Alaska Medicaid Pharmacy and Therapeutics Meeting

MINUTES OF MEETING
September 15, 2023

Committee Members Present:
John Riley, PA, Acting Chairman
Charles Semling PharmD, DHSS
Casey Gokey
Sarah Doren-Atchison, PharmD
Valarie Bixler, PharmD
Claudia Phillips, MD
Charles Ryan, MD
Trisha White, R.Ph.

Committee Members Absent:
Robert Carlson, MD

Others Present:
Ryan Ruggles, Pharm D
Umang Patel
Erin Nowak, AbbVie
Alisa Nguyen, Azeri Pharmaceuticals
Nirmal Ghuman, Janssen
Stuart O'Brochta, Gilead
Mandeep Sohul, Teva
Ray Kong, Newark and Bio Sciences Medical Affairs

1. Call to Order – Chair

Mr. Riley called the meeting to order.

2. Roll Call

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

3. Public Comments - Local Public/Health Practitioners

None.

4. Class Review, Discussion & Vote

4-A. Gastrointestinal: Anti-emetics/Anti-vertigo (green), GI Motility/Irritable Bowel Syndrome, Chronic (blue), Ulcerative Colitis (green), Cytokine & Cell-Adhesion Molecules (CAM) Antagonist – GI indicated (red), Proton Pump Inhibitors (blue)

Anti-Emetics/Anti-Vertigo (Green Class)

Umang Patel gave the Magellan presentation for anti-emetic and anti-vertigo. Given there was nothing new on this he went directly to utilization where roughly 99 percent was in line with the PDL.

Previous motion Dr. Phillips moved the drug in the class were therapeutic alternatives. Seconded by Dr. Doren-Atchison. The motion passed unanimously.

DR. RYAN MOVED THE SAME MOTION AS LAST YEAR. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

GI Motility/Irritable Bowel Syndrome, Chronic (Blue Class)

Public Comments for GI Motility/Irritable Bowel Syndrome, Chronic (Blue Class)

ERIN NOWAK, medical outcomes and science liaison with medical affairs at AbbVie., spoke on linaclotide otherwise known as Linzess. It is a guanylate cyclase-C agonist indicated for the treatment of adults with irritable bowel syndrome with constipation and chronic idiopathic constipation. She is thankful that linaclotide is available on the PDL. One update to share is that in June of 2023 linaclotide was approved for the treatment of functional constipation in pediatric patients ages 6 – 17 years making it the first FDA approved treatment for this indication. The recommended FDA approved dose is 72 mcg once daily. Functional constipation is a common gastrointestinal disorder in pediatric patients with a prevalence in the US of 14.1 percent in those 4 years of age and older. In the pivotal 12 week double blind placebo controlled trial of 328 pediatric patients linaclotide 72 mcg demonstrated significant improvement compared to placebo and the primary endpoint of * 12 week mean change from baseline in spontaneous bowel

movements. Spontaneous bowel frequency improved during week 1 and was maintained out to the 12 week treatment period. The most common adverse event in clinical trial was diarrhea and linaclotide has a boxed warning for risk of serious dehydration and is contraindicated in patients less than 2 years of age. It is also contraindicated in patients with known or suspected mechanical GI obstruction. For complete safety and efficacy information please refer to the study information. She asked that the prior authorization criteria be updated for the new indication of pediatric functional constipation.

Umang Patel gave the Magellan presentation for GI motility and irritable bowel syndrome, chronic. He started by giving the disease state description for both diseases. In 2022, guidelines for both IBS-C and IBS-D the panel provides a strong recommendation for the use of linaclotide in IBS-C over no drug treatment, Tenapanor, plecanatide and lubiprostone and suggested in IBS-C management with moderate certainty over no drug treatment. The panel also conditionally suggests the use of polyethylene glycol laxatives for IBC-C over no drug treatment. For IBS-D the suggestions for this are the use of eluxadoline, rifaximin and alosetron over no drug treatment. TSAs and antispasmodic agents are conditionally suggested with low certainty for IBS-C and IBS-D over no drug treatment. The panel suggests against the use of SSRIs for IBS-C and IBS-D treatment. The AGA also indicated that patients with mild symptoms often respond to dietary changes such as increasing fiber intake and reducing exposure to intolerant foods while pharmacologic intervention is typically reserved for patients with moderate to severe symptoms.

In June 2023, the FDA approved Linzess for treatment of functional constipation in pediatric patients ages 6-17 years of age. There were no changes to limitations, dosing or formulations.

In February 2023, the FDA approved the first generic to Allergan's Linzess capsules from Aurobindo.

Utilization shows that 75 percent is in line with PDL. Previously Mr. Riley moved the drugs in the class were therapeutic alternatives. This was seconded by Dr. Phillips and passed unanimously.

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

Ulcerative Colitis (Green Class)

Umang Patel gave the Magellan presentation on ulcerative colitis. Utilization is roughly 77 percent in line with PDL. Previous motion Dr. Ryan moved the drugs in the class were therapeutic alternatives and 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.

DR. RYAN MOVED THE SAME MOTION, SECONDED BY TRISH WHITE. THE MOTION PASSED UNANIMOUSLY.

Cytokine & Cell-Adhesion Molecules (CAM) Antagonist – GI indicated (Red class)

Public comments for Cytokine & Cell-Adhesion Molecules (CAM) Antagonist – GI indicated (Red class)

ERIN NOWAK, medical outcomes and science liaison with medical affairs at AbbVie., spoke on risankizumab also known as Skyrizi and upadacitinib also known as Rinvoq. Risankizumab is indicated for moderately to severely active Chron's disease in adults and met both primary end points of clinical remission and endoscopic response at week 12 and 52. It is contraindicated in patients with a history of serious hypersensitivity to risankizumab or accipients. She referred to the prescribing information for full efficacy and safety information. Upadacitinib is an oral JAK inhibitor that is indicated for the treatment of moderately to severely active Crohn's disease and ulcerative colitis in adults who have had an inadequate response or tolerance to one or more TNF blockers. Crohn's disease is the latest and seventh indication for upadacitinib and it met both primary endpoints of clinical remission and systemic response at weeks 12 and 52 versus placebo. Clinical response was seen in as early as 2 weeks. Again, she referred to the full prescribing and safety information online including the box warning. Upadacitinib is an oral option for IBD and is the first JAK inhibitor and oral advanced treatment option for Crohn's disease. Having an oral advanced therapy for IBD on the Alaska PDL may be advantageous for Alaskan's living in rural areas. She closed in asking that both risankizumab and upadacitinib be added to the state preferred drug list for these indications.

Umang Patel gave the Magellan presentation on cytokine and CAM antagonists GI class. They are chemical mediators involved in inflammatory processes throughout the body. He gave the disease state description of cytokines and CAMs. Next, he went on to give the disease state description of ulcerative colitis. Ulcerative colitis is a chronic inflammatory disease primarily affecting the colon and rectum. UC affects approximately 100,000 people in the US and the incidence continues to increase worldwide. The CDC estimates that the current prevalence of UC to be at 249 per 1,000,000 adults. UC may present at any age but onset typically peaks between 15 and 30 years of age. The disease is characterized by superficial infiltration of the bowel wall by inflammatory white cells resulting in multiple mucosal ulcerations and cyst abscesses. The predominant symptom of UC is diarrhea which is usually associated with blood in the stool. Additional symptoms may include pain in the lower quadrant or rectum along with systemic features including fever, malaise and weight loss which are more common if a greater portion of the colon is affected. The initial attack of UC may be fulminant with bloody diarrhea but the disease more commonly begins incidentally with non-bloody diarrhea progressing to bloody diarrhea. UC can present initially with any extent of anatomic involvement ranging from disease confined to the rectum to the entire large intestine (pancolitis). Most commonly UC follows a chronic intermittent course with long periods of quiescence interspersed with acute attacks lasting weeks to months. However, a significant percentage of patients suffer a chronic continuous course.

In 2021, the AGA issued a guideline on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease and notable recommendations regarding agents within this class are described. In adults outpatients with moderate to severe CD the AGA recommends the use of TNF antagonists or ustekinumab over no treatment for the induction and maintenance of remission and the AGA suggests the use of vedolizumab over no treatment for induction for moderate evidence and maintenance of remission for low and moderate evidence. In biologic treatment-naïve adult outpatients with moderate to severe CD the AGA recommends the use of infliximab, adalimumab or ustekinumab (moderate evidence) over certolizumab pegol (low evidence) and suggests the use of vedolizumab over certolizumab pegol for the induction of remission. In adult outpatients with moderate to severe CD who never responded to TNF antagonists the AGA recommends ustekinumab (moderate evidence) and suggests vedolizumab (low evidence) over no treatment of the induction of remission. If patients had previously responded to infliximab and the AGA recommends adalimumab or ustekinumab (moderate evidence for both) and suggests vedolizumab (low evidence) over no treatment for the induction of remission. The group also recommends the use of biologic drug monotherapy over thiopurine monotherapy for the induction of remission (moderate evidence). In adult outpatients with moderate to severe CD who are treatment-naïve to biologics and immunomodulators the AGA suggests infliximab plus thiopurines over infliximab monotherapy (moderate evidence) and adalimumab plus thiopurines over adalimumab monotherapy (very low evidence) for induction and maintenance remission. The AGA does not make recommendations regarding the use of ustekinumab or vedolizumab as monotherapy or in combination with another agent. For those with an active perianal fistula the AGA recommends infliximab over no treatment for the induction and maintenance of fistula remission (low evidence). Risankizumab-rzaa and upadacitinib were not approved for CD at the time these guidelines were developed. The role of natalizumab (Tysabri) and other agents not in this therapeutic class are also addressed in the guidance.

Drug specific updates were discussed next. Several adalimumab (Humira) biosimilars have launched per manufacturer press releases. These commercially available Humira biosimilars on the market include: adalimumab-adbm (Cyltezo) from Boehringer Ingelheim, adalimumab-bwwd (Hadlima) from Organon, adalimumab-fkjp (Hulio) from Biocon, adalimumab-adaz (Hyrimoz) high-concentration from Sandoz, adalimumab-aacf (Idacio) from Fresenius Kabi, adalimumab-aaty (Yuflyma) from Celtrion and adalimumab-aqvh (Yusimry) from Coherus. All products are available as a low-concentration formulation except Hyrimoz and Yuflyma. Hadlima, Hyrimoz and Yuflyma are available as high concentration formulation. Citrate free formulations include Cyltezo, Hadlima (high concentration), Hulio, Hyrimoz (high concentration), Idacio, Yuflyma and Yusimry. Cyltezo is interchangeable with Humira. The citrate free biosimilar adalimumab-atto (Amjevita) launched earlier in 2023.

In August 2022, The FDA approved Amjevita/Abrilada for the use in patients as young as 2 years of age for polyarticular JIA and in those as young as 6 years of age for CD. He went through all indications, precautions, dosing and formulations.

In December 2022, the FDA approved Idacio, a biosimilar to Humira for the treatment of RA, JIA, PsA, AS, CD, UC and PSO. He went through all indications, precautions, contraindications, dosing and formulations.

In March 2023, the FDA approved Yusimry, a Humira biosimilar, as a pre-filled auto injector pen for the treatment of RA, JIA, PsA, AS, CD, UC, PS and HS. He discussed the indications, precautions, contraindications, dosing and formulations.

In March 2023, the FDA approved Hyrimoz, a citrate free Humira biosimilar, as a high-concentration formulation for the treatment of RA, JIA, PsA, AS, CD, UC, Ps and HS. He discussed the available formulations as well as the indications, precautions, contraindications and dosing.

In May 2023, the FDA approved Yuflyma, a biosimilar to Humira, for the treatment of RA, JIA, PsA, AS, CD, US, PsO and HS. He discussed the indications, precautions, contraindications, dosing and formulations.

In May 2023, the FDA approved Rinvoq for adults with moderately to severely active CD who have had an inadequate response or intolerance to one or more tumor necrosis factor blockers. He discussed the indications, precautions, contraindications, dosing and formulations.

In May 2023, the FDA approved Cosentyx as a prefilled syringe or autoinjector pen. He discussed the indications, precautions, contraindications, dosing and formulations.

Roughly 75 percent is in line with PDL. Previous motion Dr. Phillips moved that the drugs in the class were a therapeutic alternative. This was seconded by Dr. Ryan and passed unanimously.

DR. PHILLIPS MOVED THE DRUGS WERE THERAPEUTIC ALTERNATIVES, SECONDED BY DR. RYAN. THE MOTION WAS PASSED UNAMIMOUSLY.

Proton Pump Inhibitors (Blue Class)

Public comments for Proton Pump Inhibitors (Blue class)

ALISA NGUYEN, specialist of medical affairs at Azurity Pharmaceuticals. She presented konvomep which she believes delivers an unmet medical need particularly for patients who require omeprazole in liquid form that enables flexible dosing and does not require compounding or crushing. It is the only FDA approved sodium bicarbonate dispensed as an oral liquid. It is strawberry flavored and is compatible with nasal, gastric and orogastric tubes. It is indicated in adults for the treatment of active benign gastric ulcer and the reduction of risk of upper GI bleeding in critically ill patients. Omeprazole is the only proton pump inhibitor that is combined with sodium bicarbonate and antacid to obtain faster absorption and suppress gastric acidity faster than delayed release tablets. She discussed the trials that support the safety and efficacy of this drug. She then discussed the importance of having a liquid medication. For full prescribing and safety information she referred to the package insert.

Umang Patel gave the Magellan presentation on proton pump inhibitors. He went over the disease state description and guidelines of proton pump inhibitors.

In September 2022, the FDA approved konvomep oral suspension containing 2 mg omeprazole and 84 mg sodium bicarbonate per mL after reconstitution packaged as a kit containing 1 bottle of omeprazole and 1 bottle of strawberry flavored diluent containing sodium bicarbonate. He discussed the indications, precautions, contraindications, dosing and formulations.

Utilization was roughly 97 percent in line with the PDL. Previous motion, Dr. Carlson moved that the drugs in the class were therapeutic alternatives. Seconded by Dr. Begay-Bruno. The motion passed unanimously.

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

4-B Endocrine/Metabolic: Antihyperuricemics (blue), Progestins for cachexia (green), Growth hormone (green), Androgenic Agents topical (green), Bone resorption inhibitors (blue), Glucagon agents (green), Hypoglycemic Metformin (green), hypoglycemics alpha-glucosidase (green), hypoglycemics, SGLT2 inhibitors (red), hypoglycemic Meglitinides (green), hypoglycemics thiazolidinedione (TZD) and combinations (green), hypoglycemics dipeptidyl peptidase-4 inhb (DPP4) and combinations (green) and hypoglycemics glucagon like peptide-1 (GLP-1) and combinations (blue)

Antihyperuricemics (Blue class)

Uman Patel gave the Magellan presentation on antihyperuricemics. Hyperuricemia can occur due to either an overproduction of uric acid, an underexcretion of uric acid or a combination of the two mechanisms. He discussed the disease state description for gout as well as the treatment management of gout.

In July 2022, labeling for pegloticase (Krystexxa) was updated to include details for coadministration of methotrexate in the treatment of chronic gout. Pegloticase is indicated for the treatment of chronic gout in adult patient's refractory to conventional therapy and labeling previously provided details for use only as monotherapy. He gave the precautions, contraindications, dosing and formulations.

Roughly 96 percent in line with PDL. Previous years motion Dr. Ryan moved the drugs in the class were therapeutic alternatives. This was seconded by Dr. Phillips and passed unanimously.

DR. PHILLIPS PROPOSED LAST YEARS MOTION. SECONDED BY DR. RYAN. THE MOTION PASSED UNANIMOUSLY.

Progestins for Cachexia (Green Class)

Umang Patel went directly to utilization due to this being a green class. Roughly 96 percent were in line with PDL. Previous motion Dr. Ryan moved a class effect. Seconded by Dr. Phillips. Motion passed unanimously.

DR. RYAN MOVED THE SAME MOTION. SECONDED BY DR. PHILLIPS. THE MOTION PASSED UNANIMOUSLY.

Growth Hormone (Green Class)

Umang Patel went directly to utilization given this is a green class.

Utilization was a bit different with this class due to it being growth hormone. He listed the actual prescription information for the committee to review. Roughly 84 percent was in line with PDL. Previously Dr. Carlson moved a class effect, seconded by Dr. Phillips and passed unanimously.

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

Androgenic Agents, Topical (Green Class)

Umang Patel again went directly to utilization given this is a green class.

The PDL has shifted to almost all non-PDL. This is largely due to generics in both this utilization and the one year utilization that the committee has access to. The previous motion Dr. Ryan moved a class effect, seconded by Dr. Phillips. Passed unanimously.

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

Bone Resorption Inhibitors (Blue Class)

Umang Patel gave the Magellan presentation on bone resorption inhibitors. He gave the disease state description for osteoporosis.

In 2023, the ACP published an update to the 2017 guidelines for the treatment of low bone mass and primary osteoporosis to prevent fractures in adults. ACP recommends physicians offer bisphosphonates for initial treatment of postmenopausal women with primary osteoporosis to reduce the risk of fractures and men with primary osteoporosis. Denosumab is suggested second line as an option in postmenopausal women or men with primary osteoporosis for whom bisphosphonates are not appropriate or who experience adverse effects with bisphosphonates. In postmenopausal women with a very high risk of fracture ACP suggests romosozumab or teriparatide followed by a bisphosphonate.

In 2022, the bone health and osteoporosis foundation recommended a treat to target approach to therapy that includes a specific bone mass density goal and no fractures. A follow up bone density measure with a dual energy DEXA scan should be conducted after 1 year of initial therapy or change in therapy however intervals between scans may be extended once chronic treatment has been established. The guidelines recognize all medications approved by the FDA

for the prevention and/or treatment of osteoporosis at the time of publication as possible options. Umang went on to discuss the indication and use for each single or combination therapies.

In December 2022, the FDA approved abaloparatide (Tymlos) for the use in men with osteoporosis at high risk for fracture defined as a history of osteoporosis fracture or multiple risk factors for fracture or patients who have failed or are intolerant to other osteoporosis therapies. He gave the indications, precautions, dosing and formulations.

Roughly 95 percent in line with the PDL. Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives. Seconded by Dr. Phillips (unsure as the prior minutes are blurry). Motion passed unanimously.

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

Glucagon Agents (Green Class)

Umang Patel gave the Magellan presented glucagon agents. Since this is a green class, he went directly into utilization.

Utilization was roughly 98 percent in line with the PDL. Previous motion Dr. Ryan moved a class effect to include nasal formulation, seconded by Dr. Phillips. Motion passed unanimously.

DR. PHILLIPS MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE A NASAL FORMULATION, SECONDED BY DR. RYAN. THE MOTION PASSED UNAIMOUSLY.

Hypoglycemics, Metformin (Green Class)

Umang Patel gave the Magellan presentation on hypoglycemics metformin. Again, this is a green class so he went right into utilization.

Utilization was roughly 98 percent in line with PDL. Previous motion Dr. Carlson moved the drugs in the class were therapeutic alternative, seconded by Dr. Begay-Bruno. Motion passed unanimously.

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

Hypoglycemics, Alpha-Glucosidase Inhibitors (Green Class)

Umang Patel gave the Magellan presentation on hypoglycemics alpha-glucosidase inhibitors. This is a green class so he went right to utilization.

Utilization shows 100 percent in line with PDL. Previous motion Dr. Phillips moved a class effect, seconded by Dr. Doran-Atchison. Motion passed unanimously.

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

Dr. Semling stated that he feels for next year if the committee is okay with it they can remove this class allowing no preferred drug. No discussion was had on this comment. Hearing no discussion John Riley took a vote. This passed unanimously.

Hypoglycemia, SGLT2 Inhibitors (Red Class)

Umang Patel gave the Magellan presentation on hypoglycemia SGLT2 inhibitors. He started with giving the disease state description of diabetes mellitus.

In 2022, the AHA published a scientific statement on comprehensive management of CV risk factors for adults with type 2 diabetes mellitus. In terms of drug therapy eight loss medications are discussed as adjuncts to diet, physical activity and behavioral therapy for certain patients with type 2 diabetes mellitus and a BMI greater than 27 kg/m². The FDA approved drugs for weight management with CV safety and A1c lowering include orlistat, lorcaserin, liraglutide, naltrexone/bupropion sustained release and phentermine/topiramate. Although long term CV event reduction has not been evaluated, notable CV risk reduction has been demonstrated for liraglutide at lower doses in patients with ASCVD or high CV risk. Additionally, once weekly semaglutide 2.5 mg has also shown weight loss and CV risk factor improvement. It is FDA approved for chronic weight management in adults with a BMI of 30 kg/m² or a BMI greater than 25 kg/m² with a comorbid condition. The CV outcome trial data for newer antihyperglycemics agents is also reviewed. Selection of diabetes agent should be individualized based on the patients' risk and preferences. Blood pressure management, lipid lowering and antithrombotic therapy are also addressed.

In 2022, the ACC/AHA/HFS published guidelines for the management of heart failure. SGLT2 inhibitors were given a 2a recommendation in HF with mildly reduced ejection fraction with weaker recommendations (2b) in this population for other agents. For HFpEF SGLT2 inhibitors received a 2a recommendation, mineralocorticoid receptor antagonists a 2b recommendation and angiotensin receptor-neprilysin inhibitors a 2b recommendation.

In 2023, the AACE updated their algorithm and separated the recommendation into complication centric algorithms and glucose algorithms. They emphasized a comprehensive approach including individualized targets for weight loss, glucose, lipid and antihypertension management. They support an A1c target of less than 6.5 for most patients if it can be reached without substantial hypoglycemia or other adverse events. Therapy choice is guided by comorbidity rather than by glycemic target. In all cases, a drug that has proven CV benefit is recommended. For these patients' metformin can also be initiated or continue to achieve glycemic targets. In the glucose centric algorithm patients with who require glycemic control should begin with lifestyle therapy plus metformin if appropriate and additional therapies may be added to achieve A1c target based on individual lives and patient factors. For those who are overweight, obese or

at risk for hypoglycemia a GLP or dual GLP/GIP receptor agonist or SGLT2 inhibitor is preferred. For patients with cost or access issues a TZD sulfonylurea or meglitinide is preferred. For patients with severe hyperglycemia basal insulin is preferred in combination with either prandial insulin or a GLP-1RA or dual GLP-1/GIP receptor agonist.

In 2021, the ADA stated that in patients using ambulator glucose profile/glucose management indicator to assess glycemia, a parallel goal is a time in range of greater than 70 percent with time below range les than 4 percent. During pregnancy, the ADA recommends, a target HbA1c of 6 – 6.5 percent is reasonable but can be adjusted based on hypoglycemia risk and more frequent monitoring may be required. For diabetes technology an automated insulin delivery system should be considered in adults with type 1 diabetes mellitus who have the skills to use the device in order to improve time in range and reduce A1c and hypoglycemia. These systems may also be useful to improve glycemia in children. Regarding obesity management, ADA states that lorcaserin should no longer be used as the FDA requested its market withdrawal. For pharmacologic type 2 diabetes mellitus therapy the ADA advises to interrupt SGLT2 inhibitor therapy before scheduled surgery to avoid diabetic ketoacidosis, this alights with label revisions for SGLT2 inhibitors. For management of CVD in patients with type 2 diabetes mellitus the ADA advises to consider an SGLT2 inhibitor in patients with HF with reduced ejection fraction to reduce the risk of worsening HF and CV death.

In 2023, the ADA standards of care in diabetes recommends initiation of pharmacologic therapy along with lifestyle change, at the time of diagnosis for children with type 2 diabetes mellitus. Metformin is recommended first line for asymptomatic children with an HbA1c of less than 8.5 percent while those with marked hyperglycemia and an HbA1c greater than 8.5 percent should be initiated on metformin along with long acting insulin. If HbA1c goals are not met with metformin (alone or combined with long acting insulin) the addition of a GLP-1RA approved for youth with type 2 diabetes mellitus should be considered in patients greater than 10 years of age. Patients who do not meet glycemic targets despite treatment with metformin, a GLP-1RA and long acting insulin should then be initiated on multiple daily insulin injections or an insulin pump. The current ADA guidelines do not discuss the use of SGLT2 inhibitors in children with type 2 diabetes mellitus.

In January 2023, the FDA approved bexagliflozin or Brenzavvy, the SGLT2 inhibitor as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. He discussed the indications, precautions, dosing and formulations.

In May 2023, the FDA approved dapagliflozin, Farxiga, as an expanded indication for dapagliflozin to reduce the risk of CV death, hospitalization for heart failure and urgent heart failure visit in adults with heart failure. Previously it was indicated to reduce the risk of CV death and hospitalization for heart failure in adults with heart failure with a reduced ejection fraction as NYHA class 224. The other indications are as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes, to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes and either established CV disease or multiple CV risk factors and to reduce the risk of sustained GFR decline, end stage kidney disease, CV death and hospitalization for heart failure in adults with chronic kidney disease at risk of progression. There were no changes to the precautions, dosing or formulation.

In May 2023, the FDA approved sotagliflozin, Inpefa, a dual SGLT1/SGLT2 inhibitor to reduce the risk of CV death, hospitalization for heart failure and urgent heart failure visits in adults with type 2 diabetes, chronic kidney disease and other CV risk factors. He then discussed indications, precautions, dosing and formulations.

In February 2023, a new indication for empagliflozin/metformin, Synjardy, has been added to state that the empagliflozin component is indicated to reduce the risk of CV death and hospitalization for heart failure in adults with heart failure. In June 2023 it was approved for an expanded indication as adjunct to diet and exercise to improve glycemic control in pediatric patients greater than 10 years of age with type 2 diabetes mellitus. It was previously only approved for use in adults. Precautions and dosing are the same. Formulations were changed and reviewed.

In June 2023 Jardiance, empagliflozin, was approved for an expanded indication as adjunct to diet and exercise to improve glycemic control in pediatric patients 10 years of age or older with type 2 diabetes mellitus. It was only previously approved for use in adults. Indications, precautions, dosing and formulations were reviewed.

Utilization was almost 98 percent in line with PDL. Previous motion Dr. Phillips moved a class effect to include at least one medication that decreases cardiovascular risks and at least one that shows renal protective effect, seconded by Dr. Ryan. Motion passed unanimously.

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

Hypoglycemics, meglitinides (Green Class)

Umang Patel gave the Magellan presentation on hypoglycemics meglitinides and since this is a green class he went right into utilization.

Utilization is 100 percent NOT in line with PDL. This was described as being because the pool of drugs is very small for this class. Previous years motion Dr. Phillips moved a class effect. Seconded by Dr. Doran-Atchison. Motion passed unanimously.

Charles Semling stated this is another class that he feels does not need to be managed anymore since there are only two drugs in the class. After this meeting they should all be included instead of being reviewed. No one was opposed to this.

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

Hypoglycemics, Thiazolidinedione (TZD) and combinations (Green Class)

Umang Patel gave the Magellan presentation on hypoglycemics thiazolidinedione (TZD) and combinations. This again is a green class so they went right into utilization.

Utilization is approximately 99 percent in line with PDL. Previous motion Dr. Ryan moved a class effect. This was seconded by Dr. Carlson and passed unanimously.

DR. RYAN MOVED A CLASS EFFECT, DR. PHILLIPS SECONDED THAT. THE MOTION WAS PASSED UNANIMOUSLY.

Hypoglycemics, DPP-4's and combinations (Green Class)

Umang Patel gave the Magellan presentation on hypoglycemics DPP-4's and combinations. This too was a green class so they went right into utilization.

Utilization was approximately 87 percent in line with PDL. Previous motion, Dr. Phillips moved a class effect. Seconded by Dr. Doran-Atchison and passed unanimously.

DR. PHILLIPS MOTIONED A CLASS EFFECT, WAS SECONDED BY CASEY GOKEY. THE MOTION WAS PASSED UNANIMOUSLY.

Hypoglycemics, Glucagon-like Peptide-1 (GLP-1) and Combination (Blue Class)

Umang Patel gave the Magellan presentation on hypoglycemics, glucagon like peptide-1 (GLP-1) and combinations.

October 2022, the FDA approved semaglutide, Ozempic, as a new presentation of the pen injector. 2 mg/3 mL (0.68mg/mL) that delivers 0.25 mg or 0.5mg per injection. Previous approved presentations include single patient use pens 2 mg/1.5 mL (1.34 mg/mL) that delivers 025 mg or 0.5 mg per injection, 4 mg/3 mL (1.34 mg/mL) that delivers 1 mg per injection and 8 mg/3 mL (2.68 mg/mL) that delivers 2 mg per injection. He reviewed the previous indications, precautions, dosing and formulations.

January 2023, the FDA approved the updated labeling of semaglutide, Rybelsus, for 7 mg and 14 mg tablets allowing use for first line treatment of type 2 diabetes mellitus in adults. For Ozempic, Rybelsus and Wevogy the FDA released drug safety information regarding medications containing semaglutide marketed for type 2 diabetes or weight loss. They received reports of compounded products using sodium and acetate salt, forms of semaglutide, which have different active ingredients from the approved semaglutide products. The FDA advises patients should not use a compounded drug if an approved drug is available to treat a patient.

In February 2023, Adlyxin, lixisenatide, was discontinued by Sanofi. Product expiration is September 30, 2023. No generics are available.

Utilization was roughly 96 percent in line with PDL. Previous motion Dr. Ryan moved a class effect to include at least one weekly injection product, seconded by Dr. Begay-Bruno and passed unanimously.

DR. RYAN MOVED A CLASS EFFECT TO INCLUDE AT LEAST ONE WEEKLY INJECTION PRODUCT AND ONE ORAL PRODUCT, SECONDED BY CASEY GOKEY. THE MOTION WAS PASSED UNANIMOUSLY.

Rapid Acting Insulin (Blue Class)

Umang Patel gave the Magellan presentation on rapid acting insulin.

In October 2022, the indication for Lyumjev to improve glycemic control in diabetes was expanded to include pediatric patients. No changes to precautions, dosing, formulations or indications.

In June 2023, Fiasp was approved by the FDA as a 1.6 mL PumpCart cartridge for use in compatible insulin pumps. No other changes.

Utilization was roughly 92 percent in line with the PDL. Previous motion Dr. Ryan moved a class effect, seconded by Dr. Phillips. The motion passed unanimously.

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

Regular Insulins (Green Class)

Umang Patel gave the Magellan presentation on regular insulins. This is a green class so they moved right into utilization.

Utilization was about 100 percent NOT in line with PDL due to a very small overall denominator for prescriptions for this one. Previously Dr. Ryan moved a class effect. This was seconded by Dr. Begay-Bruno and passed unanimously.

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

Intermediate Insulins (Green Class)

Umang Patel gave the Magellan presentation on intermediate insulins. Again, this is a green class so they moved directly to utilization.

Utilization was 100 percent in line with PDL. Previous motion Dr. Phillips moved a class effect, seconded by Dr. Doran-Atchison. The motion passed unanimously.

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

Rapid/Intermediate Acting Combination Insulins (Green Class)

Umang Patel gave the Magellan presentation on rapid/intermediate acting combination insulins. This too was a green class so they moved into utilization.

Utilization was 100 percent in line with PDL. Previously Dr. Ryan moved a class effect. Seconded by Dr. Begay-Bruno seconded and this passed unanimously.

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

Regular/Intermediate Acting Combination Insulins (Green Class)

Umang Patel gave the Magellan presentation on regular/intermediate acting combination insulins. This is a green class so they went right into utilization.

Utilization was approximately 80 percent in line with PDL. Previously Dr. Phillips moved a class effect. Dr. Doran-Atchison seconded and this passed unanimously.

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

Long Acting Insulins (Blue Class)

Umang Patel gave the Magellan presentation on long acting insulins.

In November 2022, Rezvogler was approved by the FDA as the second biosimilar insulin product to Lantus. It has all of the same dosing, indications, precautions and formulations. Indication is to improve glycemic control in adult and pediatric patients with type 1 diabetes and adults with type 2 diabetes similar to all insulins it is not recommended to treat diabetic ketoacidosis.

Utilization was approximately 85 percent in line with PDL. Previously Dr. Ryan moved a class effect, seconded by Dr. Phillips and this passed unanimously.

DR. RYAN MOVED A CLASS EFFECT. DR. DORAN-ATCHISON SECONDED THAT MOTION. THE MOTION WAS PASSED UNANIMOUSLY.

Continuous Glucose Monitors (Blue Class)

Umang Patel gave the Magellan presentation on continuous glucose monitors.

Dexcom G7 Glucose Monitor was discussed including indications, sensor-site locations, glucose range, sensor and transmitter size, reader and features.

There is no market basket because this falls under a different program called the Diabetic Supply Program therefore there is no utilization. There was no utilization in 2022 either. Previously Dr.

Ryan moved the blood glucose meters in the class were therapeutic alternatives. Seconded by Dr. Begay-Bruno. The motion passed unanimously.

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

Phosphate Binders (Green Class)

Umang Patel gave the Magellan presentation on phosphate binders. This is a green class so they went directly to utilization.

Utilization is roughly 71 percent in line with PDL. Previous motion Dr. Phillips moved the drugs in the class were therapeutic alternatives, seconded by Dr. Doran-Atchison. The motion passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS ARE THERPEUTIC ALTERNATIVES. DR. DORAN-ATCHISON SECONED THAT MOTION. THE MOTION WAS PASSED UNANIMOUSLY.

4-C Antiretrovirals: HIV/AIDs (red)

HIV/AIDs (Red Class)

Public comments HIV/AIDs (Red class)

NIRMAL GHUMAN, Pharmacist and Principal Scientific Account Lead with Janssen Scientific Affairs. She wanted to take the time today to discuss Symtuza. Symtuza is a once daily single tablet regimen indicated at a complete regimen for the treatment of HIV once infection in adults and pediatric patients who are treatment naïve or are virologically suppressed on a stable antiretroviral regimen for at least 6 months and have no darunavir or tenofovir resistance mutations. She directed everyone to view the full prescribing information for complete information. The Department of Health and Human Services recommends access to all classes of HIV medication. Darunavir is the only PI that is DHHS recommended in certain clinical situations with an A1 level of evidence due to its high genetic barrier to resistance and better tolerability profile compared with other PIs. A darunavir based regimen such as Symtuza is recommended for rapid initiation, patients with unknown resistance profiles, patients who may have adherence issues and patients who have received cabotegravir for PrEP. Incomplete adherence to antiretroviral regimens is a critical factor contributing to treatment failure and the development of drug resistance. Medicaid patients with suboptimal adherence to antiretroviral therapy have been shown to have a significantly higher total number of dates spent at the hospital, more long term care admissions and higher mean monthly medical costs compared to those with optimal adherence. Single tablet regimens have been associated with better adherence when compared to multi tablet regimens. In fact, a retrospective study found patients initiating Symtuza had higher adherence rates than those starting Prezcobix plus Descovy. Some antiretrovirals have been associated with significant weight gain, especially in female, black and

Hispanic patients which can lead to an increased incidence of cardiovascular disease or diabetes. In the two pivotal phase 3 trials patients on Symtuza gained, on average, less than or equal to 2 kg over 96 weeks and no new cases of type 2 diabetes related to studies were ever reported. Two retrospective studies assessed differences in weight and BMI changes among treatment naïve and treatment experienced adult patients following the initiation of Symtuza of Biktarvy. In both studies greater weight and BMI increases were seen in patients receiving Biktarvy than in those receiving Symtuza. Symtuza was also studied in a rapid initiation. The DIAMOND trial was a phase 3 open label single arm study which assessed the efficacy and safety of Symtuza in newly diagnosed HIV-1 infected treatment naïve patients. At week 48 in the intend to treat population 92 of 109 or 84 percent of patients achieved HIV-1 RNA less than 50 copies per mL. The most common adverse events were diarrhea, nausea, rash, vomiting and fatigue. In summary, Symtuza provides high efficacy rates, a strong genetic barrier to resistance, a favorable tolerability profile, the convenience of a single tablet regimen and is recommended in the DHHS guidelines. She thanked everyone for her time and informed them that she is available for any questions.

STUART O'BROCHTA, Executive Medical Scientist at Gilead. He wanted to discuss some of the clinical characteristics of Sunlenca or lenacapavir. This is the newest antiretroviral for the treatment of people living with HIV who are heavily treatment experienced for HTE and failing their current regimen with multiclass resistance. Sunlenca is the first in class capsid inhibitor approved for the treatment of people living with HIV who are HTE and multiclass ARV resistant. Sunlenca is dosed as two subcutaneous injections administered only every 6 months, but in combination with an optimized background and OVR of antiretroviral regimens. Sunlenca requires an oral lead in with 2 prescribing options to provide appropriate PK loading. It is important to note that the HTE population in need of this new therapy is estimated to be close to 1 percent of the people living with HIV. While its small subset of the total US HIV population this is a significant unmet need since these patients have limited or no fully active antiretrovirals available to treat and suppress their HIV. Thus, putting them at risk for significant risk for serious consequences from an uncontrolled HIV infection. Sunlenca was approved based on the CAPELLA trial, the positive results of a randomized partially randomized placebo controlled double blind multicenter study in 72 patients living with HTE HIV. The high level results demonstrated that 80 plus percent of virologic control was seen below 50 copies in the 52 week trial. This result was also seen in the majority of patients that had no fully active ARVs in their optimized background regimen. Sunlenca does have activity against broad spectrum of the known site specific mutations of the four major classes of antiretroviral regimens making it an ideal option for this HTE population. Resistance was seen in 9 of the 72 patients but 4 had no fully active ARVs and the other 5 were not taking their regimen resulting in monotherapy. From the safety highlight they had only one DC which was due to an injection site reaction. The majority of AEs were mild to moderate with most being associated with ISRs. Based on the strength and importance of this data he requested that Sunlenca be added to the Alaska PDL and available to this small but important subset of patients. He referred to the Sunlenca package insert for complete safety and prescribing information. He informed the panel that he is available for any questions.

Umang Patel gave the Magellan presentation on HIV/AIDS. He started off with the overview of the disease state. HIV is a complex disease that results in destruction of the immune system of

the HIV infected individual. There are two major subtypes of HIV, HIV-1 and HIV-2. HIV-1 is most responsible for AIDS and is more common worldwide. HIV-2 is less transmissible however both are known to cause AIDS and are transmitted by sexual contact, blood and from mother to child. HIV-2 is more concentrated in West Africa. HIV retrovirus establishes infection by killing the CD4+T cells that are crucial to a healthy immune system. Without these CD4+T cells the immune system is vulnerable to infection. It is estimated that there were 37.7 million people living with HIV by the end of 2020 with 73 percent of adults and 54 percent of children receiving antiretroviral therapy globally. It is estimated that 30,635 new HIV infections occurred in the US in 2020 which is an 8 percent decline since 2015. It is estimated that 13 percent of people in the US with HIV do not know their status. In 2019 there were 15,815 deaths among people with diagnosed HIV in the US. Of new infections, approximately 66 percent are from male to male sexual contact, 23 percent from heterosexual contact and 7 percent from injection drug use. Minority groups in the US have been disproportionately affected by the HIV/AIDS epidemic. The perinatal transmission rate of HIV from mother to child has decreased by more than 95 percent since the early 1990s. A significant reason for the decrease in the US is routine testing of pregnant women during prenatal care and the provision of antiretrovirals during pregnancy and delivery. Despite perinatal transmission being the primary means of childhood HIV infection, the risk can be reduced less than 1 percent if recommended preventative measures are followed.

Next, he went on to discuss the treatment guidelines. The Department of Health and Human Services in 2023 released guidelines stating that clinical trials have shown that using effective ART to consistently suppress plasma HIV RNA levels to less than 200 copies per mL prevents transmission of HIV to sexual partners. Patients should use an alternative form of prevention with sexual partners for at least the first 6 months of treatment and until an HIV RNA level of less than 200 copies per mL have been documented. They recommend that CD4 counts are measured every 3 – 6 months during the first 2 years of therapy. Testing is then recommended every 12 months after 2 years. Drug resistance testing is recommended at entry. Guidelines also recommend mutation testing and notably patients should be screened for both Hepatitis B and Hepatitis C virus at entry into care as having the co-infection may impact the initiation of antiretroviral therapy.

Continuing with guidelines, he discussed that some are over a year old but they are helpful in the overall picture of treatment. He discussed the IAS 2020 guidelines. He then discussed the DHHS guidelines from 2023.

In December 2022, the FDA approved lenacapavir, Sunlenca, in combination with other antiretrovirals for the treatment of HIV-1 infection in heavily treatment experienced adults with multi drug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance or safety considerations. He discussed the indication, warning and precautions, dosage and availability.

Next, he went onto discuss discontinuations and those are as follows:

August 2022 - Hepsera – generic versions are available.
January 2023 - Trizivir – this is to cease on November 27, 2023.

January 2023 – Tivicav – Distribution will cease for the 10 mg and 25 mg tablets as of January 1, 2024; however, the 50 mg and PD 5 mg tablets will still be available.
January 2023 – Selzentry – Discontinuation of 25 mg and 75 mg tablets as of January 1, 2024, though 150 mg and 300 mg tablets as well as oral solution will remain available.
January 2023 – Lexiva – Lexiva will cease as of January 1, 2024.
February 2023 – Norvir – The 80 mg/mL oral solution has been discontinued.

In October 2022, the FDA approved the first generic to Janssen's 800 mg Prezista tablet as darunavir. It was approved as a 600 mg tablet strength.

In June 2023, the indication for the use of Triumeq PD tablets for oral suspension in the treatment of HIV-1 infection was changed to include pediatric patients greater than 3 months of age and weighing greater than 6 kg. He discussed the indications, warnings and precautions, dosage and availability.

Utilization was approximately 99 percent in line with PDL. Previously 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 following inhibitor classes: Nucleoside Reverse Transcriptase, Non-Nucleoside Reverse Transcriptase, Protease, and Integrase Transfer Inhibitors as well as at least one PrEP formulation and at least one pediatric approved product. This was seconded by Dr. Doran-Atchison and passed unanimously.

Dr. Phillips proposed this year that there were many more classes but she started with the same understanding that the access and options should be as broad as they have been and include therapeutic alternative to include one PrEP formulation but if they can only have one PrEP formulation, she stated it should be Truvada over Descovy because it has both pre and post exposure prophylaxis and of course include a pediatric product. To clarify she stated – Therapeutic options as long as it remains broad and open at least one PrEP formulation and one pediatric approved product.

Charles Semling verified that both of the PrEP products are currently preferred and he does not see any changes with that.

DR. PHILLIPS MOVED THAT ACCESS WOULD REMAIN OPEN THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE PREP FORMULATION AND ONE PEDIATRIC APPROVED PRODUCT, SECONDED BY DR. DORAN-ATCHISON. THE MOTION PASSED UNANIMOUSLY.

4-D Single Class Reviews: Movement Disorders (blue)

Movement Disorders (Blue Class)

MANDEEP SOHUL, Pharmacist with Teva in Medical Affairs. He is here to provide an update on Austedo XR, deutetrabenazine extended release tablet which were FDA approved and launched in May. This is a new formulation of Austedo which is now available for patients. Austedo and Austedo XR and indicated for tardive dyskinesia and Huntington's disease Chorea.

While Austedo is dosed twice daily Austedo XR is dosed once daily. It was developed based on patient and provider feedback and simplified the dosing schedule to once a day thereby reducing pill burden, plasma fluctuation and can be taken with or without food. It is available at 6, 12 and 24 mg tablets and provides a new option for patients. He did note that the Austedo dose twice daily will still be commercially available. Austedo XR was studied in three studies establishing bioequivalence, dose proportionality and food effect study indicating no effective food on Austedo XR. The efficacy was established in three 12 week double blind randomized placebo controlled multi centered trials and a total of 505 patients. Furthermore, acute three year long term open label extension studies showed no new safety signals and long term tolerability of Austedo. He reminded the committee that while there is a boxed warning for depression and suicidality in HD it does not apply for TD. It is only for HD where there is a high background rate of depression. In summary, Austedo XR provides a new option for patients which is a once a day formulation with a reduced plasma fluctuation that may be administered with or without food. He thanked the committee for including Austedo on the preferred drug list and he respectfully asked them to consider adding Austedo XR in the state of Alaska.

RAY KONG, Manager Liaison at Newark and Bio Sciences Medical Affairs Department. He is here today with a courtesy update on Ingrezza, valbenazine. It has a newly improved expanded indication for the treatment of adults with chorea associated with Huntington's disease in addition to the previously approved indication for tardive dyskinesia. He went on to explain Huntington's disease chorea and tardive dyskinesia. Ingrezza is approved as a once daily oral medication that can be given with or without food at anytime throughout the day. For HD the recommended dosing is to start at 40 mg once daily and increase in 20 mg increments every 2 weeks to the recommended dosage of 80 mg once daily. The safety and efficacy of Ingrezza was established in a phase 3 study known as CONNECT-HD. It is a randomized double blind placebo controlled study evaluating once daily valbenazine in 128 HD patients with associated chorea. Primary efficacy endpoint was a change in TMC score or total maximal chorea score between screening baseline to the maintenance period. It met its primary endpoint at week 12 and the improvement of TMC score was significantly greater with valbenazine versus placebo with a placebo adjusted mean reduction of 3.2 points. Improvements in the TMC score with valbenazine were seen as early as week 2 and continued throughout the dose adjustment and maintenance periods. There were no safety signals in the study for increased depression or suicidality in any dose groups. Important safety information includes a new black box warning for the use of Ingrezza specifically in patients with HD. The warning reads BMAT2 inhibitors including Ingrezza can increase the risk of depression and suicidal thoughts and behavior in patients with HD. Ingrezza is contraindicated in patients with a history of hypersensitivity to valbenazine or any of its components. Hypersensitivity including angioedema. The most common reported adverse reactions were somnolence, fatigue and fall. No dose adjustments are required for elderly patients or patients with renal impairment. Ingrezza has been studied to be an effective once daily treatment for patients with HD associated chorea as well as tardive dyskinesia. He requested that they put the new expanded indication to the current PDL policy. He is available for any questions.

Umang Patel gave the Magellan presentation on movement disorders. He started off with the disease state description and guidelines for Huntington's disease chorea.

In 2012, the AAN recommended tetrabenazine (up to 100 mg daily), amantadine or riluzole for chorea associated with HD. Guidelines state that neuroleptics may be reasonable options given the behavioral concerns; reserpine and deutetrabenazine are not addressed in the AAN guidelines. Guidelines advise that the decision by physicians and patients whether chorea requires pharmacologic treatment should consider matters such as mood disturbance, cognitive decline, drug adverse effects and polypharmacy risks. These guidelines were reaffirmed in 2015.

He then went onto discuss the disease state description for tardive dyskinesia.

In 2020, the APA updated their guidelines for the treatment of schizophrenia. They recommended routine assessment for TD in patients using antipsychotics. They state that deutetrabenazine or valbenazine is preferred over tetrabenazine due to the data supporting their use. Other factors should also be considered when selecting which agent is most appropriate for a specific patient.

In April 2021, the FDA approved a new formulation of deutetrabenazine once daily XR formulation in 6 mg, 12, mg and 24 mg tablets for the treatment of chorea associated with Huntington's disease and tardive dyskinesia. He discussed the indications, warnings, dosage and availability.

Utilization was roughly 93 percent in line with PDL. Previously Dr. Phillips moved the drugs in the class were therapeutic alternatives. Dr. Doran-Atchison seconded and this passed unanimously.

DR. RYAN MOVED THE DRUGS IN THE CLASS ARE THERPEUTIC ALTERNATIVES. DR. DORAN-ATCHISON SECONED THAT MOTION. THE MOTION WAS PASSED UNANIMOUSLY.

5. End of Public Meeting

6. Review Minutes from April 2023 meeting

There were no changes to the meeting minutes from April 2023.

DR. PHILLIPS MOVED TO APPROVE THE MEETING MINUTES OF APRIL 2023. SECONDED BY CASEY GOKEY. THE MOTION WAS PASSED BY ALL MEMBERS.

7. Comments From Committee Members

Charles Semling had a comment to state that due to the work they are doing they were able to save the state about 30 million dollars this past year.

8. Adjourn

DR. PHILLIPS MOVED TO ADJOURN THE MEETING. THE NEXT MEETING WAS SCHEDULE FOR NOVEMBER 17, 2023. WITHOUT OBJECTION, THE MEETING WAS ADJOURNED.