Alaska MEDICAID PHARMACY AND THERAPEUTICS MEETING (ZOOM MEETING)

Location of Meeting
Zoom Meeting

MINUTES OF MEETING
September 16, 2022
8:00 AM

Committee Members Present:
John Riley, PA, Acting Chairman
Robert Carlson, MD
Matthew Begay-Bruno, PharmD
Sarah Doran-Atchison, PharmD
Claudia Phillips, MD
Charles Ryan, MD

Others Present:
Charles Semling Pharm D, State of Alaska
Erin Narus Pharm D, MSJ, State of Alaska
Ryan Ruggles Pharm D, MSHI, Magellan Medicaid Administration
Umang Patel, Pharm D, R.Ph., Magellan Medicaid Administration
Charlie Lovan, Medical Outcomes and Science Liaison, AbbVie Medical Affairs
Sheena Ara, Pharm D, Field Medical Director, Kaiser Medical Affairs.
Kunal Ramani, Senior Director of Regional Medical Affairs at Xeris Pharmaceuticals
Kaitlin Nguyen, Medical Science Liaison, Access Healthcare
Stuart O'Bracha, Biktarvy
Bo Nguyen, Pharmacist, Janssen

1. Call to Order -- Chair

Mr. Riley called the meeting to order at 8:01 am.

2. Roll Call

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

3. Public Comment

None.

4. Class Review, Discussion & Vote

4-A. Gastrointestinal: Antiemetic-Antivertigo Agents (Green); GI Motility & Irritable Bowel Syndrome, Chronic (Green); Ulcerative Colitis (Green); Cytokine & Cell-Adhesion Molecules (CAM) Antagonist - GI indicated (Blue); Proton Pump Inhibitors (Red)

Gastrointestinal: Antiemetic-Antivertigo Agents (Green Class)

Dr. Umang Patel gave the Magellan presentation for Gastrointestinal: Antiemetic-Antivertigo Agents. The utilization report was reviewed and 73% of the prescriptions were for preferred products, however, per Dr. Semling, generally, when this one in being reviewed, only the 5-HT3s and the NK1s are being reviewed. Per Dr. Semling, all the other ones will show up on the PDL after this meeting. So, he states that it is almost 99%, if you were just looking at the 5-HT3s and the NK1s. At the last review, a motion for therapeutic alternatives passed unanimously.

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

Gastrointestinal: GI Motility & Irritable Bowel Syndrome, Chronic (Green Class)

Dr**.** Umang Patel gave the Magellan presentation for Gastrointestinal: GI Motility and Irritable Bowel Syndrome, Chronic. The utilization report was reviewed and 81% of the prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives passed unanimously.

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

Gastrointestinal: Ulcerative Colitis (Green Class)

Dr. Umang Patel gave the Magellan presentation for Gastrointestinal: Ulcerative Colitis. Ulcerative colitis is a chronic inflammatory disease primarily affecting the colon and rectum. It affects approximately 1 million people in the US and the incidence continues to increase worldwide. The CDC estimates the current prevalence is 239 per 100,000 adults, it can be present at any age, but onset typically peaks between 15 and 30 years of age. The disease is characterized by superficial deconstruction of the bowel wall by inflammatory white cells, resulting in multiple mucosal ulcerations and crypt abscesses. The predominant symptom of ulcerative colitis is diarrhea, which is usually associated with blood in the stool. Additional symptoms include pain in the lower quadrant or rectum along with systemic features such as fever, malaise and weight loss. The initial attack may be with bloody diarrhea, but the disease more commonly begins indolently with non-bloody diarrhea progressing the bloody diarrhea. It can prevent initially with any extent of anatomic involvement ranging to disease confined to the rectum to the higher large intestine, defined as pancolitis. Most commonly, ulcerative colitis causes a chronic intermittent course with long periods of quiescence interspersed with acute attacks lasting weeks or months, however a significant percentage of patients suffer a chronic continuous course.

The utilization report was reviewed and 73% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include at least one delayed-release agent, one prodrug, short acting agent, and one rectal preparation. It passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE DELAYED-RELEASE AGENT, ONE PRODRUG SHORT-ACTING AGENT AND ONE RECTAL PREPARATION. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Public comments for Gastrointestinal: Cytokine & Cell-Adhesion Molecules (CAM) Antagonist - GI indicated (Blue Class)

CHARLIE LOVAN, a representative of AbbVie, discussed Skyrizi and RINVOQ. Skyrizi is an IL-23 antagonist, indicated for the treatment of moderately to severely active Crohn's disease in adults. Skyrizi met both co-primary endpoints of clinical remission and endoscopic response at week 12 and week 52, in both biologic naive and biologic experienced patients, rates of endoscopic response at week 12 in the two induction studies were 40 and 29% for Skyrizi versus 12 and 11 for placebo. And the rate of endoscopic response at week 52 was 48% for Skyrizi and 22 for placebo for those in the maintenance period. Adverse reaction is reported being greater than 3% of the subjects treated with Skyrizi were upper respiratory infection, headache and arthralgia. As a quick reminder, Skyrizi is also approved for the treatment of moderate to severe

plaque psoriasis and active psoriatic arthritis in adults. Another AbbVie medication, RINVOQ, has been FDA approved for adult with moderate to severely active ulcerative colitis, who have had an inadequate response or intolerance for one or more TNF blockers. RINVOQ did meet all its primary and then secondary endpoints and it's used to the placebo-controlled pivotal trials. The primary endpoint in the induction trial was clinical remission at 8 weeks, resulting in a treatment difference of 20 to 29% over placebo, respectively. The primary endpoint for the maintenance trial was remission at 2 to 3 weeks, at doses of 15 milligrams to 30 milligrams once daily, which demonstrated a treatment difference over placebo of 31 and 39%, respectively. The most common adverse events seen in the UC trials were upper respiratory tract infection increased CPK, acne, neutropenia, elevated liver enzymes and rash. RINVOQ has a well-centered clinical profile in rheumatoid arthritis, psoriatic arthritis, atopic dermatitis, and now has over 1000 patients from this ulcerative colitis case study program. And the safety in that ulcerative colitis study was consistent with what we've seen in those previous trials. As always refer to the prescribing information for full efficacy and safety information online at RXAbbVie .com for both Skyrizi and RINVOQ. I'll close by respectfully asking that Skyrizi and RINVOQ be added to this case for drug list, all indications including Crohn's disease and ulcerative colitis, respectively.

SHEENA ARA, a representative from Kaiser Medical Affairs, discussed updates to the prescribing information for tofacitinib or Xeljanz that occurred in December 2021. The first section of the prescribing information was updated, the indications and usage section, plus warnings and precautions and the clinical study section. Xeljanz is indicated for moderate to severe ulcerative colitis. Additionally, it's also indicated for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and polyarticular course juvenile idiopathic arthritis. All these indications are after inadequate trial or response in tolerance to one or more TNF blockers. In terms of moderate to severe ulcerative colitis, recommended dose induction is Xeljanz 10 milligrams twice daily or its XR formulation 22 milligrams once daily in 8 weeks. That can be extended to a maximum of 16 weeks, if there is an inadequate response during the eight weeks. It should be continued after 16 weeks, if adequate therapeutic response is not achieved. In terms of the maintenance dose of ulcerative colitis, the recommended doses of Xeljanz 5 milligrams twice a day or the XR 11 milligram once daily for patients with loss of response during maintenance or treatment or XR 10 milligrams twice a day or XR 22 once daily may be considered. In terms of the clinical study section, in confirmatory trials ankylosing spondylitis was added to the label in December 2021. Additionally, the clinical study section has been updated with results of the ORAL Surveillance Study published in the New England Journal of Medicine in January of 2022. ORAL Surveillance is a Phase IIIB/IV randomized safety endpoint study, prescribed by the FDA at the time tofacitinib was approved in the RA population. In ORAL Surveillance, RA patients, 50 years of age and older with one or more cardiovascular risk factor treated with tofacitinib had a higher rate of major adverse cardiovascular events compared to those treated with the TNF inhibitors. This brings me to the

revisions in the boxed warning section, where MACE was added to the label in 2021. The boxed warning also states that current or past patients are at additional increased risk, discontinued tofacitinib in patients that have experienced an MI or stroke. The warnings and precautions section near the details of major adverse cardiovascular events, mortality, malignancy and thrombosis. Please refer to the full prescribing information details at Xeljanz.com.

Dr. Umang Patel gave the Magellan presentation for Gastrointestinal: Cytokine and Cell-Adhesion Molecules (CAM) Antagonists – GI Indicated. The FDA approved the first interchangeable biosimilar to Humira, Cyltezo, in August 2017 as a biosimilar, but was not deemed interchangeable. The dosing is indication age and weight based and that can be found in the TCRs for the PIs. In terms of precaution there are black boxed warnings for serious infections and malignancy and the formulations are 40 mgs per 0.8 mils and 20 mgs per 0.4 mils, single dose, prefilled syringes.

In December 2021, the FDA has approved this medication, which is a biosimilar to Humira. This indicates that certain patients with the following conditions, adults with moderately to severely active rheumatoid arthritis, moderate to severe juvenile idiopathic arthritis in patients two years of age or older, adults with psoriatic arthritis, ankylosing spondylitis, moderate to severe Crohn's disease in patients 6 years of age or older, moderate to severe ulcerative colitis, and adults with moderate to severe chronic plaque psoriasis. The dosing is again indication age and weight based and three similar black boxed warning such as serious infections and low malignancy as well.

In December 2021, the FDA expanded indications for polyarticular juvenile idiopathic arthritis for patients 2 years of age or older along with Crohn's disease and patients 6 years of age or older. Dosing is indication age and weight based, precaution, black boxed warning such as serious infections, malignancy. And the formulations here are single dose autoinjectors, glass syringes, and glass vials for institutional use only.

In September 2021, the FDA released a communication regarding Xeljanz, Xeljanz XR, Olumiant, and RINVOQ. And so, the FDA is requiring revisions to the boxed warnings of the labels for these medications, include information about the increased risk of serious heart related events, cancers, blood clots and death. Now while this change is based on data, clinical trials treating rheumatoid arthritis and ulcerative colitis for Xeljanz and Xeljanz XR, Olumiant, and RINVOQ are included in the action based on their shared mechanism of action with Xeljanz and FDA considers these medications to have similar risk. The action by the FDA does not apply to JAK inhibitors, which are used in oncology settings. And the FDA is also limiting all approved uses for Xeljanz, XR, Olumiant, and RINVOQ, certain patients who have not responded or cannot tolerate at least one TNF blocker. The utilization report was reviewed and 77% of

prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

Gastrointestinal: Proton Pump Inhibitors (Red Class)

Dr. Umang Patel gave the Magellan presentation on Gastrointestinal: Proton Pump Inhibitors. Proton Pump Inhibitors demonstrate gastric acid suppression superior to H2 antagonists. They achieve a more rapid and sustained increase in gasification, they're not associated with rapid development of tachyphylaxis with H2 blockers and by offering improved treatment of various acid-peptic disorders, including GERD, PUD, and drug-induced gastropathy. Acid suppression is the mainstay therapy for GERD. PPIs are used in conjunction with various anti-microbial for the eradication of H. pylori the most common cause of PUD and anti-secretory therapy with either H2 blockers and PPIs in accelerated ulcer healing and provide benefit systematic improvement. However, failure to eradicate H. pylori resulting a 60 to 80% relapse after one year in the absence of continual mainstay antisecretory therapy. The rates of relapse following successful eradication of H. pylori range from 0.5% to 20%.

The EGA and the ECG in 2013 documented PPIs as its first line therapy for the treatment of severe GERD-related symptoms or erosive esophagitis. H2 blockers can be used in patients with mild symptoms or verified non-erosive disease and PPIs can be the most symptomatic relief until esophagitis in the highest percentage of patients.

The empiric medical therapy with the PPIs recommended with the presumptive diagnosis of GERD, in terms of heart burn and regurgitation. Patients with noncardiac chest pain suspected due to GERD should have diagnostic evaluation before institution of therapy. PPI therapy should be initiated at a once a day dosing before the first meal of the day. Traditional delayed release, PPIs should be administered 30 to 60 minutes before meal for maximal pH control, while newer PPIs such as Dexlansoprazole, Omeprazole, sodium bicarbonate, they offer dosing flexibility relative to meal timing.

In patients with partial response to PPI therapy, increasing the dose to twice daily therapy or switching to different PPI may provide additional symptom relief. And in addition, adjustment of dose timing may be considered in patients with nighttime symptoms, variable schedules and or sleep disturbances.

Patients who respond to short term PPIs should subsequently attempt to stop or reduce the dose of the PPI and those who cannot reduce should consider ambulatory esophageal pH impedance monitoring instead of lifetime PPI to help distinguish GERD from a functional syndrome. As this is the first time that these medications are being reviewed, there were no motions made for them previously or previous minutes.

Mr. Riley asked if all of the prescriptions would be covered.

Mr. Riley asked if it would circle back to them in a year.

Dr. Semling stated that the state is going to make the recommendation to remove the prior authorization on it and just retain the quantity limits for each one of those.

DR. CARLSON MOVED THAT THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BEGAY-BRUNO. THE MOTION PASSED UNANIMOUSLY.

4-B. **Endocrine/Metabolic:** Antihyperuricemics (Green); Progestins for Cachexia (Green); Growth Hormone (Red); Androgenic Agents, Topical (Green); Bone Resorption Inhibitors (Green); Glucagon Agents (Red); Hypoglycemics, Metformin (Green); Hypoglycemics, Alpha-Glucosidase Inhibitors (Green); Hypoglycemics, SGLT2 Inhibitors (Blue); Hypoglycemics, Meglitinides (Green); Hypoglycemics, Thiazolidinedione (TZD) and Combinations (Green); Hypoglycemics, Dipeptidyl Peptidase-4 Inhibitors (DPP-4) and Combinations (Green); Hypoglycemics, Glucagon-like Peptide-1 (GLP-1) and Combinations (Red); Rapid-Acting Insulins (Green); Regular Insulins (Green); Intermediate Insulins (Green); Rapid/Intermediate-Acting Combination Insulins (Green); Regular/Intermediate-Acting Combination Insulins (Green); Long-Acting Insulins (Blue); Phosphate Binders (Green)

Endocrine/Metabolic: Antihyperuricemics (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Antihyperuricemics. The utilization report was reviewed and 98% 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. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Progestins for Cachexia (Green Class)

Dr. Umang Patel gave the Magellan presentation for Endocrine/Metabolic: Progestins for Cachexia. The utilization report was reviewed and roughly 79% of prescriptions were for preferred products. At the last review, a motion for class effect passed unanimously.

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

Public Comments for Endocrine/Metabolic: Growth Hormone (Red Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Growth Hormones. Growth hormone deficiency results from inadequate production of growth hormone and can produce serious medical conditions dependent on age. Adults with growth hormone deficiency may have diminished lean body mass or bone density and a number of physical and psychological manifestations, it can be congenital or acquired in childhood or adult life, in addition of being social or complete. Condition is usually permanent and may have an isolated deficiency or occur in association with deficiencies of under pituitary hormones. In most cases, the diagnosis should be based on results from a provocative test that is recommended by the Pediatric Endocrine Society.

In 2009, the American Association of Clinical Endocrinologists guidelines clinical practice indicates no evidence exists for any specific growth hormone product over another.

In August 2021, the FDA indicated the human growth hormone for the treatment of pediatric patients one year of age or older, who weigh 11.5 kilograms or more can have growth failure due to inadequate secretion of endogenous growth hormone. As you can see in terms of precautions, there are increased risk of neoplasms, so it is important for healthcare practitioners to monitor patients with pre-existing tumors from progression or recurrence, increased risk of infection neoplasm in Childhood Cancer Survivors treated with Genotropin. In particular, meningioma in patients treated with radiation to the head for their first neoplasm being intracranial hypertension and lastly fluid retention here. Dosing recommendations were reviewed. It is available as an injection. No studies have been performed on patients with hepatic or renal impairment.

The utilization report was reviewed and about 98% of prescriptions were for preferred products. At the last review, a motion for class effect passed unanimously.

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

Endocrine/Metabolic: Androgenic Agents, Topical (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Androgenic Agents, Topical. The utilization report was reviewed and 0% of prescriptions were for preferred products.

Discontinue Notification. AbbVie has reported that AndroGel packets have motion to discontinue. Only one dose remains until June 2022, unless the supply gets exhausted earlier. Moving forward, the AndroGel pump will be the only one manufactured by AbbVie.

At the last review, a motion for class effect passed unanimously.

Dr. Semling stated that this class more than likely will change now that the AndroGel packets are no longer being made. So, the committee will definitely take into consideration utilization of the other products.

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

Endocrine/Metabolic: Bone Resorption Inhibitors (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Bone Resorption Inhibitors. The utilization report was reviewed and 91% of prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives passed unanimously.

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

Public Comments for Endocrine/Metabolic: Glucagon Agents (Red Class)

KUNAL RAMANI, a representative from Xeris Pharmaceuticals, discussed glucagon. As you're aware, glucagon is an emergency medicine. It's used when all other measures have failed and requirements to try and fail a multi-step lyophilized powder, Glucagon Emergency Kit is before accessing novel glucagon can expose patients to unnecessary risks and expenses. Dealing a powdered kit, which essentially is the inability to administer a full dose of glucagon can lead to serious complications including death. It's also important for caregivers and persons with diabetes to have choice in their glucagon delivery method in emergency situations. Therefore, I'm here to request that Gvoke glucagon for injection be added to the state PDL without restrictions. I'd like to focus on three main points, the first one being 99%, whereas the traditional emergency glucagon kit has a pass rate of 6% or a 94% failure rate. The usability

studies of glucagon with a Gvoke HypoPen have resulted in a 99% success rate in usability during an emergency-simulated protocol with simple two step administration, where you take off the yellow cap, hold the red part down for five seconds and inject the full dose. Second, Gvoke has the broadest age range of currently available ready-to-use glucagon options and is indicated for two years and above in treating severe hypoglycemia in patients with diabetes. Gvoke also provides patients and caregivers with three different dosage options, prefilled syringe, an auto injector similar to HypoPen and a single dose vial in syringe kit. And then lastly 30 months ability, Gvoke is room temperature stable for 30 months at a 1 milligram dose in ready-to-use vial and kit, which is the longest room temperature shelf life of any of the currently available novel glucagon agents. It's also premixed, pre-measured, prefilled, and liquid-able ready-to-use in a reliable administration with no refrigeration requires or required, meaning a person with diabetes can have it on them in any location when an emergency arises. In conclusion, I appeal to the committee today to remove any restrictions on Gvoke, because it provides patients and caregivers multiple choice in their glucagon delivery options. In an emergency situation, it is imperative for a patient to be able to successfully in receiving a full dose of glucagon. Currently, most commercial and Medicaid options do not require us to achieve access to ready-to-use glucagon. Thus, we ask that you offer Medicaid patients with the same level of access and choice, as in novel ready-to-use glucagon options.

Dr. Carlson asked if there were any real life studies showing that the product is more effective than the competing product.

Dr. Ramani stated that going back to the human factors studies, there aren't any head-to-head trials that you can do as a comparator. But on our website, it does do product-direct comparisons and going back to usability studies, when Eli Lilly did the Glucagon Emergency Kit, as I spoke to, there was a 6 to 33% success rate or a 94 to 67% failure rate with that medication. With our HypoPen, which is an autoinjector and a prefilled syringe, we did usability studies and 74 out of 75 patients were able to administer it correctly. And that was with untrained-trained individuals including adolescents.

Dr. Carlson asked if both of these were manufacturer studies.

Dr. Ramani stated that they were.

Dr. Ramani added that the traditional Glucagon Emergency Kit that you're used to is actually going to be discontinued by Lilly at the end of the year and will not be produced anymore.

The utilization report was reviewed and 97% of prescriptions were for preferred products. There was no previous motion made about this category.

DR. RYAN MOVED A CLASS EFFECT TO INCLUDE A NASAL FORMULATION. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Hypoglycemics, Metformin (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemics, Metformin. It is estimated that over 34 million Americans have diabetes, which 90 to 95% have Type II, and it is responsible for increased morbidity and mortality, clinically collection control is crucial to minimize chronic microvascular and macrovascular complications, exogenous supplements, sufficient levels of endogenous insulin and temporarily restores the ability of the body to properly utilize carbs and some protein. Multiple insulin products are available and are used as replacement therapy in the management for Type I and Type II, when glycemic rules are not met with oral antidiabetic agents.

In addition to exogenous insulin, there are several pathways, in which blood glucose may be regulated in diabetic patients. When it comes here, we have the ADA 2021 guideline. Now as you can see, there's a lot of information here, but hold is kind of the key takeaway points here that I'll review.

Guidelines from the American Diabetes Association, the American Heart Association and the Food and Drug Administration were reviewed.

The utilization report was reviewed and 98% of 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. BEGAY-BRUNO. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Hypoglycemics, Alpha-Glucosidase Inhibitors (Green Class)

Dr. Umang Patel gave the Magellan presentation for Endocrine/Metabolic: Hypoglycemics, Alpha-Glucosidase Inhibitors. The utilization report was reviewed and 90% of the prescriptions were for preferred products. At the last review, a motion of class effect passed unanimously.

DR. PHILLIPS MOVED CLASS EFFECT. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Endocrine/Metabolic: Hypoglycemics, SGLT2 Inhibitors (Blue Class)

There were no public comments for Endocrine/Metabolic: Hypoglycemics, SGLT2 Inhibitors.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemics, SGLT2 Inhibitors.

Guidelines from the American College of Cardiology, the American Heart Association, and the Heart Failure Society of America were reviewed.

In February 2022 of this year, the FDA expanded the indication of Jardiance to reduce the risk of CV deaths and hospitalization for heart failure in patients, in adults with heart failure. Previously indication was to reduce the risk of CV death plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction. So, as you can see, it does carry other alternative indications and changes for the updated information, no changes in precautions for pregnancy, necrotizing fasciitis, long gestation, no changes in dosage or formulation here.

The utilization report was reviewed and roughly 76% of the prescriptions were for preferred products. At the last review, a motion of class effect to include at least one medication that decreases cardiovascular risks and at least one that shows renal protective effect passed unanimously.

Dr. Phillips asked if there's something we missed, because usually we have better numbers.

Dr. Patel advised that the main player for the preferred was Jardiance and the main players in non-preferred were Farxiga and Invokana.

Dr. Carlson stated that it looks like folks are getting it by using medically necessary.

DR. PHILLIPS MOVED A CLASS EFFECT TO INCLUDE AT LEAST ONE MEDICATION THAT DECREASES CARDIOVASCULAR RISK AND AT LEAST ONE THAT SHOWS RENAL PROTECTIVE EFFECT. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Hypoglycemics, Meglitinides (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemics, Meglitinides. The utilization report was reviewed and at the last review, a motion of class effect was passed unanimously.

DR. PHILLIPS MOVED A CLASS EFFECT. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Hypoglycemics, Thiazolidinedione (TZD) and Combinations (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemics, Thiazolidinedione (TZD) and Combinations. The utilization report was reviewed and 99.5% of prescriptions were for preferred products. At the last review, a motion of class effect passed unanimously.

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

Endocrine/Metabolic: Hypoglycemics, Dipeptidyl Peptidase-4 Inhib. (DPP-4) and Combinations (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemics, Dipeptidyl Peptidase-4 Inhibitors and Combinations. The utilization report was reviewed and 84% of prescriptions were for preferred products. At the last review, a motion of class effect passed unanimously.

DR. PHILLIPS MOVED A CLASS EFFECT. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Endocrine/Metabolic: Hypoglycemics, Glucagon-like Peptide-1 (GLP-1) and Combinations (Red Class)

There were no public comments for Endocrine/Metabolic: Hypoglycemics, Glucagon-likePeptide-1 and Combinations.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Hypoglycemics, Glucagon-like Peptide-1 and Combinations. The package insert updated to add a third maintenance dose of 2 mgs subcutaneously once weekly. Previously, the maximum recommended dosage was 1 mg once weekly. However, now additional glycemic control is needed after over 4 weeks or greater on the 1 milligram dose. The dosage maybe increased to 2 mgs once weekly and the updated maximum recommendation dosage is 2 milligrams once weekly. Additionally, along with a new dosage regimen, the FDA approved the new strength of 8 mgs per 3 milliliter in a single -patient use that delivers 2 milligrams per injection. No changes to the indications or the precautions here. The dosing, as I mentioned was the only thing updated along with the perspective updated formulation here.

Mounjaro, so this is a new medication that was approved in May of this year, which is a glucose-dependent insulinotropic polypeptide receptor and GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type II. As a limitation of use, it has not been studied in patients with history of pancreatitis and it is not indicated for use in patients with Type I diabetes. Now the precautions are, you know, similar to a lot of the other medications in this subclass, first being the black boxed warning for thyroid C cell tumors along with the fact that it is contraindicated in patients with personal, family history of multiple endocrine neoplasia. Additionally, precaution with patients with acute gallbladder disease. The dosage as you can see is about 2.5 milligrams Sub-Q once weekly and after four weeks, it can be increased to 5 milligrams Sub-Q weekly and if additional glycemic control is needed then an increase in dosage in 2.5 milligram increments after at least 4 weeks of the previous dose is recommended. The maximum dose is 15 milligrams Sub-Q once weekly. And as you can see the formulations are in various strength in a single dose pen for Sub-Q injection.

The utilization report was reviewed and 97% of prescriptions were for preferred products. At the last review, a motion of class effect to include at least one weekly injection product passed unanimously.

DR. RYAN MOVED A CLASS EFFECT TO INCLUDE AT LEAST ONE WEEKLY INJECTION PRODUCT. SECONDED BY DR. BEGAY-BRUNO. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Rapid-Acting Insulins (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Rapid-Acting Insulins. The utilization product was reviewed and about 60% were for preferred products. At the last review, a motion of class effect passed unanimously.

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

Endocrine/Metabolic: Regular Insulins (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Regular Insulins. The utilization report was reviewed. At the last review, a motion of class effect passed unanimously.

DR. RYAN MOVED A CLASS EFFECT. SECONDED BY DR. BEGAY-BRUNO. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Intermediate Insulins (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Intermediate Insulins. The utilization report was reviewed and 100% of prescriptions were for preferred products. At the last review, a motion of class effect passed unanimously.

DR. PHILLIPS MOVED A CLASS EFFECT. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Rapid/Intermediate-Acting Combination Insulins (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Rapid/Intermediate-Acting Combination Insulins. The utilization report was reviewed and 80% of prescriptions were for preferred products. At the last review, a motion of class effect passed unanimously.

DR. RYAN MOVED A CLASS EFFECT. SECONDED BY DR. BEGAY-BRUNO. THE MOTION PASSED UNANIMOUSLY.

Endocrine/Metabolic: Regular/Intermediate-Acting Combination Insulins (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Regular/Intermediate-Acting Combination Insulins. The utilization report was reviewed and 77% of prescriptions were for preferred products. At the last review, a motion of class effect passed unanimously.

DR. PHILIPS MOVED A CLASS EFFECT. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Public Comments for Endocrine/Metabolic: Long-Acting Insulins (Blue Class)

There were no public comments for Endocrine/Metabolic: Long-Acting Insulins.

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Long-Acting Insulins. In December 2021, the FDA approved the second biosimilar insulin product, the Lantus. The indications are to improve glycemic control in adults and pediatric patients with Type I diabetes and in adults with Type II. The indication of use is not recommended for treating diabetic ketoacidosis. The precaution here as one can imagine with insulin, the hyper or hypoglycemia with changes in regimen. Hyperkalemia as with insulin and tracking levels need to be monitored and fluid retention and heart failure with concomitant use of TZDs. Dosing again, as insulin is individualizing in some glucose metabolic needs and the formulation is in 3 milliliter single patient-use prefilled syringe of 100 units per ml or U-100.

In November 2021 Biocon announced the US launch of interchangeable biosimilar brand Semglee and unbranded insulin glargine. The FDA approved it in July 2021 and this was reviewed by the Alaska P&T board during the September 2021 P&T meeting.

Recall Alert. In terms of recalls for Semglee, January of this year, Mylan is voluntary recalling one batch of its 3 milliliters prefilled syringes packaged and labeled cartons. The labels were missing on some of the prefilled syringes and from the labeled carton of the batch.

In April 2022, Mylan issued a voluntary recall of one batch of insulin glargine-ygfn packaged in a 10 milliliter vial that is inside a carton. There is the potential of the label be missing on some vials as well. Again, this is not branded Semglee vials, this is unbranded glargine-ygfn vial. And in July of this year, Mylan voluntarily recalled one batch of unbranded insulin glargine-ygfn, 3 milliliters prefilled pens due to the potential for the label to be missing on some pens. In the wholesaler, retailer and consumer level results, no adverse events related to the recall have been reported yet.

The utilization report was reviewed and 76% of prescriptions were for preferred products. At the last review, a motion for class effect passed unanimously.

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

Endocrine/Metabolic: Phosphate Binders (Green Class)

Dr. Umang Patel gave the Magellan presentation on Endocrine/Metabolic: Phosphate Binders. The utilization report was reviewed and about 21% of prescriptions were for preferred products. At the last review, a motion of therapeutic alternatives passed unanimously.

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

4-C. Antiretrovirals: HIV/AIDS Agents (Red Class)

Public Comments for Antiretrovirals: HIV/AIDS Agents (Red Class)

KAITLIN NGUYEN, a Medical Science Liaison with Access Healthcare, discussed the importance of open access for HIV medication. 40 years ago, HIV was considered fatal. Today, a person with HIV can take effective therapy to live a long healthy life and he can consistently prevent further transmission. The advancement of pre-exposure prophylaxis hook up empowers

people who could benefit to protect themselves. This medical development provided a light at the end of the tunnel and give us hope, something unimaginable in early days of the epidemic. As we reflect on our past and let's also look towards the future, where HIV is no longer a public health challenge, a future where new HIV infections are reduced by at least 90% and we have achieved the national goal of ending the HIV epidemic. The significant advances people with HIV are able to more easily achieve and enhance suppression, the virus suppression along appearance remain lowest in the Medicaid population. It's estimated that by 2020 in the US, more than 70% of people living with HIV will be aged 50 and older. This aging population facing polypharmacy and comorbidities reinforces the need for individualized treatment options to minimize HIV burden. When it comes to HIV, there is no one-size-fits-all. Patient-centric results provide the best opportunity for retention and care and long-term appearance. Providers should be entrusted to construct a viable regimen to achieve optimal outcomes for your members. Cabenuva and Apretude are the first long-acting options for the short adherence in treatment for PrEP, alleviating HIV stigma or fear of exposure associated with sexually acquired HIV infection. According to the AIDS Institute, this therapy and prior authorization should never be used in the treatment of HIV in one counter to the US government's sponsor guidelines. As we collectively work towards the CDC's vision of a future free of HIV that is now within our reach, we must recommit our efforts towards progress. I ask for your consideration in keeping open access for HIV medications to ensure equity, and ultimately end the AIDS epidemic.

Stuart O'Bracha, another representative, spoke about Biktarvy and the benefits of Biktarvy. To your request of indicating the new things that have occurred with Biktarvy, there have been three label updates for Biktarvy in the last year plus, since you've last looked at this class. One is new patients with renal impairment, there was an expanded indication for patients with an eGFR below 15, but on chronic hemodialysis, which is significant to treat this population of unmet need. And currently, it's only approved other patients down to an eGFR of 30, which is also a lower eGFR than many of the other available agents. It's been expanded for geriatric use, as the last speaker indicated, we are approaching or in some cases we see greater than 50% of the HIV population now that are over 50 and that demographic continues to increase. So having safe and effective therapies in that population are critical. We also have a pediatric indication now down to patients weighing less than 14 kilograms, which is also significant to treat that population of unmet need. There are a number of publications that I cited that are non-label, but one being very important the five-year data for Biktarvy. Biktarvy is the only triple drug integrated space therapy containing also TAF with long-term safety and efficacy in a broad range of people living with HIV recommended personalized guidelines. And this is demonstrated in the five-year clinical trial data, which is the longest currently to date of an HIV studied, HIV regimen. And it demonstrates virologic success in greater than 95% patients on treatment over those five years with only six discontinuations due to drug related adverse effect, which is also unprecedented in clinical trials. And with no resistance when a detectable viral load was rarely seen. The implications of this is a forgiving high barrier to resistance HIV regimen with patients even with

non-ideal adherence. With that said, Biktarvy has been shown in real world trials to have the highest level of persistence of all DHHS first line recommended regimens. Staying on therapy, it is critical to HIV success. Besides the clinical trial data, other real world trials have shown similar results to the clinical trial results that I just summarized. So, I respectfully, in my few seconds left, request that you maintain open access to all HIV recommended regimens including Biktarvy as it fills the greatest landscape need for the HIV population in Alaska and essentially all the other states in the world.

Bo Nguyen, a representative from Janssen Public Affairs, spoke about SYMTUZA. SYMTUZA, which is the only single tablet regimen that contains protease inhibitor, SYMTUZA contains services for HIV guidelines, along with cobicistat and darunavir. According to the prescription guidelines, they specifically recommended HIV regimen, when adherence is a concern or antiretroviral therapy is needed to initiate the therapy at the time of exposure rapid initiation. Moreover, the World Health Organization as well as the International AIDS Society, recommended initiation as a treatment strategy to improve the outcomes, improve retention and care for symptoms as the only single tablet regimen studied to support rapid initiation in the patient. I'll conclude that when the patient is initiated under protease inhibitor, he is less likely to experience weight gain. Janssen has a strong history of commitment in treatment of HIV and will remain committed, although access to HIV treatment for all medications should be made available as an open market access to the provider and the patient making decisions by themselves.

Dr. Umang Patel gave the Magellan presentation on Antiretrovirals: HIV/AIDS Agents. A little bit of background on HIV, human immunodeficiency virus is a complex disease that results in destruction of the immune system of the HIV infected individual. There are two major subtypes. Type 1 considered most responsible for AIDS epidemic, more common worldwide. HIV-2 is less virulent, less transmissible; however, both are known to cause AIDS and are transmitted by sexual contact and blood and from mother to child and this is more concentrated in West Africa. The HIV virus establishes infection by killing CD-4 cells, T-cells that are crucial to a healthy immune system and these are called T-helper cells, because they also signal other cells in the immune system to perform their functions. Research has shown that most interesting strains of HIV is a coreceptor molecule called CCR5, in addition to the CD-4 molecule to enter the T-cells and take over the cellular machinery for viral replication. Now without these CD-4 cells, the immune system is vulnerable to infections. The healthy uninfected people usually we have 800 to 1200 CD-4 T-cell per cubic millimeter of blood. Once infected, the number of T-cells declines, as defined maybe swifter than previously believed in the absence of early treatment and if the T-cell counts falls below 200, then this is classified as AIDS. The individual then becomes more vulnerable to opportunistic infections and cancers that are associated with this end stage of HIV.

HIV was first identified in 1983, but it likely entered the US in the late 70s. It's estimated that there were approximately 37 million people living with HIV by the end of 2020 and 73% of adults and 54% of children receive ART globally, antiretroviral therapy. Estimated that about 34,800 new HIV infections occurred in the US in 2019, which is an 8% decline since 2015 and it's estimated that 18% of people in the US with HIV do not know their status. In 2019, there were 15,815 deaths among people diagnosed with HIV in the US, of new infections approximately two thirds are from male-to-male sexual contact, 23% is from heterosexual contact and 7% is from injection drug use.

Minority groups in the US has been disproportionately affected by HIV/AIDS epidemic. A perinatal transmission rate of HIV from mother to child has decreased by more than 95% since the early 90s and a significant reason for the decrease in the US is routine testing of pregnant women during prenatal care and intervention of antiretroviral therapy during pregnancy and delivery. And despite perinatal transmission being the primary means of childhood HIV infections, the risk can be reduced to less than 1% if recommended preventive measures are followed.

There are nine therapeutic classes that represent the drug treatment options for HIV. We have nucleoside and nucleotide receptor transcriptase inhibitors or NRTIs, non-nucleoside reverse transcriptase inhibitors NNRTIs, protease inhibitors, integrase inhibitors, attachment inhibitors, CCR5 antagonist, fusion inhibitors, PK enhancers and monoclonal antibody and that's specifically Trogarzo. Initial regimen selection should be guided by patient characteristics, including comorbidities, drug-drug interactions, toxicity risk, regimen complexity and virologic efficacy.

Treatment guidelines from the Department of Health and Human Services and the International Antiviral Society were reviewed.

In December 2021, the FDA approved the new indications to include use as an oral lead in for Apretude for HIV-1 PrEP, adult patients and pediatric patients, pediatric defined 12 to less than 18 years of age weighing 35 kilograms or more and as a short-term oral therapy of PrEP to patients who will miss a planned injection dosing of Apretude. PrEP indication is for at risk adults and adolescents weighing 35 kilograms or greater or short to the PrEP to reduce the risk of sexually acquired HIV-1 infection and individuals must have a negative HIV-1 test prior to initiating PrEP.

In April 2022, HIV-1 treatment indication was extended to improve adolescents 12 years of age or older and weighing 35 kilograms or more, again no changing in warning precautions, dosage or availability here.

In December 2021, the FDA approved Apretude, which is an integrase inhibitor indicated in at risk adults and adolescents, weighing 35 kilograms or more from PrEP and reduced the risk of sexually acquired HIV infection. And speculation is individuals must have a negative HIV-1 test prior to initiating treatment for HIV-1 test. Since this is a new drug warnings and precautions, there is a black boxed warning for drug resistance in undiagnosed HIV-1 infection and hepatotoxicity has no reported indication to receive elvitegravir, so clinical and lab monitoring should be considered and there is hepatotoxicity perspective it should be discontinued. Dosing recommendations were reviewed.

In January 2022, there are two updates on DESCOVY. First being the FDA expanded indication to include treatment of HIV-1 infection in combination with antiretroviral treatments other than protease inhibitors that require CYP3A inhibitors. In pediatric patients, 14 kilograms to less than 25 kilograms, previously, it was only indicated for patients 25 kilograms to less than 35 kilos, again expanded the lower weight approval for the treatment of HIV-1 infection in combination of other treatments in patients 35 kilograms or greater. Now, with these expanded indication in a new strength approval of 120 milligrams of emtricitabine and 15 milligrams of tenofovir combo. So, as you can see in indication the holding is for the expanded date indication and then the availability just a new combined formulation.

In February 2022, the FDA approved an expanded indication to improve HIV-1 infected pediatric patients weighing 35 kilograms or greater, no prior treatment or to replace a current stable regimen in virally suppressed patients. Previously, this was only adults now approved in pediatric patients that use criteria. No changes to warnings and precautions, dosing or availability here.

In February 2022, the FDA approved an expanded indication for use in combination with Vocabria for short term treatment of HIV-1 infection in adults who are virologically suppressed on a stable regimen with no history of treatment failure and no known or suspected resistance to either cabotegravir or rilpivirine has been expanded to also include adolescents 12 years of age or older and meeting the 35 kilogram greater weight criteria.

In February 2022, the FDA approved new dosage regimen of every two months as a complete regimen for the treatment of HIV in adults to replace the current antiretroviral regimen in those who are virologically suppressed on a stable regimen, with no history of treatment failure and no known or suspected resistance to either cabotegravir or rilpivirine.

In April 2022, the FDA also approved an exchange indication to include adolescents 12 years of age or older and weighing 35 kg or greater, who are virologically suppressed on a stable regimen, with no history of treatment failure and no known or suspected resistance, through either cabotegravir or rilpivirine again, only in adults previously. No changes in warnings,

dosing or availability. A lot of these may sound similar because as you can see CABENUVA, rilpivirine together and you know, we mentioned the other two previously.

In April 2022, the FDA approved a new tablet for oral suspension formulation for this. And so, no changes in indications, warnings, that's just a new dosing that can be used for an oral suspension for a pediatric patient. And then, additionally, the minimum weight of child eligible for treatment has been lowered from 40 kilograms to 25 kilograms as well.

In December 2021, the use in patients with renal impairment now includes those with eGFR clearance of 30 to 49 milliliters. Previously, it was not recommended if your renal function was less than 50.

Discontinue Notification. In terms of discontinuations, there is one. In October of last year, the FDA announced that Boehringer Ingelheim will be discontinuing the oral suspension of VIRAMUNE. And a new generic was available beginning in February 2022, this will be the first FDA approved generic for these cells entry, both the 150 and 300 milligrams, and this will be created by Hetero Labs.

The utilization report was reviewed and 100% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives to include at least one of the following: nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase transfer inhibitors for at least one PrEP formulation and at least one pediatric approved product.

DR. PHILLIPS MOVED THAT WITH THE UNDERSTANDING THAT ACCESS WOULD REMAIN OPEN, THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE OF THE FOLLING INHIBITOR CLASSES: NUCLEOSIDE REVERSE TRANSCRIPTASE, NON-NUCELOSIDE REVERSE TRANSCRIPTASE, PROTEASE, AND INTEGRASE TRANSFER INHIBITORS; AT LEASET ONE PREP FORUMLATION, AND AT LEAST ONE PEDIATRIC-APPROVED PRODUCT. SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

Mr. Riley asked if there was any discussion about the motion**.**

Dr. Semling asked if the committee would take into consideration that there are a significant number that are no longer recommended.

Dr. Phillips asked if those drugs would not necessarily make it to the preferred list and if the committee would be addressing this.

Dr. Semling stated that they would be addressing this and that he just wanted to make sure the committee was aware of that.

4-D. Single Class Reviews: Movement Disorders (Green Class); Continuous Glucose Monitors (Green Class)

Movement Disorders (Green Class)

Dr. Umang Patel gave the Magellan presentation on Movement Disorders. The utilization report was reviewed and 97% of prescriptions were for preferred products. At the last review, a motion for therapeutic alternatives passed unanimously.

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

Continuous Glucose Monitors (Green Class)

Dr. Umang Patel gave the Magellan presentation on Continuous Glucose Monitors. At the last review, a motion that the Continuous Glucose Monitors were therapeutic alternatives passed unanimously.

DR. RYAN MOVED THAT THE BLOOD GLUCOSE MONITORS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BEGAY-BRUNO. THE MOTION PASSED UNANIMOUSLY.

Mr. Riley stated that the meeting was going into a closed session and thanked all the manufacturers that were present for the meeting. It was determined that the committee would take a 10-minute break.

The meeting moved into closed session. The public telephone lines were disconnected.

Break from 10:55 to 11:05 am.

5. Review minutes from April 2022

There were no changes to the meeting minutes of April 2022.

DR. DORAN-ATCHISON MOVED TO APPROVE THE MEETING MINUTES OF APRIL 2022. SECONDED BY DR. PHILLIPS, THE MOTION PASSED UNANIMOUSLY.

6. Other Business

There was no other business.

7. Comments from Committee Members or Chair

Dr. Semling asked if there were any other comments. As there were not, he reminded everyone of the next meeting on November 18, 2022.

8. Adjourn

DR. PHILLIPS MOVED TO ADJOURN THE MEETING. WITHOUT OBJECTION, THE MEETING WAS ADJOURNED.

The meeting adjourned at 10:21 AM.