Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner

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TO: Maine Drug Utilization Review Board
DATE: 6/29/20
RE: Maine DUR Board **Meeting** minutes from June 16, 2020

ATTENDANCE	PRESENT	ABSENT	EXCUSED
Linda Glass, MD			X
Lisa Wendler, Pharm. D., Clinical Pharmacy Specialist, Maine Medical CTR	X		
Mike Antoniello, MD			X
Kathleen Polonchek, MD	X		
Kenneth McCall, PharmD	X		
Erin Ackley, PharmD.	X		
Corinn Martineau, PharmD.	X		
Non –Voting			
Mike Ouellette, R.Ph., Change Healthcare	X		
Jacquelyn Hedlund, MD, Change Healthcare	X		
Jill Kingsbury, MaineCare Pharmacy Director	X		

Guests of the Board: Ed Bosshart, PharmD

CALL TO ORDER: 5:30PM

Jill Kingsbury called the meeting to order at 5:30 PM.

PUBLIC COMMENTS

Tobie Escher from Intra Cellular: Highlighted the attributes of Capyta.
Jessica Grussing from Neurelis: Highlighted the attributes of Valtoco.
Chelsea Leroue from Biohaven Pharmaceuticals: Highlighted the attributes of Nurtec ODT.
Gary Parenteau from Afaxys: Highlighted the attributes of Annovera.
Kristin Kollecas from Sanofi Genzyme: Highlighted the attributes of Sarclisa.
Dr. Ryan Smith, Chief of Psychiatry at UNE: Highlighted the attributes of Spravato.

OLD BUSINESS

DUR MINUTES

The March DUR meeting minutes were accepted.

Board Decision: The Board unanimously approved the above recommendation.

MAINECARE UPDATE

No update at this time.

REVISED CLINICAL CRITERIA/PREFERRED REVIEW

Biosimilars:
Trazimera® **PDL category-** Antineoplastic- Monoclonal Antibodies
Ontruzant® **PDL category-** Antineoplastic- Monoclonal Antibodies

Recommendation: Add Trazimera, Ontruzant and Herzuma to non-preferred. Move Kanjinti to preferred.

Board Decision: The Board unanimously approved the above recommendation.

NEW BUSINESS

DATA PRESENTATION: PDL COMPLIANCE (PICK 6 CATEGORIES)

Pharmacy formularies are constructed to guide providers in the commercial insurer world to use efficacious and cost-effective therapies in accordance with covered products. For Medicaid, the Preferred Drug List (PDL) is constructed with all out-patient drugs being available in accordance with Social Security Act 1927 and is posted publicly. While not mandated by Social Security Act 1927, states are allowed to maintain a Preferred Drug List and to enter rebate agreements with manufacturers to maximize savings while guaranteeing access and quality. The criteria used to determine authorization for non-preferred drugs is transparent and vetted through the state Pharmacy and Therapeutics Committee. These criteria for prescribing non-preferred medications are posted on the PDL. While not meant to be burdensome for providers, a well- constructed PDL should allow for prescribing of appropriate medications in most circumstances without requiring prior authorization of non-preferred medications. Evaluating the compliance with prescribing of preferred medications is a way to evaluate the rigor and adherence to criteria of the PA process. Additionally, if the PA process is sound, and many members are getting non-preferred medications appropriately, it may indicate a need to reevaluate the medication class and possible reorganization of preferred and non-preferred drug categorizations. States strive to stay current with new drugs and new indications for established medications, making PDLs fluid documents that change regularly. Auditing compliance of major drug classes is a way to monitor performance of pharmacy benefit management.

We will use paid, non-reversed Medicaid pharmacy and medical claims date from calendar year 2019 excluding members with Part D, MaineRX and TPL. We will evaluate these following categories to see how often the dispensed medication was preferred for the following categories:

- Multiple sclerosis: interferon and non-interferon medications
- Diabetes mellitus: incretin mimetics (GLP1 agonists and DPP-4 inhibitors)
- Hypercholesterolemia: statins and more potent drugs and combinations (ezetimibe, Repatha, Praluent)
- Seizure disorders: anticonvulsants
- Asthma: inhaled corticosteroids, beta adrenergic agonists and combination inhalers

We will audit a sampling of charts in each category to evaluate the adherence to criteria for approval of non-preferred medications.

Recommendation: PDL compliance for the drugs we investigated was quite good and supports the continued use of a preferred drug list to provide high value to members and the state Medicaid program. In the MS category, which has the lowest rate, a 73% compliance rate is actually impressive, given the heterogeneity of disease behavior, lack of clinical data that supports use of one drug over others, broad FDA labeling of most drugs and number of drugs in the class that are given by injection, rather than orally. Tecfidera, an oral drug, accounts for a significant amount of non-preferred prescribing and authorization. Regular PDL compliance investigations, looking at other classes of medications, is worthwhile to identify areas where provider education, pharmacy examination of changing guidelines and practice patterns and/or renegotiation with manufacturers for certain drugs might be worthwhile.

Board Decision: The Board unanimously approved the above recommendation.

INTRODUCE: PREP THERAPY TO PREVENT HIV IN AT RISK POPULATION

Pre-exposure prophylaxis (PrEP) with antiretroviral drugs has become standard of care for those at high risk of contracting HIV. People considered at high risk include those who have sex with HIV-infected partners, those who have recent histories of STDs and/or high numbers of sex partners, those who are commercial sex workers and IV drug users, especially those who injecting partners are HIV positive. Eligible patients should have documented negative HIV test prior to starting PrEP and have no symptoms of acute HIV infection. Additionally, they should be tested for hepatitis B and appropriately vaccinated, as PrEP treatment can worsen hepatitis B infections. Renal function should be tested and be normal and there should be documentation of other drugs taken, as there are significant drug/drug interactions with antiretroviral medications.

Once the decision is made to start PrEP therapy, it is necessary to education the patient about the monitoring that will need to be adhered to in order to continue therapy. This includes an HIV test every 3 months, medication adherence counseling, side effect assessment and STD symptom assessment. Renal function should be assessed at 3 months, and if stable, every 6 months thereafter. Women should have a pregnancy test every 3 months.

The recommended treatment for PrEP therapy is Truvada, a combination of tenofovir disoproxil fumarate (an NSTI) and emtracibine (an integrase inhibitor), or Descovy (tenofovir alafenamide and emtricitabine), if the patient has renal insufficiency. We will use paid, non-reversed Medicaid pharmacy and medical claims date from October 2018 through calendar year 2019 excluding members with Part D, MaineRX and TPL.

We will identify members getting either Truvada or descovy alone and examine medical claims to see if the guidelines for monitoring have been followed, including pre-prescribing HIV and Hep B testing, documentation of recent creatinine or BMP, as well as pregnancy test in women. Additionally, will see if HIV testing, Creatinine and pregnancy testing was done at 3 months intervals, as recommended in guidelines. Will also monitor prescribing adherence rates, with over 80% days covered considered adequate adherence.

Board Decision: No action needed at this time.

NEW DRUG REVIEW

Annovera® (segesterone acetate & ethinyl estradiol vaginal system); **PDL category-**

Annovera® is a vaginal system that contains a progestin (segesterone acetate) and an estrogen (ethinyl estradiol). Combination hormonal contraceptives (CHCs) lower the risk of becoming pregnant mainly by suppressing ovulation. It is indicated for use by females of reproductive potential to prevent pregnancy. Annovera® has not been adequately studied in females with a BMI >29kg/m2. (The study that supported approval removed women with BMI >29 kg/m2 after 2 women experienced VTEs.) The efficacy of Annovera® was assessed in two 1-year multicenter studies (N=2265) that included females aged 18-40 years, who were healthy and sexually active with regular menstrual cycles. Most females were Caucasian (71.2%), while the mean age was 26.7 years and the mean BMI was 24.1kg/m2. At about 50% enrollment, women with BMI >29kg/m2 were no longer enrolled and all women with a BMI >29kg/m2 were discontinued from the trials. It is the first vaginal ring contraceptive that will provide contraception for 13 cycles. Two multicenter studies found Annovera® to be effective, with a pregnancy rate assessed by the Pearl Index of 2.98 per 100 woman-years of Annovera® use. There is no evidence at this time to support that Annovera® is safer or more effective than other currently preferred medications.

Recommendation: Annovera® to non-preferred.

Board Decision: The Board unanimously approved the above recommendation.

Arazlo® lotion (tazarotene); **PDL category-** Topical- Acne Preparations

Tazarotene, the active ingredient of Arazlo®, is a member of the acetylenic class of retinoids. It is a retinoid prodrug that is converted to its active form, tazarotenic acid, the carboxylic acid of tazarotene, by de-esterification. Tazarotenic acid binds to all 3 of the retinoic acid receptor (RAR) family, including RARα, RAR¥ and RARγ, but shows relative selectivity for RARβ and RARγ and may modify gene expression. However, the clinical significance of these findings for the treatment of acne vulgaris is not known. It is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older. The safety and efficacy of once daily use of Arazlo for the treatment of acne vulgaris were assessed in 2 multicenter, randomized, double-blind studies that included subjects 9 years of age with facial acne vulgaris. There are currently other tazarotene dosage forms available, including a cream and a gel, with a generic available for the cream under the brand name Tazorac®. Tazorac® has been available for numerous years and has been found to be effective treatment for acne vulgaris[3]; however, this is the first tazarotene lotion FDA approved. Arazlo® Lotion was found to be more effective than placebo in 2 clinical trials assessing success on the EGSS and absolute changes in non-inflammatory and inflammatory lesion counts. Per the full text by Tanghetti et al[2], differences between tazarotene lotion and placebo were statistically significant for reducing inflammatory and non-inflammatory lesion counts at week 12 in favor of tazarotene ($p<0.001$ for both studies), as well as for treatment success ($p<0.001$ for both studies). There is no evidence at this time that Arazlo® Lotion is safer or more effective than the currently preferred medications

Recommendation: Arazlo® lotion to non-preferred.

Clinical Criteria:

- For the treatment of patients ≥ 9 years of age.

Board Decision: The Board unanimously approved the above recommendation.

Caplyta® (lumateperone); **PDL category**- Antipsychotics- Atypicals

Lumateperone, the active ingredient of Caplyta®, is an atypical antipsychotic. While the exact mechanism of action is not known, the efficacy of lumateperone could be mediated through a combination of antagonist activity at central serotonin 5-HT2A receptors and postsynaptic antagonist activity at central dopamine D2 receptors. It is indicated for the treatment of adults with schizophrenia. The efficacy of Caplyta® was assessed in two placebo-controlled trials. Study 1 was a randomized, double-blind, multicenter, placebo-controlled trial that included adult patients with a diagnosis of schizophrenia per DSM-IV-TR criteria of 4 weeks in duration. . In clinical trials compared with placebo, Caplyta® had statistically significantly greater reductions from baseline in PANSS total score. In safety studies, the frequency of EPS was similar to placebo (6.7% Caplyta® vs 6.3% for placebo). In addition, the mean change in body weight after 175 days of treatment with Caplyta® was -2kg. Studies with active comparators were not found.

Recommendation: Caplyta® to non-preferred.

Board Decision: The Board unanimously approved the above recommendation.

Dayvigo® (lemborexant); **PDL category-** Sedative Hypnotics

Lemborexant, the active ingredient of Dayvigo®, is an orexin receptor antagonist. Its mechanism of action is presumed to be through antagonism of orexin receptors. The orexin neuropeptide signaling system plays a role in wakefulness. Blocking the binding of wake-promoting neuropeptides orexin A and orexin B to receptors OX1R and OX2R is thought to suppress wake drive. Dayvigo® is a Schedule IV controlled substance. As individuals with a history of abuse or addiction to alcohol or other drugs may be at increased risk for abuse and addiction to Dayvigo®, follow such patients carefully. It is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. The efficacy of Dayvigo® was assessed in 2 clinical trials that included patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Study 1 was a 6-month, multicenter, randomized, double-blind, placebo-controlled study that included adults (≥18 years of age) who met DSM-5 criteria for insomnia disorder (N=971). The included patients had a median age of 55 years, while 68% were female and 72% were white. It also demonstrated statistically significant improvement in secondary outcomes as compared with placebo. There is some evidence from a phase 3 study to suggest that Dayvigo® may be more effective than zolpidem extended release 6.25mg, though this is a relatively low dose for this comparator drug; however, there is no evidence at this time that Dayvigo® is safer or more effective than the other currently preferred medications.

Recommendation: Dayvigo® be non-preferred.

Clinical Criteria:

- Quantity Limit of 12 per 34 days.

Board Decision: The Board unanimously approved the above recommendation.

Fetroja® (cefidereocol); **PDL category**- Cephalosporins

Cefidereocol, the active ingredient of Fetroja®, is a cephalosporin antibacterial agent with activity against Gram negative-aerobic bacteria. Cefiderocol functions as a siderophore and binds to extracellular free ferric iron. It exerts bactericidal action by inhibiting cell wall biosynthesis through binding to penicillin-binding proteins. It is indicated in patients 18 years of age or older who have limited or no alternative treatment options for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis caused by the following susceptible Gram-negative microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, and *Enterobacter cloacae* complex. Approval of this indication is based on limited clinical safety and efficacy data for Fetroja®. The efficacy of Fetroja® was assessed in a multinational, double-blind randomized study that included adults hospitalized with cUTI, including pyelonephritis, and was compared with imipenem/cilastatin. The median duration of therapy in both treatment groups was 9 days. Approval of this indication is based in limited clinical safety and efficacy data of Fetroja®. In a clinical study assessing the composite clinical and microbiological response rates, Fetroja® was non-inferior to imipenem/cilastatin at the test of cure visit. However, there was an increase in all-cause mortality in patients treated with Fetroja® as compared to best available therapy in critically ill patients with carbapenem-resistant Gram-negative bacterial infections. There is no evidence at this time that Fetroja® is safer or more effective than the currently preferred medications.

Recommendation: Fetroja® be non-preferred.

Clinical Criteria:

- Approvals will only be considered for patients 18 years of age or older who have limited or no alternative treatment options for the treatment of complicated urinary tract infections (cUTIs)

Board Decision: The Board unanimously approved the above recommendation.

Isturisa® (osilodrostat); **PDL category**- Cushing's Disease Agents

Osilodrostat, the active ingredient of Isturisa®, is a cortisol synthesis inhibitor. It inhibits 11beta-hydroxylase (CYP11B1), the enzyme responsible for the final step of cortisol biosynthesis in the adrenal gland. It is indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. The safety and efficacy of Isturisa® were assessed in a 48-week multicenter study that consisted of 4 study periods, including: Period 1: 12-week, open-label, dose titration period, Period 2: 12-week, open-label, maintenance treatment period, Period 3: 8-week, double-blind, placebo-controlled, randomized withdrawal treatment period which provided the data for the primary efficacy endpoint, Period 4: open-label treatment period of 14 to 24 weeks duration. In a clinical trial, the percentage of complete responders for the primary endpoint was significantly higher with Isturisa® as compared with placebo. There is no evidence at this time that Isturisa® is safer or more effective than the currently preferred medications.

Recommendation: Isturisa® be non-preferred.

Clinical Criteria:

- Approvals will only be considered for patients 18 years of age or older who have limited or no alternative treatment options for the treatment of complicated urinary tract infections (cUTIs)

Board Decision: The Board unanimously approved the above recommendation.

Jatenzo® (testosterone indecanoate); **PDL category**- Androgens/Anabolics

Testosterone, the active ingredient of Jatenzo®, is a fatty-acid ester of the androgen testosterone. Endogenous androgens, including testosterone, are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. It is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. The safety and efficacy of Jatenzo® in males less than 18 years of age have not been established. The safety and efficacy of Jatenzo® were assessed in a 4-month open-label study that included adult hypogonadal males. Use is contraindicated in men with hypogonadal conditions, such as 'age-related hypogonadism', that are not associated with structural or genetic etiologies. In clinical studies, Jatenzo® use resulted in 87% of men having a mean total testosterone concentration within the normal eugonadal range at the end of treatment. Jatenzo® is the first and only oral softgel testosterone undecanoate and the first oral testosterone approved in the US in over 60 years. There is no evidence at this time to support that Jatenzo® is safer or more effective than other currently preferred medications.

Recommendation: Jatenzo® be non-preferred.

Board Decision: The Board unanimously approved the above recommendation.

Koselugo® (selumetinib); **PDL category**- Cancer

Selumetinib, the active ingredient of Koselugo®, is a kinase inhibitor. It is an inhibitor of mitogen-activated protein kinases 1 and 2 (MEK1/2), which are upstream regulators of the extracellular signal-related kinase (ERK) pathway. Both MEK and ERK are critical components of the RAS-regulated RAF-MEK-ERK pathways, which is often activated in different types of cancers. It is indicated for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN). The efficacy of Koselugo® was assessed in SPRINT phase II Stratum 1, an open label, multicenter, single arm study that included patients who were required to have NF1 with inoperable PN, defined as a PN that could not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN. Patients were also required to have significant morbidity related to the target PN. The median age of included pediatric patients was 10.2 years (range 3.5 to 17.4 years), while 60% were male and 84% were white. The major efficacy outcome measure was overall response rate (ORR), defined as the percentage of patients with complete response (defined as disappearance of the target PN) or confirmed partial response (defined as ≥20% reduction in PN volume conformed at a subsequent tumor assessment within 3-6 months). It is the first agent FDA approved as treatment for this rare condition. Its efficacy was

based on a single arm study that included pediatric patients (N=50) who had an overall response rate of 66%.

Recommendation: Koselugo® be non-preferred.

Board Decision: The Board unanimously approved the above recommendation.

Nexletol® (bempedoic); **PDL category**- Lipotropics, Non- Statins

Bempedoic acid, the active ingredient of Nexletol®, is an adenosine triphosphate-citrate luase (ACL) inhibitor that lowers LDL-C by inhibition of cholesterol synthesis in the liver. ACL is an enzyme upstream of 3-hydroxy-3-methyl-glutaryl-coenzyme A (HMG-CoA) reductase in the cholesterol biosynthesis pathway. Bempedoic acic and its active metabolite (ESP15528) required coenzyme A (CoA) activation by very long-chain acyl-CoA synthetase 1 (ACSVL1) to ETC-1002-CoA and ESP15228-CoA, respectively. ASCVL1 is expressed mainly in the liver. Inhibition of ACL by ETC-1002-CoA results in decreased cholesterol synthesis in the liver and lowers LDL-C in blood via upregulation of low-density lipoprotein receptors. It is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. The effect of Nexletol® on cardiovascular morbidity and mortality has not been determined. The primary outcome was the Positive and Negative Syndrome Scale (PANSS) total score, with the PANSS total score ranging from 30 to 210 with higher scores reflecting greater overall symptom severity. Results suggested that compared to placebo, patients randomized to Caplyta® 42mg demonstrated a statistically significant reduction from baseline to day 28 in the PANSS total score. The effect of Nexletol® on cardiovascular morbidity and mortality has not been determined.

Recommendation: Nexletol® to be non-preferred.

Board Decision: The Board unanimously approved the above recommendation.

Nurtec® ODT (rimegepant tablet, orally disintegrating); **PDL category**- Antimigraine Agents

Rimegepant, the active ingredient of Nurtec® ODT, is a calcitonin gene-related peptide (CGRP) receptor antagonist. It is indicated for the acute treatment of migraine with or without aura in adults. Nurtec® ODT is not indicated for the preventive treatment of migraine. The efficacy of Nurtec® ODT for the acute treatment of migraine with or without aura in adults was assessed in a randomized, double-blind, placebo-controlled study.

Recommendation: Nurtec® ODT be non-preferred. Additional changes in the Migraine- Selective serotonin agonist(5HT)- Injectables Imitrex vial, Imitrex cartridge, Sumatriptan syringe and Sumatriptan pen injection will be preferred and the Imitrex pen injection will be non-preferred. In the Migraine-Selevtive Serotonin Agonists (5HT)- Tablets/Nasal Sumatriptan nasal spray and Zolmitriptan tablets will be preferred and Imitrex nasal spray and Migranal nasal spray will be non-preferred.

Clinical criteria:

- Dosing limits apply, please see the dose consolidation list.
- Migranal nasal spray established users will be grandfathered.

Board Decision: The Board unanimously approved the above recommendation.

Palforzia® (peanut (Arachis hypogaea) allergen powder-dnfp); **PDL category**- Allergen Immunotherapy

Palforzia (peanut [Arachis hypogaea) allergen powder-dnfp) is a powder for oral administration manufactured from defatted peanut flower. The exact mechanism of action has not been established. It is indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. Palforzia® is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial dose escalation may be administered to patients aged 4 through 17 years. Up-dosing and maintenance may be continued in patients 4 years of age and older. Palforzia® is to be used in conjunction with a peanut-avoidant diet. It is not indicated for the emergency treatment of allergic reactions, including anaphylaxis. The efficacy of Palforzia® for the mitigation of allergic reactions was assessed in a phase 3, randomized, double-blind, multicenter, placebo-controlled trial that included patients with peanut allergy aged 4 through 55 years. There is a box warning listed with Parforzia®, warning of the risk of anaphylaxis, which can be life-threatening and can occur at any time during Palforzia® therapy. It is the first therapy approved for peanut allergy. In a large study, the use of peanut allergen-dnfp compared with placebo resulted in a significantly greater number of patients able to ingest a single-dose of 600mg of peanut protein during the exit food challenge in patients 4 to 17 years of age, but not among patients 18 to 55 years of age. Response rates were not significantly different in the various doses for adults 18 to 55 years of age.

Recommendation: Palforzia® Pen be non-preferred.

Clinical Criteria:

- Palforzia® is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial dose escalation may be administered to patients aged 4 through 17 years. Up-dosing and maintenance may be continued in patients 4 years of age and older.

Board Decision: The Board unanimously approved the above recommendation.

Pemazyre® (pemigatinib); **PDL category**- Cancer

Pemigatinib, the active ingredient of Pemazyre®, is a kinase inhibitor. It is a small molecule kinase inhibitor that targets fibroblast growth factor receptor (FGFR) 1, 2, and 3. It is indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA approved test. 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 efficacy of Pemazyre® was assessed in a multicenter, open-label, single arm study that included patients with locally advanced unresectable to metastatic cholangiocarcinoma whose disease had progressed on or after at least 1 prior therapy and who had an FGFR2 gene fusion or non-fusion rearrangement. 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). In a single arm, open-label study (N=107), 36% had an overall response rate, with 33% having a partial response.

Recommendation: Pemazyre® be non-preferred.

Board Decision: The Board unanimously approved the above recommendation.

Sarclisa® (isatuximab-irfc); **PDL category**- Cancer

Isatuximab-irfc, the active ingredient of Sarclisa®, is a CD380 directed cytolytic antibody, a chimeric immunoglobulin G1 (IgG1) monoclonal antibody. It binds to CD38 expressed on the surface of hematopoietic and tumor cells, including multiple myeloma cells, inducing apoptosis of tumor cells and activation of immune effector mechanisms. Isatuximab-irfc can activate natural killer cells in the absence of CD38-positive target tumor cells and suppresses CD38-positive T-regulatory cells. It is indicated in the combination with pomalidomide and dexamethasone for the treatment of adults with multiple myeloma who have received at least 2 prior therapies, including lenalidomide and a proteasome inhibitor. The efficacy of Sarclisa® in combination with pomalidomide and low dose dexamethasone as compared with pomalidomide and low dose dexamethasone was assessed in a multicenter, randomized, open-label, 2-arm, phase 3 study (ICARIA-MM) that included patients with relapsed and refractory multiple myeloma (MM). The efficacy of Sarclisa® was based on progression-free survival (PFS). PFS results were assessed by an Independent Response Committee based on central lab data for M-protein and central radiologic imaging review using the International Myeloma Working Group (IMWG) criteria. Pre-infusion medications should be administered, and Sarclisa should be administered by a healthcare professional with immediate access to emergency equipment and appropriate medical support to manage infusion-related reactions if they occur. In an active-comparator trial, the improvement in progression free survival represented a 40% reduction in the risk of disease progression or death in patients treated with Sarclisa®.

Recommendation: Sarclisa® to be non-preferred.

Board Decision: The Board unanimously approved the above recommendation.

Talicia® (omeprazole magnesium, amoxicillin, & rifabutn capsules, delayed release); **PDL category**- GI-Ulcer Anti-infective

Talicia delayed-release capsules contain omeprazole magnesium (a proton pump inhibitor), amoxicillin (a semisynthetic antibacterial agent), and rifabutin (an antibacterial agent). It is indicated for the treatment of Helicobacter pylori (H. pylori) infection in adults. The safety efficacy of Talicia® were assessed in a randomized, double-blind, controlled study that included treatment-naïve H. pylori-positive adult patients complaining of epigastric pain/discomfort. It is the first and only FDA approved rifabutin-based H. pylori therapy, designed to deal with the growing bacterial resistance of clarithromycin-based standard-of-care therapy. In a clinical trial compared with placebo, Talicia had a statistically significantly higher eradication rate. In a second study compared with a control of omeprazole and high dose amoxicillin, Talicia® also had a statistically significantly higher eradication rate.

Recommendation: Talicia® be non-preferred.

Board Decision: The Board unanimously approved the above recommendation.

Trijardy® XR (empagliflozin, linagliptin and metformin ER); **PDL category**- SGLT2 Inhibitor Combinations

Trijardy® XR is a fixed dose combination tablet that consists of an extended-release metformin (a biguanide) core tablet that is coated with the immediate-release drug substances of empagliflozin (a sodium-glucose co-transporter 2 [SGLT2] inhibitor) and linagliptin (a dipeptidyl peptidase-4 [DPP-4] inhibitor). It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 DM. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 DM and established cardiovascular disease. There were 3 clinical trials reported in the Trijardy® XR clinical trial section. Two studies were those included with the prescribing information for empagliflozin (brand name Jardiance®) and one study was included with the prescribing information for linagliptin (brand name Tradjenta®). These agents, along with metformin, have been available for numerous years and have proven to be safe and effective. Note that Trijardy XR is not recommended for patients with type 1 DM or for the treatment of diabetic ketoacidosis. In addition, Trijardy XR has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Trijardy® XR. Trijardy® XR is the first FDA approved triple-combination therapy with Jardiance (empagliflozin).

Recommendation: Trijardy® XR to be non-preferred.

Board Decision: The Board unanimously approved the above recommendation.

Tukysa® (tucatinib); **PDL category**- Cancer

Tucatinib, the active ingredient of Tukysa®, is a tyrosine kinase inhibitor of HER2. In vitro, tucatinib inhibits phosphorylation of HER2 and HER3, resulting in inhibition of downstream MAPK and AKT signaling and cell proliferation, and demonstrated anti-tumor activity in HER2 expressing tumor cells. The combination of tucatinib and trastuzumab demonstrated increased anti-tumor activity in vitro and in vivo as compared to either drug alone. It indicated in combination with trastuzumab and capecitabine for the treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. The efficacy of Tukysa® in combination with trastuzumab and capecitabine was assessed in a randomized, double-blind, placebo-controlled trial that included patients required to have HER2-positive, unresectable locally advanced or metastatic breast cancer, with or without brain metastases. In a placebo-controlled trial, Tukysa® significantly prolonged median progression free survival and median overall survival as compared with placebo.

Recommendation: Tukysa® to be non-preferred.

Board Decision: The Board unanimously approved the above recommendation.

Valtoco® (diazepam spray); **PDL category**- Anticonvulsants

Diazepam, the active ingredient of Valtoco®, is a benzodiazepine anticonvulsant. The exact mechanism of action for diazepam is not fully understood, but it is thought to involve potentiation of GABAergic neurotransmission resulting from binding at the benzodiazepine site of the GABA-A receptor. It is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, active repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 6 years of age and older. Valtoco® has a box warning regarding the risks from concomitant use with opioids. Concomitant use of benzodiazepines and opioids may result in profound

sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are not adequate. Limit dosages and duration to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation. The efficacy of Valtoco® is based on the relative bioavailability of Valtoco® nasal spray as compared to diazepam rectal gel in healthy adults. The efficacy of diazepam rectal gel has been established in 2 adequate and well-controlled clinical studies in children and adults exhibiting seizure patterns. The efficacy of Valtoco® is based on the relative bioavailability of Valtoco® nasal spray compared to diazepam rectal gel in healthy adults.

Recommendation: Valtoco® to be preferred. Additional changes Diazepam gel and Nayzilam will be preferred. Diastat will be moved to non-preferred.

Clinical Criteria:

- Quantity limit. 5/month

Board Decision: The Board unanimously approved the above recommendation.

Vyepti® (eptinezumab- jjimr); **PDL category**- Antimigraine Agents

Eptinezumab-jjmr, the active ingredient of Vypeti®, is a humanized immunoglobulin G1 (IgG1) monoclonal antibody specific for calcitonin gene-related peptide (CGRP) ligand. It binds to CGRP ligand and blocks its binding to the receptor. It is indicated for the preventive treatment of migraine adults. The efficacy of Vyepti® was assessed as a preventive treatment of episodic and chronic migraine in 2 randomized, multicenter, placebo-controlled studies, both with 6-month double-blind periods. In clinical studies compared with placebo, Vyepti® treatment demonstrated statistically significant improvements compared to placebo for the primary endpoint of the change from baseline in mean monthly migraine days over months 1-3. These studies included adults with episodic or chronic migraine. The studies were 6 months in duration, but the primary endpoint included results at 12 weeks. Comparator studies against other active treatments were not found.

Recommendation: Vypeti® to be non-preferred.

Clinical Criteria:

- Dosing limits apply, please see the dose consolidation list.

Board Decision: The Board unanimously approved the above recommendation.

Xepi® (ozenoxacin cream); **PDL category**- Topical- Antibiotics

Ozenoxacin, the active ingredient of Xepi®, is a quinolone antimicrobial agent. It's mechanism of action involves the inhibition of bacterial DNA replication enzymes, DNA gyrase A, and topoisomerase IV. It is indicated for the topical treatment of impetigo due to Staphylococcus aureus or Streptococcus pyogenes in adult and pediatric patients 2 months of age and older. The safety and efficacy of Xepi® were assessed in two multicenter, randomized, double-blind, placebo-controlled trials. In 2 clinical trials, Xepi had a significantly higher treatment success as compared with placebo. There is no evidence at this time to support that Xepi® cream is safer or more effective than the currently preferred medications.

Recommendation: Xepi® to be non-preferred.

Board Decision: The Board unanimously approved the above recommendation.

Zerviate® (cetirizine solution/drops); **PDL category**- Op- Anti-Allergics

Cetirizine, the active ingredient of Zerviate®, is a histamine-1 (H1) receptor antagonist and an inhibitor of release of histamine from mast cells. It is indicated for the treatment of ocular itching associated with allergic conjunctivitis. The efficacy of Zerviate® was established in 3 randomized, double-masked, placebo-controlled, conjunctival allergen challenge (CAC) clinical trials that included patients with a history of allergic conjunctivitis. In 2 clinical trials, patients treated with Zerviate® demonstrated statistically and clinically significantly less ocular itching as compared to vehicle at both 15 minutes and 8 hours after treatment. There is no evidence at this time to support that Zerviate® is safer or more effective than the currently preferred, more cost-effective medications.

Recommendation: Zerviate® to be non-preferred.

Board Decision: The Board unanimously approved the above recommendation.

FDA SAFETY ALERTS

Clozaril, Fazaclo ODT, Versacloz (clozapine): Drug Safety Communication - FDA Strengthens Warning That Untreated Constipation Can Lead to Serious Bowel Problems
https://www.fda.gov/safety/medical-product-safety-information/clozaril-fazaclo-odt-versacloz-clozapine-drug-safety-communication-fda-strengthens-warning-untreated?utm_campaign=FDA%20MedWatch%3AClozaril%2C%20Fazaclo%20ODT%2C%20Versacloz%20%28clozapine%29-%20Drug%20Safety%20Communication&utm_medium=email&utm_source=Eloqua
FDA Approves Three Drugs for Nonprescription Use Through Rx-to-OTC Switch Process
https://www.fda.gov/news-events/press-announcements/fda-approves-three-drugs-nonprescription-use-through-rx-otc-switch-process?utm_campaign=022420_PR_FDA%20Approves%20Three%20Drugs%20for%20Nonprescription%20Use&utm_medium=email&utm_source=Eloqua
Singulair (montelukast) and All Montelukast Generics: Strengthened Boxed Warning - Due to Restricting Use for Allergic Rhinitis
https://www.fda.gov/safety/medical-product-safety-information/singulair-montelukast-and-all-montelukast-generics-strengthened-boxed-warning-due-restricting-use?utm_campaign=FDA%20MedWatch%20Singulair%20%28montelukast%29%3A%20Strengthened%20Boxed%20Warning&utm_medium=email&utm_source=Eloqua
FDA Approves Label Changes to SGLT2 Inhibitors Regarding Temporary Discontinuation of Medication Before Scheduled Surgery
http://s2027422842.t.en25.com/e/es?s=2027422842&e=312214&elqTrackId=376c7bc788024cd5a73d955f2e3dcbdc&elq=d700e2d071b343878fdae02a4ebbbf19&elqaid=11643&elqat=1

FDA alerts patients and health care professionals of EpiPen (epinephrine) and EpiPen Jr (epinephrine) auto-injector errors related to device malfunctions and user administration
https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-patients-and-health-care-professionals-epipen-auto-injector-errors-related-device?utm_campaign=FDA%20alerts%20patients%20and%20health%20care%20professionals%20of%20EpiPen%20auto-injector%20errors&utm_medium=email&utm_source=Eloqua
FDA Requests Removal of All Ranitidine Products (Zantac) from the Market

https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market?utm_campaign=040120_PR_FDA%20Requests%20Removal%20of%20Ranitidine%20Products%20%28Zantac%29%20from%20the%20Market&utm_medium=email&utm_source=Eloqua

FDA Approves Label Changes for Montelukast (Singulair) Regarding the Potential Risk of Serious Mental Health Side Effects
http://s2027422842.t.en25.com/e/es?s=2027422842&e=328327&elqTrackId=376c7bc788024cd5a73d955f2e3dcbdc&elq=bb3dd6d269764f269f7b497fd4704f1b&elqaid=12344&elqat=1

FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems
http://s2027422842.t.en25.com/e/es?s=2027422842&e=326625&elqTrackId=376c7bc788024cd5a73d955f2e3dcbdc&elq=ac707a3bff784a399dcd62181c0aa736&elqaid=12264&elqat=1

Board Decision: No formal action required

ADJOURNMENT: 8:30PM

The next meeting will be held on **September 8, 2020** 5:30pm –8:30pm at the Augusta Armory.