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

Department of Health and Human Services
MaineCare Services
Pharmacy Unit
11 State House Station
Augusta, Maine 04333-0011
Toll Free (866) 796-2463; Fax: (207) 287-8601
TTY Users: Dial 711 (Maine Relay)

TO: Maine Drug Utilization Review Board
DATE: March 13, 2015
RE: Maine DUR Board **Meeting** minutes from March 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		
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

CALL TO ORDER: 6PM

PUBLIC COMMENTS

OLD BUSINESS

DUR MINUTES

The February 10, 2015 minutes were approved.

PSYCH WORK GROUP UPDATE

No update at this time

MAINECARE UPDATE

No update at this time

NEW BUSINESS

ADURS MEETING UPDATE

Mr. Ouellette presented an update on the yearly ADURS Meeting. This year CMS compile a report of all the annual DUR reports that are sent in by each state. One of the things of interest to compare among the states was how each state handles opiates/suboxone. 84% of the states are some kind of quantity limits on short acting opiates, these vary from state to state, 82% have it on long acting as well. The state of Maine sets it limit by MSEs equivalent dosing on 18% do Some of the topics that were discussed at the meeting included narcotic limitations, hepatitis C, use of benzos and opiates and treatment with childhood depression.

Dr. Weiss asked if any other states are trying to eliminate methadone.

Mr. Ouellette answered that states are looking into restricting or limiting the use of methadone.

Dr. Barkin asked if there were interventions that other states were doing that we should look at in Maine.

Mr. Ouellette answered that he would like to look into what Tennessee is doing with methadone.

TAMIFLU AND RELENZA UPDATE

Mr. Ouellette presented to the board two articles one from the CDC stating that this year's influenza vaccine was only 18% effective. As part of GHS's work we give updates to the state during this season showing the number of prescription and patients being effective. This information is also broken down further by age and county.

Mr. Bondsen asked because the CDC stated the flu vaccine was less effective was this season worse than prior seasons when the vaccine was more effective.

Dr. Weiss answered that it is hard to answer because we d not know the severity of the illness as well as the amount of patients that may have had the flu but were untreated.

Mr. Ouellette added that it may be worth taking a look at the cost difference between the different vaccines. It may make sense to pay a higher cost premium that may have a higher effective rate.

Mr. Ouellette stated that in gathering the data for this topic as well conversation from the ADURS Meeting Synagis was brought up. With the new guidelines and PA form that went into effect at the beginning of the season. Some of the other states also incorporated the new guidelines; one state was anticipating a 70% drop in synagis use. Included in the packets are two handouts; one looking at the state of Maine's utilization for 2011-2014 SFY. With the new guidelines we are seeing 40% decreases by using the new guidelines. The second document shows information in regards to the RSV season. In order to qualify as the season starting you need to have two weeks in a row of 10% or greater. For this year we did not reach that until the week of 2/14 and 2/21. Other states that GHS works with use a set date for the season and an end date of March 1st whether the season is done or not. In review, the changes that the DUR board has done has had a positive impact as far as utilization and spend.

FDA SAFETY ALERTS

FDA Drug Safety Communication: FDA requires label warnings to prohibits sharing of multi- dose diabetes pen devices among patients

Testosterone products: Drug safety communication- FDA cautions about using testosterone products for low testosterone due to again; requires labeling change to inform of possible increased risk of heart attack and stoke.

Dr. Weiss stated that since the unitizations of these are low we should send a letter to the patients stating the warning.

Dr. Barkin added that we should reference this is the quarterly newsletter.

Mr. Ouellette added that we should also copy the providers the letter.

NEW CRITERIA REVIEW

Afrezza

- Not to be as a monotherapy. Obtain lab values of pulmonary function and recent smoking history

Akynzeo-

- Approvals will require diagnosis of chemo-induced nausea/vomiting and failed trials of all preferred anti-emetics, including 5-HT3 class (Ondansetron) and Marinol. Concomitant use should be avoided in patients who are chronically using a strong CYP3A inducer such as rifampin.

Arnuity Ellipta

- Not approved for children <12 years of age

Belsomra

- DDI: Belsomra® with strong CYP3A inhibitors (e.g. ketoconazole, itraconazole, posaconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, boceprevir, telaprevir, telithromycin, and conivaptan) is not recommended.

Bunavail

- 24 month lifetime limit for treatment of opioid addication

Zubsolv

- 24 month lifetime limit for treatment of opioid addiction

Esbriet

- Diagnosis required. The concomitant use with strong CYP1A2 inhibitors (e.g. fluvoxamine, enoxacin) is not recommended

Ofev

- Diagnosis required. Avoid concomitant use with P-gp and CYPA4 inducers (e.g. carbamazepine, phenytoin, and St. John's wort).

Hysingla

- Concomitant use should be avoided with mixed agonist/antagonist analgesics, partial agonist analgesics, and MAOIs. Verify prior trials and failures or intolerance of preferred treatments

Incruse Ellipta

- Quantity limit of 1 inhalation daily

Kerydin

- Diagnosis required. Verify prior trials and failures or intolerance of preferred treatments, including both topical and oral agents.

Keytruda

- PA required to confirm FDA approved indication. Verify prior trials and failures or intolerance of ipilimumab. If BRAF V600 mutation positive, also verify prior trial/failure or intolerance of a BRAF inhibitor

Lynparaza

- PA required to confirm FDA approved indication. Strong and moderate CYP3A inhibitors and Strong and moderate CYP3A inducers should be avoided with use of Lynparza

Mircera

- Clinical PA is required to establish medical necessity and that appropriate lab monitoring is being done.

Onexton

- Not approved for use in children <12 years of age

Soolantra

- Dosing limits apply, please see dosing consolidation list

Oralair

- Prescriber must provide the testing to show that the patient is allergic to the components in the prescribed therapy and must provide a clinically valid rationale why single agent sublingual therapy is being chosen over subcutaneous therapy Treatment must start 12 weeks before expected onset of pollen season and only after confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen (Ragwitek), timothy grass or cross-reactive grass pollens (Grastek), or any of the 5 grass species contained in Oralair. Have an auto-injectable epinephrine on-hand
- Grastek : Patient age ≥5 years and ≤65 years
- Oralair: Patient age ≥10 years and ≤65 years
- Ragwitek: Patient age ≥18 years and ≤65 years

Plegridy

- Clinical PA is required to establish diagnosis and medical necessity

Savaysa

- Diganosis required. DDI: Rifampin will require prior authorization if being used in combination with Savaysa

Trulicity

- Diagnosis required. Verify prior trials and failures or intolerance of preferred treatments from other diabetic categories and that is not being used as first-line treatment.

Tybost

- Diagnosis and verify prior trials and failures or intolerance of preferred treatments is required. DDI:Aatazanavir or darunavir and the following drugs are contraindicated (due to potential for serious and/or life-threatening events or loss of therapeutic effect): alfuzosin, dronedarone, rifampin, irinotecan, dihydroergotamine, ergotamine, methylergonovine, cisapride, St. John's wort, lovastatin, simvastatin, pimozide, nevirapine, sildenafil (when given as Revatio® for treatment of PAH), indinavir, triazolam, or PO midazolam will be non-preferred and require prior authorization if it is currently being used in combination with Tybost.

Uceris Rectal Foam/Tab

- Diagnosis required. Concomitant use with CYP3A inhibitors (e.g. ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, cyclosporine, and grapefruit juice) should be avoided. Verify prior trials and failures or intolerance of preferred treatments.

Viekira PAK

- Approvals will require clinical PA. Please see the Hepatitis PA form for criteria. DDI: Viekira Pak is contraindicated with: drugs that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events, drugs that are strong inducers of CYP3A and CYP2C8 and may lead to reduced efficacy of Viekira® pak, and drugs that are strong inhibitors of CYP2C8 and may increase dasabuvir plasma concentrations and the risk of QT prolongation. The following list of drugs is contraindicated with Viekira® pak: alfuzosin, carbamazepine, phenytoin, phenobarbital, gemfibrozil, rifampin, ergot derivatives (ergotamine, dihydroergotamine, ergonovine, and methylergonovine), ethinyl estradiol-containing medications (such as combined oral contraceptives), St. John's Wort, lovastatin, simvastatin, pimozide, efavirenz, sildenafil when dosed as Revatio® for the treatment of PAH, triazolam, and orally administered midazolam

Xigduo

- Diagnosis required. Verify prior trials and failures or intolerance of preferred treatments from other diabetic categories

ADJOURNMENT: 8PM

The next meeting will be held on **April 14, 2015** 6:00p.m. – 8:00p.m at the Augusta Armory.