Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner

Maine Department of Health and Human Services
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TO: Maine Drug Utilization Review Board
DATE: 3/21/23
RE: Maine DUR Board Meeting minutes from March 21, 2023

ATTENDANCE	PRESENT	ABSENT	EXCUSED
Linda Glass, MD	X		
Kathleen Polonchek, MD			X
Erin Ackley, PharmD.	X		
John Deason, MD	X		
Charmaine Patel, MD			X
Caitlin Morrow, PharmD.	X		
Non –Voting			
Mike Ouellette, R.Ph., Change Healthcare	X		
Jeff Barkin, MD, Change Healthcare	X		
Anne-Marie Toderico, PharmD MaineCare Pharmacy Director	X		

Guests of the Board:

CALL TO ORDER: 6:30PM

Erin Ackley called the meeting to order at 6:30 PM.

PUBLIC COMMENTS

No public comments

MAINECARE UPDATE- ANNE-MARIE TODERICO

- We welcome, John Deason, ambulatory care pharmacist joining the DUR as a committee member.
- In response to the federal government's removal of the XDEA license at the end of 2022, MaineCare pharmacy benefit removed the system requirement of an XDEA license for prescribing buprenorphine products.
- On March 17, OMS closed the respiratory syncytial virus season. The percent positivity had been below 3%, for over a month.
- We are in the process of updating our Biosimilar PDL on the medical side. The 2023 preferred drug list for biosimilars will be released in early April.

OLD BUSINESS

DUR MINUTES

Approval of March 14, 2023, DUR meeting minutes

Board Decision: The Board unanimously approved the above recommendation.

FOLLOW UP: ASTHMA RETRODUR

- Looking at prescribers with greater than 12 inhaler patients, no provider had more than 3 patients meeting the criteria and the majority had only one patient.
- Reviewed data by county.

Recommendation: No changes at this time.

Board Decision: The Board unanimously approved the above recommendation.

BIOSIMILAR

- Stimufend (pegfilgrastim-fpgk)- biosimilar to Neulasta

Recommendation: Add Stimufend to non-preferred on the PDL.

Board Decision: The Board unanimously approved the above recommendation.

NEW BUSINESS

PRESENTATION: BLOOD GLUCOSE TEST STRIPS IN CGM USERS

The use of continuous glucose monitors (CGMs) has become accepted standard of care for both type 1 diabetes and insulin dependent type 2 diabetes mellitus. While the value of CGM in type 2 diabetics not requiring insulin is uncertain due to rare occurrence of hypoglycemia, there are studies that show improvement in A1c levels compared with conventional blood glucose monitoring. In addition, blood glucose monitoring with fingersticks has potential errors due to poor compliance, dirty or contaminated meters, improper storage of test strips, expired test strips and poor skin preparation. Use of CGMs has improved glycemic control and over time, as technology has improved, there is less need to rely on testing to verify the CGM results. Initially when CGMs came on the market, conventional testing with finger sticks was recommended multiple times a day. As CGMs have evolved, however, the recommendation now is to corroborate results when the CGM reading seems inaccurate, either due to symptoms or unexplained fluctuations in the readings. Blood glucose monitoring is still required during CGM warm-up periods, to double check high and low values and sometimes for calibrating CGMs. For members using CGMs, it is expected that the increased expense of the monitors, sensors and supplies would be somewhat offset by decreased need to do fingerstick testing, and therefore decreased cost of glucose test strips. We used paid, non-reversed Medicaid pharmacy claims from April 2020 – April2022 excluding members with Part D, MaineRX and TPL. We looked at all pharmacy claims for members who began Dexcom G6 or Freestyle Libre CGM and evaluated blood glucose test strip usage in the 1-year time frame prior to the CGM period and for 1 year after the CGM period.

Recommendation: Unexpectedly, there was not a dramatic decrease in the number of test strips members obtained from the pharmacy. The claim count fell from 1723 pre-CGM to 1545 post. The average number of strips per member fell from 1112 to 1038. 216 members did decrease usage, but 157 members had increased test strip usage. 61 members had no change. While it would not be unusual for the member to test as usual for the first several months of using the CGM until gaining comfort with usage of the CGM, a bigger decrease in test strip usage is touted as one of the benefits of using CGMs. Increased usage of strips in not easily explained. In reviewing the data some increase in the utilization may be associated when the member started the CGM and test strip utilization prior to the CGM

prescription, but we had 28 members that had over 2400 test strip utilization even after the CGM was initiated. Possible interventions would be:

- To reach out to a sample of providers who ordered the CGMs and review the data for particular members who had no change or an increase in test strip usage, in order to try to explain the findings.
- Send targeted intervention to those providers with members with greater than 2400 test strips of utilization post one year after initiation of CGM device to understand clinical rationale for the continued use of 8-10/day of testing.
- To place quantity limits on test strips or create edit within the pharmacy claims system after initiation of CGM device that would trigger a PA if exceeding certain limitations.

Board Decision: After board discussion, it was decided to do a combination of sending targeted intervention to the providers, educational notice to pharmacies and quantity limits on test strips. Change Healthcare will research suggested limits.

INDTRODUCE: EFFECT OF TRIKAFTA ON COST AND QUALITY OF CARE PATIENTS WITH CYSTIC FIBROSIS

Cystic fibrosis is a debilitating progressive, hereditary disease which causes progressive pulmonary decline resulting in untimely death. Mutations in the CF transmembrane conductance regulator (CFTR) protein lead to impaired sodium and potassium transport across cell membranes and leads to high viscosity sputum, dehydration and impaired sputum clearance. CFTR modulator drugs have substantially decelerated disease progression, however recurrent respiratory infections and hospitalizations are still a reality for most patients. Until recently, available CFTR modulators included lumacaftor and tezacaftor. Ivacaftor is a chloride channel opener, also used to manage disease in combination with a CFTR. Ivacaftor (Kalydeco) is approved for those ages 6 months and older. Lumacaftor/ivacaftor (Orkambi) is approved for those 2 years and older and tezacaftor/ivacaftor (Symdeko) is approved for those 6 years of age and older. The newest medication, Trikafta, is a combination of 3 drugs, 2 CFTR modulars (elexacaftor, teazacaftor) and ivacaftor and is considered a breakthrough in therapy for those who have at least one F508del mutation and for those with any other CFTR gene mutation that is responsive, based on in vitro and/or clinical trial data. Approximately 92% of people with CF in the US have a CFTR genotype that make them eligible for this treatment once they are 6 years of age. Studies have shown significant benefits in improvements in FEV1, sweat chloride measurements and even significant improvements in patients with advanced disease. The cost of Trikafta is significantly more than Symdeko, however the increased cost of the drug may be offset by decreases in other medical expenses, mainly hospital admissions. We will use paid, non-reversed Medicaid medical claims, excluding members with Part D, MaineRX and TPL. For members taking Trikafta, we will analyze medical claims, looking at number and cost of hospitalizations, ER visits and provider visits for the year prior to and 1 year after starting the medication, to see if the increased cost of Trikafta is offset by decreased utilization of medical care.

Recommendation: None at this time.

Board Decision: None needed.

NEW DRUG REVIEW

Briumvi® (ublituximab-xiiy); **PDL category-** Multiple Sclerosis Agents

Ublituximab-xiiy, the active ingredient of Briumvi®, is a recombinant chimeric monoclonal IgG1 antibody with reduced fucose content directed against CD20-expressing B-cells. The precise mechanism of action for its approved indication is not known, but it is presumed to involve binding to CD20, a cell surface antigen present on pre-B and mature B lymphocytes. Following cell surface binding to B lymphocytes, ublituximab-xiiy results in cell lysis through mechanism including antibody-dependent cellular cytolysis and complement-dependent cytolysis. It is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. The efficacy of Briumvi® was demonstrated in two randomized, double-blind, double-dummy, parallel group, active comparator-controlled trials of identical design that included patients with RMS treated for 96 weeks. Results suggested that Briumvi® significantly lowered the ARR (primary endpoint) compared to teriflunomide. Briumvi® also statistically significantly reduced the number of T1 Gd-enhancing lesion and the number of new or enlarging T2 lesions in both studies compared to teriflunomide; however, there was no statistically significant difference in disability progression confirmed at 12 weeks between treatments. There are two other products with a similar mechanism of action as Briumvi®, including Kesimpta and Ocrevus®. While Briumvi® is to be administered every 24 weeks as a 1 hour infusion, Kesimpta® can be self-administered but is dosed monthly and Ocrevus® is a twice yearly IV infusion but with a longer infusion time than Briumvi®.

Recommendation: Briumvi® to non-preferred.

Clinical criteria:

- Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drugs will be approved (in step order), unless an acceptable clinical exception is offered on the Prior Authorization form, such as the presence of a condition that prevents usage of the preferred drug or a significant potential drug interaction between another drug and the preferred drug(s) exists.

Ermeza® (levothyroxine sodium solution); **PDL category-** Thyroid Hormones

Ermeza® contains synthetic levothyroxine (T4) sodium. Synthetic T4 is chemically identical to that produced in the human thyroid gland and is very slightly soluble in water. Thyroid hormones exert their physiologic actions through control of DNA transcription and protein synthesis. Triiodothyronine (T3) and L-thyroxine (T4) diffuse into the cell nucleus and bind to thyroid receptor proteins attached to DNA. This hormone nuclear receptor complex activates gene transcription and synthesis of messenger RNA and cytoplasmic proteins. The physiological actions of thyroid hormones are produced mainly by T3, the majority of which (about 80%) is derived from T4 by deiodination in peripheral tissues. Oral levothyroxine sodium is a synthetic T4 hormone that exerts the same physiologic effect as endogenous T4, thus maintaining normal T4 levels when a deficiency is present. It is indicated for hypothyroidism: As a replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism in adult and pediatric patients, including neonates. Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer in adult and pediatric patients, including neonates. Limitations of use include: Ermeza® is not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients as there are no clinical benefits and overtreatment with Ermeza® may induce hyperthyroidism. Ermeza® is not indicated for treatment of hypothyroidism during the recovery phase of subacute thyroiditis. There is no clinical trials section for Ermeza®. Synthetic levothyroxine has been able available for many years, both as brand and generic

versions. Ermeza® is a new liquid dosage formulation to be administered with an oral syringe that allows for individualized dosing. A prior liquid formulation was FDA approved but at a different dose than Ermeza®. Per the Ermeza® website, it is bioequivalent to Synthroid® tablets. There is no evidence at this time to support that Ermeza® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation: Ermeza® to non-preferred.

Clinical criteria:

- Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drugs will be approved (in step order), unless an acceptable clinical exception is offered on the Prior Authorization form, such as the presence of a condition that prevents usage of the preferred drug or a significant potential drug interaction between another drug and the preferred drug(s) exists.

Hemgenix® (etranacogene dezaparvovec- drlb); **PDL category**- Antihemophilic Agents

Hemgenix® is an adeno-associated viral vector-based gene therapy for IV infusion after dilution. It is an adeno-associated virus serotype 5 (AAV5) based gene therapy designed to deliver a copy of a gene encoding the Padua variant of human coagulation Factor IX (hFIX-Padua). Single IV infusion of Hemgenix® results in cell transduction and increase in circulating Factor IX activity in patients with Hemophilia B. It is indicated for the treatment of adults with Hemophilia B (congenital Factor IX deficiency) who: Currently use Factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or Have repeated, serious spontaneous bleeding episodes. The efficacy of Hemgenix® was evaluated in a prospective, open-label, single-dose, single-arm, multinational study that enrolled adult male subjects aged 19 to 75 years of age (N=54) with severe or moderately severe Hemophilia B, who received a single IV dose of 2 X 1013 gc/kg body weight of Hemgenix®, and who entered a follow-up period of 5 years. This study is on-going. The efficacy of Hemgenix® was assessed in a single-arm, single-dose, open-label study that included adult male subjects with severe or moderately severe Hemophilia B. The main efficacy outcome was a non-inferiority test of ABR during months 7 to 18 after Hemgenix® treatment compared with ABR during the lead-in period. The estimated mean ABR during months 7 to 18 after Hemgenix® treatment was 1.9 bleeds/year as compared with an estimated mean ABR of 4.1 during the lead-in period. The ABR ratio was 0.46, demonstrating non-inferiority of ABR during months 7 to 18 compared to the lead-in period. Hemgenix® is the first and only FDA-approved gene therapy for hemophilia B.

Recommendation: Hemgenix® to non-preferred.

Clinical Criteria:

- Hemgenix® is an adeno-associated viral vector-based gene therapy for IV infusion after dilution. For treatment of adults with Hemophilia B (congenital Factor IX deficiency) who: Currently use Factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or Have repeated, serious spontaneous bleeding episodes.

Imjudo® (tremelimumab) **PDL category-** Cancer

Tremelimumab-actl, the active ingredient of Imjudo®, is a cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking human IgG2 monoclonal antibody produced by recombinant DNA technology. CTLA-4 is a negative regulator of T-cell activity. Tremelimumab binds to CTLA-4 and blocks the interaction with its

ligands CD80 and CD86, releasing CTLA-4 mediated inhibition of T-cell activation. In synergistic mouse tumor models, blocking CTLA-4 activity resulted in decreased tumor growth and increased proliferation of T cells in tumors. It is indicated in combination with durvalumab, indicated for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC); In combination with durvalumab and platinum-based chemotherapy, indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations. The safety and efficacy of Imjudo® in combination with durvalumab was assessed in the HIMALAYA study, a randomized, open-label multicenter study that included patients with confirmed uHCC who had not received prior systemic treatment for HCC. Its efficacy for uHCC was assessed in the HIMALAYA study, an open-label randomized study with overall survival assessed between Imjudo® plus durvalumab compared with sorafenib. The number of deaths was significantly lower with Imjudo® and durvalumab as compared with sorafenib.

Recommendation: Imjudo® to non-preferred.

Lytgobi® (futibatinib); **PDL category**- Cancer

Futibatinib, the active ingredient of Lytgobi®, is a kinase inhibitor. It is a small molecule kinase inhibitor of FGFR 1, 2, 3, and 4 that covalently binds FGFR. Constitutive FGFR signaling can support the proliferation and survival of malignant cells. Futibatinib inhibited FGFR phosphorylation and downstream signaling and decreased cell viability in cancer cell lines with FGFR alterations, including FGFR fusions/rearrangements, amplifications, and mutations. It is indicated for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). The safety and efficacy of Lytgobi® were assessed in a multicenter, open-label, single-arm study that included patients (N=103) with previously treated, unresectable, locally advanced, or metastatic intrahepatic cholangiocarcinoma. Throughout treatment, perform a comprehensive ophthalmological examination, including OCT of the macula, and monitor for hyperphosphatemia. The efficacy of Lytgobi® was assessed in a single-arm, open-label study that included 103 patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma. The overall response rate (ORR) was 42% and the median duration of response (DoR) was 9.7 months. It is recommended that Lytgobi® be non-preferred in order to confirm the appropriate diagnosis and clinical parameters for use.

Recommendation: Lytgobi® to non-preferred.

Rezlidhia® (olutasidenib); **PDL category**- Cancer

Olutasidenib, the active ingredient of Rezlidhia®, is an isocitrate dehydrogenase-1 (IDH1) inhibitor. It is a small molecule inhibitor of mutated IDH1. In patients with AML, susceptible IDH1 mutations are defined as those leading to increased levels of 2-hydroxyglutarate (2-HG) in the leukemia cells and where efficacy is predicted by 1.) clinically meaningful remissions with the recommended dose of olutasidenib and/or 2.) inhibition of mutant IDH1 enzymatic activity at concentrations of olutasidenib sustainable at the recommended dosage per validated methods. The most common of such mutations in patients with AML are R132H and R132C substitutions. In vitro, olutasidenib inhibited mutated IDH1 R132H, R132L, R132S, R132G, and R132C proteins; wild-type IDH1 or mutated IDH2 proteins were not inhibited. Olutasidenib inhibition of mutant IDH1 led to decreased 2-HG levels in vitro and in animal models. It is indicated for the

treatment of adults with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test. The safety and efficacy of Rezlidhia® were assessed in an open-label, single-arm, multicenter study that included adult patients with relapsed or refractory AML with an IDH1 mutation. Efficacy was established on the basis of the rate of complete remission (CR) plus complete remission with partial hematologic recovery (CRh), the duration of CR+CRh, and the rate of conversion from transfusion dependence to transfusion independence. Results demonstrated a CR+CRh rate of 35%, while the CR rate was 32% and the CRh rate was 3%. It is recommended that Rezlidhia® should be non-preferred in order to confirm the appropriate diagnosis and clinical parameters for use.

Recommendation: Rezlidhia® to non-preferred.

Leqembi® (lecanemab injection); **PDL category**- Alzheimer's Agents

Lecanemab-irmb, the active ingredient of Leqembi®, is a recombinant humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease. Leqembi® reduces amyloid beta plaques, as evaluated in Study 1. It is indicated for the treatment of Alzheimer's disease. Treatment with Leqembi® should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Leqembi®. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial. The efficacy of Leqembi® was assessed in a double-blind, placebo-controlled, parallel group, dose finding study (Study 1) that included patients with Alzheimer's disease (patients with confirmed presence of amyloid pathology and mild cognitive impairment [64%] or mild dementia stage of disease [36%] consistent with Stage 3 and Stage 4 Alzheimer's disease). Study 1 had a 79-week double-blind, placebo-controlled period followed by an open-label extension period for up to 260 weeks, which was initiated after a gap period (range 9 to 59 months) off treatment. There is no evidence at this time to support that Leqembi® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation: Leqembi® to non-preferred.

Clinical Criteria:

- PA is required to establish dementia diagnosis and baseline mental status score.
- Must fail all preferred products before moving to non-preferred.
- Leqembi: Testing to rule out reversible causes of dementia (CBC, CMP, TSH, B12, urine drug screen, RPR/VDRL, (folate (if alcohol abuse is present), HIV (if risk present) and an assessment including a review of current medications as a cause of intellectual decline. Prescribed by or in consultation with a neurologist or geriatrician or geriatric psychiatrist. Diagnosis of Alzheimer's disease defined as: Confirmed presence of amyloid pathology and mild cognitive impairment or mild dementia stage of disease, consistent with Stage 3 and Stage 4 Alzheimer's disease OR Confirmed presence of amyloid pathology and prodromal or mild dementia stage of disease, consistent with Stage 3 and Stage 4 Alzheimer's disease. Testing: Clinical Dementia Rating (CDR) global score of 0.5 or 1.0 OR Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index score ≤ 85 OR Mini-Mental State Examination (MMSE) score of 20-30 OR Montreal Cognitive Assessment (MoCA) score ≤ 22. Member is age 50 or older. Obtain

recent (within one year) brain magnetic resonance imaging (MRI) prior to initiating treatment. Provider attestation to obtain MRIs prior to the 7th infusion (first dose of 10 mg/kg) and 12th infusion (sixth dose of 10 mg/kg). Member does NOT have history or increased risk of amyloid related imaging abnormalities-edema (ARIA-E), which includes brain edema or sulcal effusions and amyloid related imaging abnormalities hemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis. Member does NOT have hypersensitivity to any components of Aduhelm or Leqembi. Failure of or inability to tolerate at least two other preferred Alzheimer therapies for at least four months each, one of which should include a combination of a cholinesterase inhibitor with memantine. If the initial drug utilized is the combination of a cholinesterase inhibitor and memantine, then only that single trial of two drugs is required.

Relyvrio® (sodium phenylbutyrate/taurursodil powder for suspention); **PDL category**- ALS Agents

Relyvrio® contains two active ingredients, including sodium phenylbutyrate and taurursodiol, also known as tauroursdeoxycholic acid. This latter agent is an ambiphilic bile acid and is the taurine conjugate of ursodiol, also known as ursodeoxycholic acid. The mechanism by which Relyvrio® exerts its therapeutic effects for its approved indication is not known. It is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults. The safety and efficacy of Relyvrio® for the treatment of ALS were demonstrated in a 24-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group study, that included adults with ALS. Results suggested that there was a statistically significant difference in the rate of reduction in the ALSFRS-R total score from baseline to week 24 in those treated with Relyvrio® compared to placebo. This provides another treatment option for ALS and helps slow disease progression. There is no evidence at this time to support that Relyvrio® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation: Relyvrio® to non-preferred.

Clinical criteria:

- Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drugs will be approved, unless an acceptable clinical exception is offered on the Prior Authorization form, such as the presence of a condition that prevents usage of the preferred drug or a significant potential drug interaction between another drug and the preferred drug(s) exists.
- Clinical PA for indication required.

Rolvedon® (eflapegrastim-xnst); **PDL category**- Granulocyte CSF

Eflapegrastim-xnst, the active ingredient of Rolvedon®, is a granulocyte colony-stimulating factor (G-CSF). It is a recombinant human granulocyte growth factor that binds to G-CSF receptors on myeloid progenitor cells and neutrophils, triggering signaling pathways that control cell differentiation, proliferation, migration, and survival. It has been shown to elevate neutrophil counts in healthy subjects and in cancer patients. It is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. Rolvedon® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. The safety and efficacy of Rolvedon® to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs were assessed in two randomized, open-label, active-controlled, non-inferiority studies of similar design (Study 1 and Study 2)

that enrolled patients (N=643) with early-stage breast cancer. Docetaxel and cyclophosphamide were administered IV every 21 days for up to 4 cycles. Results suggest that Rolvedon® was non-inferior to pegfilgrastim in both studies. The authors concluded that results demonstrated non-inferiority and comparable safety for eflapegrastim-xnst at a lower G-CSF dose versus pegfilgrastim.

Recommendation: Rolvedon® to non-preferred.

Sezaby® (phenobarbital sodium injection) **PDL category**- Anticonvulsants

Phenobarbital, the active ingredient of Sezaby®, is a barbiturate. The exact mechanism of action for phenobarbital for the treatment of neonatal seizures is not fully understood; however, it is thought to involve potentiation of synaptic inhibition through an action on the GABA-A receptor. It is indicated for the treatment of neonatal seizures in term and preterm infants. The efficacy of phenobarbital for the treatment of neonatal seizures was established in a randomized, double-blind, active-controlled study in neonates who were experiencing seizures. Patients were neonates younger than 14 days of age with gestational ages between 36 and 44 weeks, while 52% were male and 56% were white. Results suggested that a statistically significantly greater percentage of phenobarbital-treated patients met this primary endpoint compared to levetiracetam-treated patients. There is some evidence at this time to suggest that Sezaby® may be more effective than levetiracetam for the primary endpoint of percentage of neonates with seizure termination for at least 24 hours without the need for a second drug for the treatment of their seizures; however, there is no evidence at this time to support that Sezaby® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation: Sezaby® to non-preferred.

Clinical criteria:

- Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drugs will be approved, unless an acceptable clinical exception is offered on the Prior Authorization form, such as the presence of a condition that prevents usage of the preferred drug or a significant potential drug interaction between another drug and the preferred drug(s) exists.

Sunlenca® (lenacapavir sodium); **PDL category**- Antiretroviral Agents

Lenacapavir sodium, the active ingredient of Sunlenca®, is an HIV-1 antiretroviral agent. It is a multistage, selective inhibitor of HIV-1 capsid function that directly binds to the interface between capsid protein (p24) subunits in hexamers. Surface plasmon resonance sensorgrams demonstrated dose-dependent and saturable binding of lenacapavir to cross-linked wild-type capsid hexamer. Lenacapavir inhibits HIV-1 replication by interfering with multiple essential steps of the viral lifecycle, including capsid-mediated nuclear uptake of HIV-1 proviral DNA (by blocking nuclear import proteins binding to capsid), virus assembly and release (by interfering with Gag/Gag-Pol functioning, reducing production of capsid protein subunits), and capsid core formation (by disrupting the rate of capsid subunit association, leading to malformed capsids). It is indicated in combination with other antiretroviral(s) for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations. The safety and efficacy of Sunlenca® were assessed in a randomized, placebo-controlled, double-blind, multicenter study that included HIV-1 infected, heavily treatment-experienced subjects with multidrug resistance. The primary efficacy endpoint (the

proportion in cohort 1 achieving ≥0.5 log10 copies/ml reduction from baseline in HIV-1 RNA at the end of the functional monotherapy period) was achieved by 87.5% of the Sunlenca® group as compared with 16.7% of the placebo group (calculated NNT by CHC of 2). After initial titration, this is a twice-yearly, first-in-class capsid inhibitor for injection to be used in combination with other antiretroviral(s).

Recommendation: Sunlenca® to non-preferred.

Clinical Criteria:

- Clinical PA required.
- Sunlenca: In combination with other antiretroviral(s) for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.
- DDI: Combined P-gp, UGT1A1 and strong CYP3A inhibitors may significantly increase plasma concentrations of Sunlenca®. Concomitant administration of Sunlenca® with these inhibitors is not recommended.

Xaciato® (clindamycin phosphate vaginal gel); **PDL category**- Vaginal Antibacterial

Clindamycin phosphate, the active ingredient of Xaciato®, is an antibacterial agent that inhibits bacterial protein synthesis by binding to the 23S RNA of the 50S subunit of the ribosome. Clindamycin is predominantly bacteriostatic. Although clindamycin phosphate is inactive in vitro, rapid in vivo hydrolysis converts it to active clindamycin. It is indicated for the treatment of bacterial vaginosis in females 12 years and older. The efficacy of Xaciato® for the treatment of bacterial vaginosis in females of 12 years of age and older (N=307) was demonstrated in a randomized, double-blind, placebo-controlled clinical study that compared a single dose of Xaciato® with a single dose of placebo vaginal gel. Results suggested that a statistically significantly greater percentage of patients experienced clinical cure, bacteriological cure, and therapeutic cure at the test of cure visit (days 21-30) in the Xaciato® arm compared to placebo. While other clindamycin products are FDA approved for the treatment of bacterial vaginosis, this is the first single use clindamycin vaginal gel.

Recommendation: Xaciato® to non-preferred.

Xelstrym® (dextroamphetamine patch, extended release); **PDL category**- Stimulant- Long-Acting Amphetamines Salts

Dextroamphetamine, the active ingredient of Xelstrym®, is a CNS stimulant and is the dextro isomer of the compound d, l-amphetamine. Amphetamines are non-catecholamine sympathomimetic amines with CNS stimulant activity. The exact mode of therapeutic action in ADHD is not known. It is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older. Limitation of use includes that pediatric patients younger than 6 years of age experienced more long-term weight loss than patients 6 years and older. The efficacy of Xelstrym® for the treatment of ADHD in adults and pediatric patients 6 to 17 years of age was established in a study with Xelstrym® in pediatric patients (presented below) and also based on adequate and well-controlled studies of lisdexamfetamine in pediatric and adult patients. Efficacy of lisdexamfetamine in the treatment of ADHD has been established in many trials in both adults and pediatric patients. In the double-blind, placebo-controlled study with Xelstrym®, results suggested a statistically significant separation from placebo was observed with the use of Xelstrym® per the SKAMP total score averaged over a classroom day in pediatric patients with ADHD. This offers prescribers another treatment option.

Recommendation: Xelstrym® to non-preferred.

Clinical Criteria:

- For the treatment of patients 6 years of age and older

Board Decision: The Board unanimously approved all the above recommendation.

FDA SAFETY ALERTS

None at this time

Board Decision: No action.

ADJOURNMENT: 8:00PM

The next meeting will be held on **June 13, 2023** 530pm-8pm hybrid.