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: June 16, 2015
RE: Maine DUR Board **Meeting** minutes from June 9, 2015

ATTENDANCE	PRESENT	ABSENT	EXCUSED
Linda Glass, M.D.		X	
Lisa Wendler, Pharm. D., Clinical Pharmacy Specialist, Maine Medical CTR	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: Jeffrey S. Barkin MD, DFAPA, Ed Bosshart, PharmD

CALL TO ORDER: 6PM

PUBLIC COMMENTS

Syed Mahmud from Shire presented Natpara®. Natpara® is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism. Because of a potential risk of osteosarcoma, use Natpara® only in patients who cannot be well controlled on calcium and active forms of vitamin D alone and for whom the potential benefits are considered to outweigh this potential risk. Drug to drug interactions are as follows: monitoring the serum calcium more frequently when using Natpara® in patients receiving digoxin and co-administration of alendronate and Natpara® leads to reduction in the calcium sparing effect, which can interfere with the normalization of serum calcium. Concomitant use of Natpara® with alendronate is not recommended.

Limor Ouziel- Yahalom from Sanofi presented Toujeo®. Toujeo® is a long- acting human insulin analog indicated to improve glycemic control in adults with diabetes mellitus. The molecular structure of

Toujeo® is very similar to Lantus®. However, the profile fraction is totally different. When you look at the profile look Toujeo® is flatter and longer duration of fraction. The benefit is that there is better glycemic coverage and less hypoglycemic events.

Tom Algozzine from Novartis presented Cosentyx®. Cosentyx is a human interleukin-17A antagonist indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. Recommended dose is 300 mg by subcutaneous injection weekly for 5 doses as an induction followed by 4weeks of no weight base dosing. It is available as an auto injector or a pre filled syringe. No black box warning. In all trials, the endpoints were the proportion of subjects who achieved a reduction in Psoriasis Area Severity Index(PASI) score of at least 75% (PASI 75) from baseline to Week 12 and treatment success (clear or almost clear) on the Investigator's Global Assessment modified 2011 (IGA). Other evaluated outcomes included the proportion of subjects who achieved a reduction in PASI score of at least 90% (PASI 90) from baseline at Week12, maintenance of efficacy to Week52, and improvements in itching, pain and scaling at Week12 based on the Psoriasis Symptom Diary.

Jenni Boynton from Amgen presented Corlanor®. Corlanor is indicated for a patient with stable, symptomatic chronic HF with LVEF ≤ 35% and in sinus rhythm with resting heart rate ≥ 70 bpm.

Dr. Barkin asked if there were any improvement in cardiovascular death.

Mrs. Boynton answered that in the SHIFT trial the death rate was 9% reduction and that was not significant but when they looked at the hospitalization rate that is where there was a significant reduction. The benefit of Corlanor is in hospitalization, keeping patients out of the hospital minimizing cost and the downward spiral that comes with hospitalization.

OLD BUSINESS

DUR MINUTES

The April 2015 minutes were approved.

PSYCH WORK GROUP UPDATE

No update at this time

MAINECARE UPDATE

MaineCare will be working on moving the board to a memorandum of understanding (MOU) instead of a contract for board members. In an effort to get more members on the board we are looking at having a conference call number available for board members to be able to call into the meeting.

NEW BUSINESS

ANNUAL SYNAGIS UTILIZATION

Mr. Ouellette presented Synagis utilization data. At the beginning of the Synagis season new guidelines had come out. As a result changes to the Synagis PA form were made. The data presented shows that the member count was half of what it was in 2014. Basically with the changes made it so that only those at high risk received the medication. Because those received the medication were at higher risk the data shows that the number of doses has gone up. Even with the dose amounts increased we still saw significant savings.

Board Decision: No action required

UTILIZATION OF HEP C DRUGS

Mr. Ouellette presented the monthly Hepatitis C utilization data. The data shows all the different hep C products, number of scripts, and number of patients per month. As well as comparing 2015 SFY year to 2014 SFY year amount paid, patients and scripts. This report shows the large increase in Harvoni and Sovaldi. GHS closely monitors this report to see if reached peek, flat line or see a decrease. Another thing that GHS is tracking is SVR rates. More detailed data will be presented at the September meeting.

Board Decision: No action required

NALOXONE NASAL INJECTION

Mr. Ouellette stated that due to an accident over the weekend Steve Rolfe from MMC will not be presenting this data. In his place board member Lisa Wendler will be presenting.

Ms. Wendler stated that she has spoken with both Steve Rolfe and the psychiatric pharmacist at Maine Medical Center (MMC) as they have been working diligently on this topic. I have provided two documents to the board member for review. The first is a letter from prescriber in Portland who is in support of the Naloxone nasal injection. The second document is the latest draft of an educational document that MMC is hoping to provider to patient along with the naloxone nasal kit. Other states have moved in the direction of providing nasal Naloxone kits and Maine is working toward that. Although unaware of the details Maine General received a grant to give out the kits to populations. Also a couple of clinics in Portland were able to obtain injectable kit at no cost and have been distributing those. This topic is also being discussed in the legislator, also though not aware of all the details Maine as passed bills that give immunity to the administrator of the drug. Also it is believed that an amendment to LD 140 to give immunity to those that dispense the Naloxone. This amendment came because some pharmacies are reluctant to provider this drug without that kind of protection. Looking ahead in the Portland area with Maine Medical Center willing to put this kit together if the cost can get covered for the patient then other sites in the state may follow.

Dr. Barkin stated that during the winter he went on a ride along with the police and saw the Naloxone nasal injection in use. He saw people that were going to die and within minutes they were thrashing and combative but alive. From a public health prospective Maine has an opiate epidemic and the single most effective is Naloxone. In Massachusetts where because of Naloxone a 95% reduction in death rates and

that was only in law enforcement. GHS look into this further and discuss with MaineCare options to see if making is it's something that can be covered.

Board Decision: No action required

NEW DRUG REVIEW

Auryxia the common name is ferric citrate in the PDL category phosphate binders. It is for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis. There is no data found to suggest that Auryxia® is safer or more effective than the currently available, more cost-effective medications.

Recommendation: The recommendation is for Auryxia® it to be non-preferred.

Cholbam the common name is cholic acid in the PDL category GI, bile acid. For the treatment of bile acid synthesis disorders due to single enzyme defects (SEDs) AND for the adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption.

Recommendation: It is recommended that Cholbam® remain non-preferred and require clinical prior authorization to verify diagnosis and appropriate lab testings.

Corlanor the common name is ivabradine in the PDL category cardiac sinus node inhibitors. To reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤35%, who are in sinus rhythm with resting heart rate ≥70 beats per minute (bpm) and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.

Recommendation: The recommendation is for it to be non-preferred.

Cosentyx the common name is secukinumab in the PDL category psoriasis biological. For the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. Cosentyx®, is a recombinant human monoclonal IgG1/k antibody that is expressed in a recombinant Chinese Hamster Ovary (CHO) cell line. There were 4 multicenter, randomized, double-blind, placebo-controlled that assessed the safety and efficacy of Cosentyx® in adults (N=2403) with plaque psoriasis.

Recommendation: The recommendation is for it to be non-preferred.

Cresemba the common name is isavuconazonium sulfate in the PDL category antifungal,assorted. It is for patients ≥18 years of age for the treatment of invasive aspergillosis AND for the treatment of invasive mucormycosis. Also noted, in the overall success of the end of treatment group was seen almost identically to Voriconazole. There is no evidence at this time to support that Cresemba® is more efficacious or safer than the currently available, more cost effective medications based on data from the registration trials and other reference sources.

Recommendation: The recommendation is for it to be non-preferred.

Evekeo the common name is amphetamine sulfate in the PDL category stimulant- amphetamines, short acting. For narcolepsy AND Attention Deficit Disorder with Hyperactivity (ADDH) as an integral part of a total treatment program AND for exogenous obesity as a short term (a few weeks) adjunct in a regimen

of weight reduction based on caloric restriction for patients refractory to alternative therapy (e.g. repeated diets, group programs, and other drugs). Amphetamine sulfate, the active ingredient of Evekeo®, is a sympathomimetic amino of the amphetamine group with CNS stimulant activity. It is a 1:1 racemic mixture of dextroamphetamine and levo-amphetamine

Recommendation: The recommendation is for it to be non-preferred.

Evzio the common name is naloxone HCL in the PDL category narcotic- antagonists. It is used for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Evzio® is intended for immediate administration as emergency therapy in settings where opioids may be present. Evzio® does contain a speaker that provides voice instructions to guide the user through each step of the injection; however, if this voice system does not operate properly, the dose can still be administered.

Recommendation: The recommendation is for it to be non-preferred to verify diagnosis.

Farydak the common name is panobinostat lactate in the PDL category cancer. Used in combination with bortezomib and dexamethasone for the treatment of patients with multiple myeloma (MM) who have received ≥2 prior regimens, including bortezomib and an immunomodulatory agent.

Recommendation: The recommendation is for it to be non-preferred.

Kitabis the common name is tobramycin solution in the PDL category aminoglycosides. It is used for the management of cystic fibrosis (CF) in adults and pediatric patients ≥6 years of age with *P aeruginosa*. Safety and efficacy have not been demonstrated in: patients <6 years of age, patients with FEV1 <25% or >75% predicted, or patients colonized with *Burkholderia cepacia*.

Recommendation: The recommendation for Kitabis® is for it to be preferred. Move Tobi Nebu and Tobramycin Sulfate Soln to non-preferred allowing them a grace period until 10/1/15 to transition to preferred Kitabis®

Namzaric the common name is memantine HCL and donepezil HCL in the PDL category Alzheimer-Cholinomimetics/other. Treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on: memantine (10mg BID or 28mg ER QD) and donepezil 10mg OR memantine (5mg BID or 14mg ER QD) and donepezil 10mg (in patients with severe renal impairment). This is a pregnancy category C medication. Namzaric® was found to be bioequivalent to the co-administration of the individual ingredients memantine ER and donepezil.

Recommendation: The recommendation is for it to be non-preferred.

Natesto the common name is testosterone in the PDL category androgens/anabloics. Use for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Gel for intranasal use in a dispenser with a metered dose pump

Natpara the common name is parathyroid hormone in the PDL category parathyroid hormones. Indications and usage is adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

Recommendation: The recommendation for Natpara® should be non-preferred and require clinical prior authorization to assess diagnosis, prior trials of preferred agents, and appropriate lab monitoring.

Nuvessa the common name is metronidazole gel in the PDL category vaginal- antibacterials. Nuvessa® is indicated for the treatment of bacterial vaginosis in non-pregnant women.

Recommendation: The recommendation is for it to be non-preferred.

Proair Respiclick the common name is albuterol in the PDL category antiasthmatic-beta adrenergics. It is used for the treatment or prevention of bronchospasm in patients ≥12 years with reversible obstructive airway disease AND for the prevention of exercise-induced bronchospasm (EIB) in patients ≥12 years of age.

Recommendation: The recommendation is for it to be non-preferred.

Spririva Respimat the common name is tiotropium bromide in the PDL category antiasthmatic-beta adrenergics. It is indicated for the long-term, once-daily maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema AND to reduce exacerbations in COPD patients. The Respimat inhaler and aluminum cylinder (cartridge), each actuation delivers 2.5mcg of tiotropium from the mouthpiece.

Recommendation: The recommendation is for it to be non-preferred.

Toujeo the common name is insulin glargine U-300 in the PDL category Diabetic-Insulin. The indication is to improve glycemic control in adults with diabetes mellitus (DM). A limitation of use is that Toujeo® is not recommended for the treatment of diabetic ketoacidosis.

Recommendation: The recommendation is for it to be non-preferred.

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

FDA SAFETY ALERTS

Mucinex Fast-MAX Products: Recall - Incorrect Labeling
Including certain lots of Mucinex Fast-MAX Night Time Cold & Flu; Mucinex Fast-MAX Cold & Sinus; Mucinex Fast-MAX Severe Congestion & Cough and Mucinex Fast-MAX Cold, Flu & Sore Throat
http://www.fda.gov/Safety/Recalls/ucm444028.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA issues final guidance on the evaluation and labeling of abuse-deterrent opioids
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm440713.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Counterfeit Version of Botox Found in the United States
http://www.fda.gov/Drugs/DrugSafety/ucm443217.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Amyotrophic Lateral Sclerosis (ALS) Statement
http://www.fda.gov/Drugs/DrugSafety/ucm443242.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Drug Safety Communication: FDA warns that SGLT2 inhibitors for diabetes may result in a serious condition of too much acid in the blood
http://www.fda.gov/Drugs/DrugSafety/ucm446845.htm

Board Decision: No action required

ADJOURNMENT: 8PM

The next meeting will be held on **September 9, 2015** 6:00p.m. – 8:00p.m at the Augusta Armory.