9.1%. Last year's motion was for therapeutic alternatives and the motion passed unanimously.

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

16. Re-review of Hepatitis C Agents – Ribavirins (Green Class)

Ms. Narus gave the Magellan presentation for Hepatitis C Agents – Ribavirins. This group was originally part of a larger group. Hepatitis C has now been broken down into three separate groups. The ribavirins are used in combination with peginterferons. Ribavirins are grouped inside analons, which disrupts the ____ metabolic processes _____ in antivirus mutagens. Ribavirins are not to be used as monotherapy in HCV. Didanosine and ribavirin therapy is contraindicated. Ribaririn is genotoxic and mutagenic, and

should be considered a potential carcinogen. Fetal death may occur if administered to pregnant women. Administration should be avoided in male partners of females who are pregnant. Two forms of contraception should be used during therapy and for six months following therapy. US Preventative Services Task Force has a recommendation that doctors should offer a Hep C testing to all US baby boomers. This is a turn around from their November 2012 draft guidance where they said that there was inadequate evidence putting benefit of screening for Hep C in this population. That was posted in June 2013. Utilization statistics are 8 claims in September. Topping the list for the ribavirins capsule and tablet tied with 2 claims. Because this was previously lumped as one group, the previous discussion was for therapeutic alternatives with at least one agent from each subclass.

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

17. Re-review of Hepatitis C Agents – Interferons (Green Class)

Ms. Narus gave the Magellan presentation on the Hepatitis C Agents – Interferons. The interferons act to inhibit virus replication inside the infected cells via complex cascade. The pegylaton of the interferons alter the clearance of the molecular, thus increasing the half life of the agents and allowing these agents to be administered once weekly. Monotherapy is not recommended unless the patient has a contraindication to, or significant intolerance to ribavirin. Combination therapy provides substantially better response rates that monotherapy. Safety and efficacy have not been demonstrated for treatment longer than 48 weeks. Safety and efficacy has not been established for liver or other organ transplant recipients. Utilization statistics for interferons are a total of 6 claims. 1 for the Redipen, 2 for the Proclick, and 3 for the syringe. Previous discussions were for therapeutic alternatives with at least one agent from each subclass and the motion passed unanimously.

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

Mr. Hope clarified that this motion was just for interferons.

THE MOTION PASSED UNANIMOUSLY.

18. Re-review of Hepatitis C Agents – Oral Protease Inhibitors (Green Class)

Ms. Narus gave the Magellan presentation on Hepatitus C Agents – Oral Protease Inhibitors. There are two agents within this class, Incivek and Victrelis. There was zero utilization in September 2013. These agents are indicated for chronic hepatitis C genotype 1 infection. It is used in combination with peginterferon alfa and ribavirin triple therapy in adult patients, and should never be used as monotherapy. Telaprevir resistance has been observed. Treatment of patients with genotype 1 infection utilizing triple therapy approach has shown higher rates of sustained biologic response. Telaprevir must always be taken with food while boceprevir may be taken independent of food. Both agents are contraindicated in patients

who are on concurrent drug therapy, reliant on CYP 3 and 4 ___ pathway for clearance. _____. Other warnings and risks include decreased hemoglobin, worsening of neutropenia for both agents, and drug rash with eosinophilia and systemic symptoms, and specifically Stevens-Johnson with telaprevir. No utilization for those two agents in the past two months. Previous discussions were for therapeutic alternatives. There have been some changes over the past year for Victrelis and Incivek. For Incivek, there is an increased focus on lab testing and focus on the frequency of monitoring. They are recommending hemotologic evaluations at weeks 2, 4, 8, and 12, and as clinically appropriate, as well as looking at specific chemistry evaluations such as serumcratin, uric acid and ____ enzymes, ____ and TSH. The indication now includes prior no responder patients on Victrelis without cirrhosis who were previously end treated, or who previously failed interferon and ribavirin therapy, you can assess HCBR in week 8 then week 24, and can continue all three mets and finish through week 48. Victrelis also had additional drug interactions studies, and they found additional interactions with methadone, saboxone, digoxin, and so forth. Increased levels of rameprozol, and rotegrateres had no change in their levels.

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

19. Re-review of Erythropoiesis Stimulating Agents (Green Class)

Ms. Narus gave the Magellan presentation on Erythropoiesis Stimulating Agents. ESA's are indicated previous is patients with anemia with chronic renal failure or anemia resulting from chemotherapy for ____ intent only and should be discontinued when there is less than 1-2 g/dL increase in hemoglobin. Non-responders should be checked for tumor progression and a deficiency or idealogicies for anemia. Ind_____ Procrit can be used in pediatric patients. They are also indicated in patients with zico_____ therapy induced anemia. A single dose vial should be used for pregnant women to avoid benzyl alcohol issues. Utilization statistics for September; there were 9 claims. Topped by Procrit at 44%, Epogen at 33%, and Aranesp combined had 22% utilization. Significant changes within that particular group were in March 2013, a portion of the REMS was removed, which eliminated the requirement of prescriber and hospital re-enrollment every 3 years in the _____ Oncology Program. Enrollment is still required for Q-3 year, re-enrollment has been eliminated. Last year's motion was for therapeutic alternatives and the motion passed with one opposed.

Mr. Hope explained that newer drugs appeared, and quickly disappeared. This was almost a red or blue class.

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

20. Re-review of Phosphate Binders (Green Class)

Ms. Narus gave the Magellan presentation on Phosphate Binders. The entities in this class include two different salts of the same active drug calcium acetate and sevelamer hydrochloride or carbonate, as well as Fosrenol, which is lanthanum carbonate. Lanthanum is contraindicated in bowel obstruction, ileus, and fecal impaction. It is advised that the tablet be chewed thoroughly to reduce the risk of GI events. All agents are FDA approved for treatment of elevated phosphate levels in renal disease. Although Renagel and Renvela have similar adverse event profiles, it was noted that Renvela has slightly higher incidents of upper GI events. Phoslyra, which is calcium acetate, is available and is indicated to reduce serum phosphorus in patients with ESRD. Maintenance dosing is 15-20 ml with each meal. Significant changes in July 2013 include an analysis in lancet which suggested that compared with calcium based phosphate binders, 9 calcium phosphates are associated with a lower risk for all cause mortality in patients with chronic kidney disease. Utilization statistics for this class: 80 claims in September 2013. Topped by calcium acetate capsules at 48%, Renvela tablet at 32%, Renagel at 16%, and Renvela powder pak at 2.5%. Previous discussions included therapeutic alternatives and the motion passed unanimously.

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

21. Re-review of 2nd Generation Antipsychotics – Oral (Green Class)

Ms. Narus gave the Magellan presentation on 2nd Generation Antipsychotics. Indications in the class vary and include schizophrenia, bipolar disorder, psychotic disorder, treatment resistant depression and irritability associated with autistic disorder. 2nd generation agents are serotonin-dopamine antagonists. There are produced incidents of EPS, lesser impact on proactine levels with an increased efficacy on negative symptoms over 1st generation agents. The ____ changes have been observed. Clozapine and lurasidone are Pregnancy Category B, and all others are listed as Pregnancy Category C. Medication guides must be dispensed with several of the products. Seroquel, and Latuda, lurasidone medication guides were updated in 2013. Significant changes include, in July 2013, Latuda obtained two new indications. One for monotherapy for major depressive episodes associated by bipolar 1 disorder, and the second being adjunctive therapy with either lithium or valproate for treatment of major depressive episodes associated with bipolar 1 disorder. Utilization within this class for September 3013 included 3,385 claims. Topping off the claims was Risperdal tablet at 26.1%, quetiapine tablets at 21%, Abilify tablet at 19.2%, olanzapine at 16.4%, and the remainder at less than 5%. Previous discussions on this topic were that these were therapeutic alternatives and the motion passed unanimously. That was followed by a motion that these were therapeutic alternatives including an oral preparation, one from 1st and one from 2nd generation. That was when we were looking at the 1st generations within that class, but they are no longer within this review.

Dr. Phillips commented that it is important to keep the number of drugs available broad as possible because it is not just hitting people with schizophrenia, but also children with bipolar disorder, and who are not responsive to the _____ medications, and so _____, for autism also. It's hitting a broad heterogeneous population and the larger number of opportunities we have, the better it is.

DR. PHILLIPS MOVED THE DRUGS N THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BERGESEN. THE MOTION PASSED UNANIMOUSLY.

22. Review minutes from April 19, 2013 meeting

DR. LOVE MOVED TO ACCEPT THE MINUTES AS AMENDED, WITH THE CORRECTIONS BY DR. DEMAIN. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

23. Comments from Committee Members or Chair

None

24. Adjourn

Without objections, the meeting adjourned at 10:30 a.m.