MaineCare Services
An Office of the Department of Health and Human Services
Paul R. LePage, Governor Mary C. Mayhew, Commissioner

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TO: Maine Drug Utilization Review Board
DATE: February 17th, 2015
RE: Maine DUR Board **Meeting** minutes from February 10th, 2015

ATTENDANCE	PRESENT	ABSENT	EXCUSED
Robert Weiss, M.D., Cardiologist, Chair			X
Linda Glass, M.D.	X		
Lisa Wendler, Pharm. D., Clinical Pharmacy Specialist, Maine Medical CTR	X		
Lindsey Tweed, M.D., Psychiatrist	X		
Mark Braun, M.D., FACP, Internist/Geriatrician	X		
Mike Ouellette, R.Ph., GHS	X		
Non –Voting			
Jan Yorks-Wright, Pharmacy Supervisor, OMS	X		
Kevin Flanigan, M.D., Internist, Medical Director, OMS			X
Roger Bondeson, Director of Operations, OMS	X		

Guests of the Board: Ed Bosshart, PharmD,

CALL TO ORDER: 6PM

PUBLIC COMMENTS

Janet Thompson from Abbvie presenting Viekira Pak. Viekira Pak with or without ribavirin is indicated for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis. VIEKIRA PAK includes ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, ritonavir, a CYP3A inhibitor and dasabuvir, a hepatitis C virus non-nucleoside NS5B palm polymerase inhibitor. VIEKIRA PAK is not recommended for use in patients with decompensated liver disease. The efficacy and safety of VIEKIRA PAK was evaluated in six randomized, multicenter, clinical trials in 2,308 subjects with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection,including one trial exclusively in subjects with cirrhosis with mild hepatic impairment. Recommended dosage: Two ombitasvir, paritaprevir, ritonavir 12.5/75/50mg tablets once

daily (in the morning) and one dasabuvir 250 mg tablet twice daily (morning and evening) with a meal without regard to fat or calorie content.

Limor Ouziel from Sanofi presenting Afrezza. Afrezza is a rapid acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus. Administer using a single inhalation per cartridge.Administer at the beginning of a meal AFREZZA is available as single-use cartridges of: 4 units & 8 units. Afrezza has a risk of acute bronchospasm in patients with chronic lung disease. Acute bronchospasm has been observed in patients with asthma and COPD using Afrezza. Afrezza is contraindicated in patients with chronic lung disease such as asthma or COPD. Before initiatingAFREZZA, perform a detailed medical history, physical examination, and spirometry (FEV) to identify potential lung disease in all patients.

Mr. Ouellette asked how Afrezza was packaged.

It is different depending on the prescription they are packaged with two inhalers.

OLD BUSINESS

DUR MINUTES

The January 13,2015 minutes were approved.

PSYCH WORK GROUP UPDATE

No update at this time

NEW BUSINESS

FINAL HEPATITIS C PA FORM AND STATUS

Mr. Ouellette presented the updated Hep C PA from. Dr. Biczak and GHS has diligently worked on this PA form. The updated PA form shows a clear separation of the genotypes On the new form you will see that we have separated it out by genotype. The new form breaks it down by different treatment regimens based on if the patient is treatment naïve, no cirrhosis or treatment naïve, compensated cirrhosis etc. Also added was a box for a couple different treatment regimen under Genotype 1b and Genotype 4 for decompensated cirrhosis. The form makes it very clear on what the PA requirements are.

Dr. Glass stated that the form is very clear.

FDA SAFETY ALERTS

FDA Drug Safety Communication: FDA recommends not using lidocaine to treat teething pain and requires new Boxed Warning (6/26/2014) http://www.fda.gov/drugs/drugsafety/ucm402240.htm

Mr. Ouellette suggested that we could put an age edit that for Lidocaine Viscous a PA will be required for anyone 3 and under.

Dr. Glass agreed

Approved by the board

Drug Safety and Availability: Methylphenidate HCl ER tablets (generic Concerta) made by Mallinckrodt and Kudco: FDA concerns about therapeutic equivalence with 2 generic versions of Concerta tablets (11/13/2014) http://www.fda.gov/drugs/drugsafety/ucm422568.htm

Mr. Ouellette stated that in the mean time they have been allowing Concerta to go through.

Dr. Tweed asked if a notification has been sent out.

Mr. Ouellette answered no.

Dr. Tweed stated that he would like to put something on the List Serv.

FDA Drug Safety Communication: FDA reviews long-term antiplatelet therapy as preliminary trial data shows benefits but a higher risk of non-cardiovascular death (11/16/2014)
http://www.fda.gov/Drugs/DrugSafety/ucm423079.htm

FDA Drug Safety drug Communication: FDA reporting mental health ziprasidone (Geodon) associated with rare but potentially fatal skin reaction (12/11/2014) http://www.fda.gov/ FDA Drug Safety Communication: FDA warns about case of rare brain infection PML with MS drug Tecfidera (dimethyl fumarate) (11/25/2014)
http://www.fda.gov/Drugs/DrugSafety/ucm424625.htm

FDA News Release: FDA issues final rule on changes to pregnancy and lactation labeling information for prescription drug and biological products (12/3/2014)
http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm425317.htm

Mr. Ouellette mentioned GHS would continue to monitor once final rule is in place for program or system edit changes.

FDA Drug Safety Communication: FDA has reviewed possible risks of pain medicine use during pregnancy (1/9/2015) http://www.fda.gov/Drugs/DrugSafety/ucm429117.htm

NEW DRUG REVIEW

Mr.Ouellette presented that following new drug reviews.

Afreeza common name inhaled human insulin in the PDL category Diabetic- Insulin the recommendation is for it to be non-preferred. This is a rapid acting inhaled insulin indicated to improve glycemic control in adult patients with DM. Limitations of use include that it's not a substitute for long-acting insulin; it must be used in combination with long-acting insulin in patients with type 1 DM. The most frequently reported adverse events included cough and throat pain or irritation.

Akynzeo common name netupitant and palonosetron combination in the PDL category Antiemetic- 5-HT3 receptor antagonists/Suboxone P Neurokinin the recommendation is for it to be non-preferred. For the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy (HEC). With this oral fixed-dose combination product, palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy. Patients should be monitored for the development of serotonin syndrome, especially with concomitant use of Akynzeo and other serotonergic medications.

Arnuity Ellipta common name fluticasone furoate in the PDL category Antiasthmatic- Steroid Inhalants the recommendation is for it to be non-preferred. For the once-daily maintenance treatment of asthma as prophylactic therapy in patients aged ≥12 years. A limitation of use is that it is NOT indicated for the relief of acute bronchospasm. Foil blister strip containing Powder for inhalation, each blister contains: 100mcg or 200mcg. Administer one inhalation orally QD, with the usual recommended starting dose of 100mcg. If no response after 2 weeks, may increase to 200mcg dose administered QD, which is the highest recommended daily dose. After each dose, rinse mouth with water without swallowing. Per the National Heart, Blood, and Lung Institute (NHBLI) expert panel in their stepwise approach to treating asthma an anti-inflammatory medication is recommended for mild-persistent asthma. Inhaled glucocorticoids are recommended to be used as the first long-term controller therapy.

Belsomra common name suvorexant in the PDL category Sedative/Hypnotic- Non- Benzodiazepines the recommendation is for it to be non-preferred. For the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance. The lowest effective dose should be used. Take 10mg once per night within 30 minutes of going to bed and with ≥7 hours remaining before the planned time of awakening. If the 10mg dose is tolerated but not effective, the dose may be increased to a maximum of 20mg. Dose adjustments are not required in those with renal or mild-to-moderate hepatic impairment.

Bunavail common name buprenorphine HCl & naloxone HCl dihydrate in the PDL category Opioid Dependence Treatments the recommendation is for it to be non-preferred. For the maintenance treatment of opioid dependence and to be used as part of a complete treatment plan to include counseling and psychosocial support. Dosage forms are Buccal Film: 2.1/0.3mg, 4.2/0.7mg, and 6.3/1mg of buprenorphine/naloxone. Films should not be cut or torn. Should only be used in those who have been initially inducted using buprenorphine SL tablets. A buccal film should be applied to the buccal mucosa as a single daily dose, with the recommended target dose of 8.4/1.4mg daily as a single daily dose and the maintenance dose range of 2.1/0.3mg to 12.6/2.1mg per day. The films should not be chewed or

swallowed, and drinking and eating should be avoided until the film has dissolved. Treatment should be started under supervised administration, but should progress to unsupervised administration as the patients clinical stability allows.

Esbriet common name pirfenidone in the PDL category Pulmonary Fibrosis the recommendation is for it to be non-preferred. For the treatment of idiopathic pulmonary fibrosis (IPF). Dosage form is a 267mg capsule. Prior to initiating treatment, liver function tests should be obtained. The maintenance dose is 801mg TID with food (2,403mg/day total), after a 14 day titration period. If significant adverse reactions occur (i.e. GI, photosensitivity reaction, or rash), consider a temporary dose reduction or interruption of treatment to allow for resolution of symptoms. There is currently no cure for IPF; however, supportive care plays a vital role, and this includes supplemental oxygen when needed, education, pulmonary rehabilitation, and seasonal influenza vaccination. Esbriet® is now one of two FDA approved medications in the US that has data which demonstrates slowing of disease progression.

Hysingla ER common name hydrocodone bitartrate, extended-release in the PDL category Narcotics, Long-acting the recommendation is for it to be non-preferred. For the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Dosage forms is a Bi-convex, film-coated extended-release tablets: 20mg, 30mg, 40mg, 60mg, 80mg, 100mg, and 120mg. This product should not be crushed, chewed, or dissolved. It is recommended that Hysingla® ER only be prescribed by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. It should be administered QD, initiated at 20mg for first opioid analgesic users or who are not opioid tolerant. Specifically, the box warning for Hysingla® ER warns of the increased risk of addiction, abuse, and misuse; life-threatening respiratory depression; accidental ingestion; neonatal opioid withdrawal syndrome; and CYP3A4 drug interactions.

Incruse Ellipta common name umeclidiniumbromide in the PDL category Antiasthmatic- Anticholinergics the recommendation is for it to be non-preferred. Indicated for the long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. It's an Inhalation powder, with 30 blisters per strip, each containing powder for oral inhalation.

Keytruda common name pembrolizumab in the PDL category Cancer the recommendation is for it to be non-preferred. For the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. This indication is approved under accelerated approval based on tumor response rate and durability of response. An improvement in survival or disease-related symptoms has not yet been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Kerydin common name tavaborole the PDL category Topical-Antifungals the recommendation is for it to be non-preferred. Treatment of onychomycosis of the toenails. Apply to affected toenails QD X48 weeks, applied to entire toenail surface and under the tip of each toenail being treated.

Lynparza common name olaparib in the PDL category Cancer the recommendation is for it to be non-preferred. Indication as monotherapy in patients with deleterious or suspected deleterious germline *BRCA* mutated (as detected by an FDA-approved test) advanced ovarian cancer who have been treated with ≥3 prior lines of chemotherapy. This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefits in confirmatory trials. The recommended dose is 400mg BID

taken until disease progression or unacceptable toxicity. A dose reduction (to 200mg BID) or interruption of treatment may be needed to manage adverse reactions.

Mircera common name methoxy polethlene glycol-epoetin beta in the PDL category Erythropoitins the recommendation is for it to be non-preferred. For the treatment of anemia associated with chronic kidney disease (CKD) in adult patients on dialysis and patients not on dialysis. Dosing of Mircera® should be individualized, with the lowest dose necessary to reduce the need for RBC transfusions. It should be given either IV or SC; when given SC, it should be injected in the abdomen, arm, or thigh. The box warning indicates that in controlled trials in a population with CKD, patients experienced greater risks for death, serious adverse CV reactions, and stroke when given ESAs to target a hemoglobin level of >11g/dl.

Onexton common name clindamycon phosphate & benzoyl peroxide gel in the PDL category Topical-Acne Preparations the recommendation is for it to be non-preferred. For the topical treatment of acne vulgaris in those ≥12 years of age.

Ofev common name nintedanib in the PDL category Pulmonary Fibrosis the recommendation is for it to be non-preferred. Treatment of idiopathic pulmonary fibrosis.

Oralair common name anthoxanthum odoratum pollen, dactylis glomerata pollen, lolium perenne pollin, phleum pretense pollen, & poa pratensis pollen the PDL category Allergen Immunotherapy the recommendation is for it to be non-preferred. Treatment should be started 4 months before the expected onset of each grass pollen season and maintained throughout the grass pollen season.

Plegridy common name peginterferon beta-1a in the PDL category Multiple Sclerosis- Interferons the recommendation is for it to be non-preferred. For the treatment of patients with relapsing forms of multiple sclerosis (MS). The recommended maintenance dose is 125mcg SC Q14 days after the following titration schedule of 63mcg SC on day 1, 94mcg on day 15 (14 days later), and then 125mcg on day 29 (another 14 days later).

Savaysa common name edoxaban in the PDL category Anticoagulants the recommendation is for it to be non-preferred. To reduce the risk of stroke and systemic embolism (SE) in patients with non-valvular atrial fibrillation (NVAF) AND for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) following 5-10 days of initial therapy with a parenteral anticoagulant.

Soolantra common name ivermectin in the PDL category Topical- acne the recommendation is for it to be non-preferred. Treatment of inflammatory lesions of rosacea.

Trulicity common name dulaglutide in the PDL category Incretin Mimetics the recommendation is for it to be non-preferred. Indication is adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Trulicity® is not recommended to be used as a first-line treatment for those who have inadequate glycemic control on diet and exercise. It should not be used in those with type 1 DM or for the treatment of diabetic ketoacidosis; it is not a substitute for insulin.

Tybost common name cobicistat in the PDL category Antiretrovirals the recommendation is for it to be non-preferred. **:** This is a CYP3A inhibitor indicated to increase systemic exposure of atazanavir or darunavir (QD dosing regimen) in combination with other antiretroviral agents in the treatment of HIV-1 infection.

Uceris tab common name budesonide ER tablet in the PDL category GI- Inflammatory Bowel Agents the recommendation is for it to be non-preferred. For the induction of remission in patients with active mild to moderate distal ulcerative colitis extending up to 40cm from the anal verge.

Uceris rectal foam common name budesonide in the PDL category GI- Inflammatory Bowel Agents the recommendation is for it to be non-preferred. For the induction of remission in patients with active, mild to moderate ulcerative colitis (UC). As this product contains flammable contents, the patient should avoid fire, flame, and smoking during and immediately following use.

Viekira Pak common name ombitasvir, paritaprevir & ritonavir tabs; dasabuvir tabs in the PDL category Hepatitis C Agents the recommendation is for it to be preferred with conditions. To be used with or without ribavirin for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis.

Xigduo XR common name dapagliflozin & metformin ER in the PDL category SGLT-2 Inhibitor Combinations the recommendation is for it to be non-preferred. As an adjunct to diet and exercise to improve glycemic control in adults with type 2 DM when treatment with both dapagliflozin and metformin is appropriate. Use of this product is not recommended for patients with type 1 DM or diabetic ketoacidosis. One tablet QAM with food and gradual dose escalation to reduce GI side effects, to a max of 10/2000mg based on effectiveness and tolerability. Volume depletion should be corrected prior to starting treatment

The board voted and approved all above recommendations.

ADJOURNMENT: 6PM

The next meeting will be held on **March 10, 2015** 6:00p.m. – 8:00p.m at the Augusta Armory.