Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner

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TO: Maine Drug Utilization Review Board
DATE: 09/13/2019
RE: Maine DUR Board **Meeting** minutes from September 10, 2019

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
Steve Diaz, MD			X
Erin Ackley, PharmD.	X		
Corinn Martineau, PharmD.	X		
Non –Voting			
Mike Ouellette, R.Ph., Change Healthcare	X		
Jeffrey Barkin, 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

Joseph Biji from Pfizer: Highlighted cardiac amyloidisis.
Nicole Trask from Janssen: Highlighted the attributes of Spravato.
Frank Nagy from Xeris: Highlighted the attributes of Gvoke.
Ryan Giegg from Ironshore: Highlighted the attributes of Jornay PM.

OLD BUSINESS

DUR MINUTES

The September DUR meeting minutes were accepted as written.

Board Decision: The Board unanimously approved the above recommendation.

MAINECARE UPDATE

No update at this time.

REVISED CLINICAL CRITERIA/PREFERRED REVIEW

Spravato® (esketamine); **PDL category-** Antidepressants - Selected SSRI's

Re-reviewing clinical criteria after inquiry from a provider. Current criteria Spravato is non-preferred and requires administered in an equipped and accredited conscious sedation facility or department. Psychiatry recommended.

Board Decision: After much discussion the Board unanimously approved the to maintain the current critiera and will continue to monitor PA request and will re-review again at a future meeting.

Isentress® (raltegravir); **PDL category-** Antiretrovirals

Move Isentress 400mg to preferred for post- exposure prophylaxis.

Board Decision: The Board unanimously approved the above recommendation.

Buprenorphine/naloxone tablets; **PDL category-** Opioid Dependence Treatments

Move Buprenorphine/naloxone tablets to preferred. The following criteria from buprenorphine remains unchanged: Buprenorphine prescribers must have their DEA X-waiver, Appropriate diagnosis must be, included on the prescription, Daily doses >16 mg/day of buprenorphine require a PA, Maximum dose for buprenorphine induction is 32 mg/day, Induction period for a new start of buprenorphine is limited to a maximum of 60 days.

Board Decision: The Board unanimously approved the above recommendation.

NEW BUSINESS

DATA PRESENTATION: APPROPRIATE USE OF ASTHMA CONTROLLER MEDICATIONS

The National Heart, Lung and Blood Institute has published Guidelines for the Diagnosis and Management of Asthma. The treatment of asthma is done in a step-wise manner, and depending on disease severity, a combination of several agents may be needed. For anyone who requires use of a short acting agent ≥ 2 days/week, a controller medication daily is recommended. The Guidelines state that the frequency of short acting beta-adrenergic inhaler (SABA) use can be clinically useful as a measure of disease activity since increased use of a SABA has been associated with increased risk for death or near death in patients who have asthma. Use of more than one SABA canister every one to two months is also associated with an increased risk of an acute exacerbation. Therefore, the use of more than one SABA canister (e.g., albuterol 200 puffs per canister) during a one-month period most likely indicates over reliance on this drug and suggests inadequate control of asthma. Additionally, inhaled corticosteroids (ICS) are the preferred long-term control therapy in asthma for all ages, although leukotriene receptor antagonists (LTRA) are listed as an alternative. Long-acting beta-adrenergic inhalers

(LABAs) should never be used without first using ICS inhalers due to the increased risk of asthma exacerbations and death.

We will use paid, non-reversed Medicaid pharmacy claims from January 2018 through December 2018, excluding members with Part D, MaineRX and TPL. Change Healthcare will review paid non-reversed pharmacy and medical claims with dates of service from 1/1/2018 through 12/31/2018, excluding members who had a diagnosis of cystic fibrosis, COPD or emphysema. Members will be stratified by age and the number of short acting inhalers used per year. In addition, the number of members in each group who had an ER visit or hospitalization associated with an asthma diagnosis during the study period will be reported. We will compare the rates of ER visits and hospitalizations to the rates seen in the 2015 analysis, examining whether the educational interventions provided by the Board had an impact in reducing rates of asthma exacerbations, understanding that the populations are not identical. Additional analysis will be done on those using more than 12 short acting inhalers/year and sorted geographically. The prescribers for these members will be identified to look at providers who are possibly practicing outside of guideline recommendations, perhaps identifying those who would be appropriate for more targeted education.

Recommendation: For the providers who prescribed more than 12 short-acting inhalers/year for individual members, see how many of those members were also on a long-acting controller medication, such as a corticosteroid inhaler and/or leukotriene antagonist. Another strategy would be to contact providers who had very high numbers of prescriptions/year (over 20) to investigate the reasons for need for so many short-acting inhalers. IN the cases where there were between 13 and 16 inhalers dispensed, some could have been so that the member could have inhalers kept in different locations, such as with school nurses, at work, etc. it is hard to assume that each of the dispensed inhalers were used completely within a given month.

Board Decision: The Board unanimously approved the above recommendation.

INTRODUCATION: USE OF STATINS IN MEMBERS WITH DIABETES MELLITUS

Guidelines for the treatment of diabetes mellitus due to the vascular effects of elevated blood sugar include lifestyle changes, including diet and exercise, management of hypertension and lipid-lowering therapy. Both micro and macrovascular complications are high in the diabetic population and increase as diabetics age. Among the most common complications are myocardial infarctions, peripheral vascular disease and strokes. ASCVD is the leading cause of morbidity and mortality in DM, and annual spending related to CV complications of DM recently topped 37 billion dollars. Over the past decade however the 10-year CHD risk has improved and ASCVD morbidity and mortality have decreased, likely in large measure due to efforts to lower cholesterol levels. Multiple trials have shown the benefits of lowering cholesterol in those with and without ASCVD. 14 randomized clinical trials including 18,000 patients have shown a 9% reduction in all-cause mortality and 13% reduction in vascular mortality for every 39mg/dl decrease in LDL. Current recommendations are that in patients over the age of 40, or in those with CVD, statins should be added to the treatment regimen, which includes lifestyle changes, regardless of baseline lipid levels. Additionally, lipid therapy should be considered in those under 40 who have multiple cardiac risk factors. Which statin to use, and the target dose, is based on the patient's CVD risk, side effects, tolerability and LDL cholesterol level. Those who have known CVD should aim for high-intensity statin therapy. 2019 ADA

guidelines recommend high intensity statin therapy in those under 40 who have ASCVD and those whose 10-year risk exceeds 20%. In those over 40 without ASCVD risk of greater that 20%, moderate intensity statin therapy is recommended, while high intensity therapy is recommended in all others. In both age groups, if LDL remains above 70 in the high-risk patients, consideration should be given to adding a PCSK9 therapy or ezetimibe. Even in those unable to tolerate moderate or high intensity therapy, low doses of statins have been shown to confer benefit. We will use paid, non-reversed Medicaid pharmacy and medical claims date from CYY 2018 excluding members with Part D, MaineRX and TPL.

Board Decision: No action needed at this time.

NEW DRUG REVIEW

Baqsimi® (glucagon powder); **PDL category-** Glucose Elevating Agents with Glucagon

Glucagon, the active ingredient of Baqsimi®, is an anti-hypoglycemic agent used to treat severe hypoglycemia. Glucagon increases blood glucose concentration by activating hepatic glucagon receptors, thus stimulating glycogen breakdown and release of glucose from the liver. Hepatic stores of glycogen are necessary for glucagon to produce an anti-hypoglycemic effect. It is indicated for the treatment of severe hypoglycemia in patients with diabetes ages 4 years and older. The safety and efficacy of Baqsimi® were assessed in two adult trials and one pediatric trial. The first adult trial was a randomized, multicenter, open-label, 2-period crossover study that included adults with type 1 diabetes mellitus. It is for intranasal use only and emergency assistance should be called immediately after administering the dose. In clinical studies, intranasal glucagon was shown to be effective for severe hypoglycemia and was non-inferior to IM glucagon for treatment success in one adult study and in reversing insulin-induced hypoglycemia in another adult study. In a pediatric study, all patients in both treatment arms of intranasal glucagon and IM glucagon achieved an increase in glucose ≥20mg/dL from glucose nadir within 20 minutes of administration.

Recommendation: Baqsimi® be non-preferred.

Clinical Criteria:

- For the treatment of patients ≥ 4 years of age.
- 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.

Board Decision: The Board unanimously approved the above recommendation.

Cutaquig® (immune globulin subcutaneous (Human)-hipp; **PDL category-** Immune Globulins

Cutaquig® is a solvent/detergent (S/D)-treated, sterile preparation of highly purified immunoglobulin G (IgG) derived from large pools of human plasma. It contains a broad spectrum of IgG antibodies against bacterial and viral agents that are capable of opsonization and neutralization of microbes and toxins. In addition, it contains maltose, but no preservatives or sucrose. All units of human plasma used in the manufacturing of Cutaquig® are provided by FDA-approved blood and plasma establishments and are tested by FDA-licensed

serologic tests for HBsAg, antibodies to HCV and HIV and Nucleic Acid Test (NAT) for HCV and HIV-1 and found to be non-reactive (negative). Cutaquig® supplies a broad spectrum of opsonizing and neutralizing IgG antibodies against a wide variety of bacterial and viral agents. While the mechanism of action has not been fully clarified, adequate doses may restore abnormally low immune globulin G levels to the normal range and thus help in preventing infections. Immune globulin solution for subcutaneous infusion (IGSC) is indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. In a prospective, single-arm study, there were no serious bacterial infections reported during any time of the study.

Recommendation: Cutaquig®, Cuvitru, Hizentra, Hyqvia be non-preferred.

Clinical Criteria:

- Cutaquig is indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults.

Board Decision: The Board unanimously approved the above recommendation.

Duobrii® (halobetasol propionate and tazarotene lotion); **PDL category**- Nonbiologic Agents for Psoriasis- Topical

Duobrii® is a combination product containing halobetasol propionate (corticosteroid) and tazarotene. Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the exact mechanism of action in plaque psoriasis is not known. Tazarotene is a retinoid prodrug that is converted to its active form, tazarotenic acid. Tazarotenic acid binds to all 3 members of the retinoic acid receptor (RAR) family with relative selectivity to 2 of the 3 receptors and may modify gene expression. The clinical significance of these findings for the treatment of plaque psoriasis is not known. A vasoconstrictor assay in healthy adults indicated that Duobrii® lotion is in the high to super-high range of potency as compared to other topical corticosteroids; however, similar blanching scores do not necessarily imply therapeutic equivalence. It is indicated for the topical treatment of plaque psoriasis in adults. The safety and efficacy of Duobrii® were assessed in 2 prospective, multicenter, randomized, double-blind, vehicle-controlled studies that included adults ≥18 years of age with moderate to severe plaque psoriasis. Duobrii® lotion is a combination product indicated for the topical treatment of plaque psoriasis in adults. A vasoconstrictor assay in healthy subjects indicated that Duobrii® lotions is in the high to super-high range of potency as compared to other topical corticosteroids. Compared with vehicle, it was more effective for the primary endpoint of treatment success.

Recommendation: Duobrii® be 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.

Board Decision: The Board unanimously approved the above recommendation.

Jornay® PM (methylphenidate extended-release); **PDL category**- Stimulant- Methylphenidate, Long-asting

Methylphenidate, the active ingredient of Jornay® PM, is a central nervous system (CNS) stimulant. The exact mode of action in ADHD is not known. Methylphenidate is thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extra neuronal space. Jornay® PM capsules contain beads with 2 functional film coatings (outer delayed-release and inner extended-release) surrounding a drug core coated with methylphenidate HCl. The outer, delayed-release coating delays the initial release of methylphenidate while the inner extended-release coating controls the release throughout the day. Jornay® PM is a Schedule II controlled substance. It is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years and older. The safety and efficacy of Jornay® PM were established in two clinical studies that included pediatric patients 6 to 12 years of age who met DSM-5 criteria for ADHD inattentive, hyperactive-impulse, or combined inattentive/hyperactive impulsive subtypes. It was found to be significantly more effective than placebo in clinical trials assessing efficacy, based on SKAMP scores and ADHD-RS-IV scores, with demonstrated efficacy in the morning and throughout the day. There is no evidence at this time that Jornay® PM is safer or more effective than the currently preferred medications. It is therefore recommended that Jornay® PM remain non-preferred and require prior authorization and be available to those who are unable to tolerate or who have failed on preferred medications.

Recommendation: Jornay® PM be non-preferred.

Clinical Criteria:

- For the treatment of patients ≥ 6 years of age.

Board Decision: The Board unanimously approved the above recommendation.

Lexette® (halobetasol propionate aerosol, form); **PDL category**- Steroids (Topical), Very High Potency

Lexette® is a hydroethanolic aerosol foam that contains the corticosteroid halobetasol propionate. Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the exact mechanism of action in plaque psoriasis is not known. It is indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older. The safety and efficacy of Lexette® were assessed in 2 multicenter, randomized, double-blind, vehicle-controlled studies that included adults ≥18 years of age with moderate to severe plaque psoriasis. It was found to be more effective than a vehicle foam for overall treatment success. As Lexette® is flammable, avoid fire, flame, or smoking during and immediately following application.

Recommendation: Lexette® be non-preferred.

Clinical Criteria:

- At least 1 drug from each potency of 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.

Board Decision: The Board unanimously approved the above recommendation.

Nubeqa® (darolutamide); **PDL category**- Cancer

Darolutamide, the active ingredient of Nubeqa®, is an androgen receptor (AR) inhibitor. It competitively inhibits androgen binding, AR nuclear translocation, and AR-mediated transcription. Darolutamide decreased prostate cancer cell proliferation in vitro and tumor volume in animal models of prostate cancer. It is indicated for the treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC). The safety and efficacy of Nubeqa® have not been established in females. The safety and efficacy of Nubeqa® were assessed in a multicenter, randomized, double-blind, placebo-controlled study that included adults with non-metastatic castration resistant prostate cancer with a prostate-specific antigen doubling time (PSADT) of ≤10 months. Patients with a history of seizures were not excluded. In a clinical trial, treatment with Nubeqa® resulted in a statistically significant improvement in metastasis free survival as compared to placebo.

Recommendation: Nubeqa® be non-preferred.

Clinical Criteria:

- Nubeqa is non-preferred and is for the treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC).

Board Decision: The Board unanimously approved the above recommendation.

Nuzyra® (omadacycline); **PDL category**- Tetracyclines

Omadacycline tosylate, the active ingredient of Nuzyra®, is an aminomethylcycline which is a semisynthetic derivative of the tetracycline class of antibacterial drugs. Omadacycline binds to the 30S ribosomal subunit and blocks protein synthesis. It is indicated for the treatment of adult patients with

- community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila pneumoniae.
- Acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp (includes S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae, and Klebsiella pneumoniae.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Nuzyra® and other antibacterial drugs, Nuzyra® should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy. The safety and efficacy of Nuzyra® were assessed in a multinational, double-blind, double-dummy trial comparing Nuzyra® to moxifloxacin in adults with CABP. In clinical trials, treatment success

rate with Nuzyra® were similar to those achieved with moxifloxacin in the treatment of CABP and were similar to those achieved with linezolid in the treatment of ABSSSI.

Recommendation: Nuzyra® be non-preferred.

Clinical Criteria:

- For the treatment of patients ≥ 8 years of age.

Board Decision: The Board unanimously approved the above recommendation.

Oxervate® (cenegermin-bkbj); **PDL category**- Ophthalmics- Of Interest

Cenegermin-bkbj, the active ingredient of Oxervate®, is a recombinant form of human nerve growth factor produced in E. coli. Nerve growth factor is an endogenous protein involved in the differentiation and maintenance of neurons, which acts through specific high-affinity (i.e. TrkA) and low-affinity (i.e. p75NTR) nerve growth factor receptors in the anterior segment of the eye to support corneal innervation and integrity. It is indicated for the treatment of neurotrophic keratitis. The safety and efficacy of Oxervate® were assessed in 2 randomized, multicenter, double-masked, vehicle-controlled studies of 8 weeks in duration. In clinical trials, compared with vehicle, Oxervate® produced significantly higher rates of complete corneal healing in adults with unilateral or bilateral neurotrophic keratitis. Oxervate® is the first FDA approved product approved for neurotrophic keratitis, a rare eye disease. It is recommended that Oxervate® should be non-preferred in order to confirm the appropriate diagnosis and clinical parameters for use.

Recommendation: Oxervate® be non-preferred.

Clinical Criteria:

- Oxervate is non-preferred and is indicated for the treatment of neurotrophic keratitis.

Board Decision: The Board unanimously approved the above recommendation.

Piqary® (alpelisib); **PDL category**- Cancer

Alpelisib, the active ingredient of Piqray®, is a kinase inhibitor. It is an inhibitor of phosphatidylinositol-3 kinase (PI3K) with inhibitory activity predominantly against PI3Kα. In vivo, alpelisib inhibited the PI3K/AKT signaling pathway and reduced tumor growth in xenograft models, including models of breast cancer. It is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen. The safety and efficacy of Piqray® plus fulvestrant were assessed in a randomized, double-blind, placebo-controlled study (SOLAR-1) that included patients (N=572) with HR-positive, HER2-negative, advanced or metastatic breast cancer whose disease had progressed or recurred on or after an aromatase inhibitor-based treatment (with or without CDK4/6 combination). Patients received treatment until radiographic disease progression or unacceptable toxicity. Tumor assessments were performed every 8 weeks for the first 18 months and every 12 weeks thereafter. In a clinical trial compared with placebo plus fulvestrant, Piqray® plus fulvestrant had a significantly improved progression-free survival. It is recommended that Piqray® should be non-preferred

in order to confirm the appropriate diagnosis and clinical parameters for use, as well as multiple trials of preferred agents.

Recommendation: Piqray® be non-preferred.

Clinical Criteria:

- Piqray is non-preferred and is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.
- Piqray has a DDI with a strong CYP3A4 inducer may decrease alpelisib concentrations, avoid the concomitant use of Piqray® with strong CYP3A4 inducers.

Board Decision: The Board unanimously approved the above recommendation.

Ruzurgi® (amifampridine); **PDL category**- Neurologics, Miscellaneous

Amifampridine, the active ingredient of Ruzurgi®, is a potassium channel blocker. The mechanism by which it exerts its therapeutic effects for its indication has not been fully established. Amifampridine is a broad-spectrum potassium channel blocker. It is indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 years to less than 17 years of age. The safety and efficacy of Ruzurgi® for the treatment of LEMS were assessed in a randomized, double-blind, placebo-controlled withdrawal study that included patients with an established diagnosis of LEMS, confirmed by documentation and an independent neurologist review. Patients were required to be on adequate and stable dosage (30mg to 100mg daily for at least 3 months) of Ruzurgi® prior to entering the study. The randomized patients had a median age of 56 years, 66% were female, and 91% were white. Significantly fewer patients randomized to Ruzurgi® experienced a >30% deterioration in the final post-dose 3TUG test as compared with placebo (0% vs 72%). In addition, compared with Ruzurgi®, those treated with placebo showed a significantly greater decrease in the W-SAS score, indicating that patients randomized to placebo perceived a worsening of weakness compared to those on Ruzurgi®.

Recommendation: Ruzurgi® be non-preferred.

Clinical Criteria:

- For the treatment of patients between ages 6-16 years of age.
- Ruzurgi is recommended for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 years to less than 17 years of age.

Board Decision: The Board unanimously approved the above recommendation.

Seysara® (sarecyclines); **PDL category**- Tetracyclines

Sarecycline, the active ingredient of Seysara®, is a tetracycline class drug. Its exact mechanism of action in treatment acne vulgaris is not known. It is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older. The efficacy of Seysara® beyond 12 weeks and the safety beyond 12 months have not been established. Seysara® has not been

evaluated in the treatment of infections. To reduce the development of drug resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Seysara® should be used only as indicated. The safety and efficacy of Seysara® were assessed in 2 multicenter, randomized, double-blind, placebo-controlled studies that included subjects 9 years of age and older. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Seysara® should be used only as indicated. Compared with placebo in 2 clinical trials, sarecycline was found to be significantly more effective for the co-primary efficacy endpoints per the full-length study by Moore et al2.

Recommendation: Seysara® be non-preferred.

Clinical Criteria:

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

Board Decision: The Board unanimously approved the above recommendation.

Sunosi® (solriamfetol); **PDL category**- Stimulant – Stimulant Like

Solriamfetol, the active ingredient of Sunosi®, is a dopamine and norepinephrine reuptake inhibitor (DNRI). While its exact mechanism of action is unclear, its efficacy could be mediated through its activity as a NDRI. Sunosi® is a Schedule IV controlled substance and has the potential for abuse. Physicians should carefully evaluate patients for a recent history of drug abuse, especially those with a history of stimulant or alcohol abuse, and follow such patients closely, observing them for signs of misuse or abuse of Sunosi®. It is indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). Sunosi® is not indicated to treat the underlying airway obstruction in OSA. Ensure that the underlying airway obstruction is treated (e.g. continuous positive airway pressure (CPAP)) for at least one month prior to initiating Sunosi® for excessive daytime sleepiness. Modalities to treat the underlying airway obstruction should be continued during treatment with Sunosi®. Sunosi® is not a substitute for these modalities. The safety and efficacy of Sunosi® for improving wakefulness and reducing excessive daytime sleepiness were assessed in a multicenter, randomized, double-blind, placebo-controlled, parallel-group study of 12 weeks in duration that included adults with a diagnosis of narcolepsy per ICSD-3 or DSM-5 criteria. Compared to the placebo group, patients in the Sunosi® 150mg group demonstrated statistically significant improvements on the MWT (treatment difference 7.7 minutes) and on the ESS (treatment effect difference 3.8 points) at week 12. In clinical trials, Sunosi® significantly improved changes in MWT, ESS, and PGI-C as compared with placebo at 12 weeks in patients with narcolepsy and in patients with OSA.

Recommendation: Sunosi® be non-preferred. Move Modafinil tabs to preferred.

Clinical Criteria:

- Sunsosi is non-preferred and is indicated for to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).
- DDI: Sunosi® is contraindicated with MAO inhibitors or within 14 days after discontinuing the MAO inhibitor.

Board Decision: The Board unanimously approved the above recommendation.

Vyndaqel® (tafamidis meglumine); **PDL category**- Neurologics- hATTR Agents

Tafamidis meglumine, the active ingredient of Vyndaqel®, is a selective stabilizer of transthyretin (TTR). Tafamidis binds to TTR at the thyroxine binding sites, stabilizing the tetramer and slowing dissociation into monomers, the rate-limiting step in the amyloidogenic process. It is indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization. The efficacy of Vyndaqel® was assessed in a multicenter, randomized, double-blind, placebo-controlled study that included patients with wild type or hereditary ATTR-CM (N=441). Adults were randomized to receive Vyndaqel® 20mg, Vyndaqel® 80mg, or matching placebo QD for 30 months, in addition to standard of care (e.g. diuretics). Transplant patients were excluded from the study. Compared with placebo, Vyndaqel® significantly reduced all-cause mortality, cardiovascular-related hospitalization rate, and functional decline in a 30-month clinical trial.

Recommendation: Vyndaqel® be non-preferred.

Clinical Criteria:

- PA required for appropriate diagnosis.

Board Decision: The Board unanimously approved the above recommendation.

Xpovio® (selinexor); **PDL category**- Cancer

Selinexor, the active ingredient of Xpovio®, is an orally available nuclear export inhibitor. In nonclinical studies, selinexor reversibly inhibits nuclear export of tumor suppressor proteins (TSPs), growth regulators, and mRNAs of oncogenic proteins by blocking exportin 1 (XPO1). XPO1 inhibition by selinexor leads to accumulation of TSPs in the nucleus, reductions in several oncoproteins (such as c-myc and cyclin D1), cell cycle arrest, and apoptosis of cancer cells. It is indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least 4 prior therapies and whose disease is refractory to at least 2 proteasome inhibitors, at least 2 immunomodulatory agents, and an anti-CD38 monoclonal antibody. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. The efficacy of Xpovio® in combination with dexamethasone was assessed in a multicenter, single-arm, open-label study (STORM) that included patients with RRMM. In a single study with a pre-specified subgroup analysis of 83 patients, the overall response rate was 25%. It is recommended that Xpovio® should be non-preferred in order to confirm the appropriate diagnosis and clinical parameters for use, as well as multiple trials of preferred agents.

Recommendation: Xpovio® be non-preferred.

Clinical Criteria:

- Xpovio is non-preferred and is indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least 4 prior therapies and whose disease is refractory to at least 2 proteasome inhibitors, at least 2 immunomodulatory agents, and an anti-CD38 monoclonal antibody.

Board Decision: The Board unanimously approved the above recommendation.

FDA SAFETY ALERTS

FDA approves Boxed Warning about increased risk of blood clots and death with higher dose of arthritis and ulcerative colitis medicine tofacitinib (Xeljanz, Xeljanz XR)
https://www.fda.gov/drugs/drug-safety-and-availability/fda-approves-boxed-warning-about-increased-risk-blood-clots-and-death-higher-dose-arthritis-and

FDA warns about rare occurrence of serious liver injury with use of hepatitis C medicines Mavyret, Zepatier, and Vosevi in some patients with advanced liver disease
https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-rare-occurrence-serious-liver-injury-use-hepatitis-c-medicines-mavyret-zepatier-and?utm_campaign=Hep%20C%20DSC%20liver%20injury&utm_medium=email&utm_source=Eloqua

Board Decision: No formal action required

ADJOURNMENT: 8:30PM

The next meeting will be held on **October 8, 2019** 1:30pm –4:30pm at the Augusta Armory.