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: July 12, 2013
RE: Maine DUR Board **Meeting minutes** from **June 11, 2013**

ATTENDANCE	PRESENT	ABSENT	EXCUSED
Robert Weiss, M.D., Cardiologist, Chair	X		
Amy Enos, Pharm. D. Waltz LTC Pharmacy			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		
Rebecca M. St. Amand, R.Ph., Staff Pharmacist Community Pharmacy - Pittsfield	X		
Steve Gefvert, D.O.		X	
Lourie Paul, NP	X		
Linda Glass, M.D.		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

CALL TO ORDER: 6PM

PUBLIC COMMENTS

Mark Sumeray from Aegerion Pharmacy is here today to talk to you about homozygous familial hypercholesterolemia and an appropriate way to identify patient with this disease because identify patient with this disease is central to the PA process for treatment with Lomitapide. There is no single diagnostic test to identify patient with homozygous FH. It is a genetic disease so one approach is to diagnose is to sequence the DNA. When that is positive and two mutant alloys are identified then that is a very useful way to identify patients. Unfortunately, about 20% of the time the DNA sequencing fails to pick up patients that do have the homozygous FH because they are only finding one mutation. This is

due to the fact that we are constantly finding new mutations and some are yet to be discovered. It's much more common in clinical practice to use the physical disease characteristics of the patients. There are a number of different ways accessing that one is to measure the patients LDL cholesterol. It is also common to add other criteria in while trying to identify these patients. One example is if patients have skin or tendon xanthomas is a very useful sign in diagnosing. It is also useful to add in a family history because in order to have homozygous hypercholesterolemia both parents must have heterozygous familial hypercholesterolemia. At the end of the day it is the patient choice how the identification is done.

Dr. Weiss asked in the PA form from Humana that was handed out there is no mention of the family history. Is that something that you have seen others including that in the PA requirements?

Mr. Sumeray answered that when available that is acceptable information however, it shouldn't be required because that information isn't always known.

Dr. Weiss asked how do you separate out the serious heterozygous from the homozygous.

Mr. Sumeray answered that it isn't easy when it comes down to it you would need to select criteria and in some cases you might get a serious heterozygous.

Stephen Lash from Genentech would like to briefly discuss a common misconception that Avastin and Lucentis is not the same drug for age-related macular degeneration. Lucentis is FDA approved for the treatment of patients with wet age-related macular degeneration (wAMD), macular edema following retinal vein occlusion (RVO), and diabetic macular edema (DME). The safety of Lucentis is outstanding; the only real side effect is risk of eye puncher. Lucentis meets FDA standard for ocular injections Avastin does not. Lucentis is an antibody fragment that is designed to penetrate the retina down to the core where the disease starts. Avastin cannot penetrate the retina it stays in the retina fluid. The half life for Lucentis in 9days and it is unknown for Avastin. Lucentis is sold in kits, it is a powder stored in glass vials then reconstituted at time of use with needles for reconstitution and administration. Avastin is often shipped in plastic, sometimes frozen and it is unknown what happens to he once frozen. To wrap up, we can provider clinical trials; we have support for patients and copays.

Julie Foster from Merck would like the committee to consider Liptruzet. Liptruzet is a combination of Ezetimibe and atorvastatin it is FDA approved with adjunctive diet to reduce elevated total-C, LDL-C, Apo B, TG, and non-HDL-C, and to increase HDL-C in patients with primary (heterozygous familial and non-familial) hyperlipidemia or mixed hyperlipidemia reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to other lipid-lowering treatments. Liptruzet can help the prescribers have patients reach goal with dosing range of 10/10mg, 10/20mg, 10/40/mg, 10/80mg. High risk patients will have a 53-63% reduction in the LDL levels. If you were only to increase a statin only you would only see and 6-7% reduction. In closing, she would like the committee to add Liptruzet to the preferred side of the PDL.

Tom Algozzine from Novartis here to update the board on adherence data of the TOBI Podhaler. The study was an open label perspective study done in Ireland. The study looked at patients with consecutive Adult Cystic Fibrosis over a ten month period of time enrolled patients into a trail of the

inhaled powder. The patients were given a satisfactory and adherence survey, they were given this at enrollment, 3months, 6months and 9months. They looked at a total of 72 patients, 50 of the were on TOBI solutions at baseline. Of the 22 that were not a third were not do to adherence, about another third do to cough, and quarter had never been on TOBI solution. All the patients that were non adherent to the solution were to the powder, the patients that were never on TOBI solution were adherent to the powder, of those that had the cough with the solution about 60% did tolerate the powder and 40% didn't. Important to note that adherence was self reported of the 72 enrolled into the study about 11% stopped the drug due to cough. If anyone is interested in the slides I can provide those.

Ruchir Parith from Boehringer Ingelheim here to discuss COPD and the new Combivent Respimat. Some of the differences between the resipmat vs. the inhaled aerosol, it is one inhalation vs. two, it is a slow moving cloud so there is no need for a spacer, no shaking needed, dose counter. Also there is no longer a peanut allergy with the Combivent resipmat.

Ms. Paul asked when the adapters for ventilators are going to be available.

Mr. Parith answered that BI is working with a different manufacture for those and doesn't have a date for that but will update when available.

Ms. Paul asked if there are any assistance programs for those without insurance.

Mr. Parith answered yes if the patient qualifies we do have patient assistance programs.

OLD BUSINESS

DUR MINUTES

The May 14, 2013 minutes were approved

PSYCH WORK GROUP MONTHY UPDATE

Dr. Tweed stated that the Psych Work Group discussed LD 716, a bill to make recommendations on appropriate prescribing of certain medications for children with attention deficit hyperactivity disorder. The work group will be producing a report for review of this.

NEW BUSINESS

PWG FOR 2013-14

Dr. Tweed stated they are looking for some clarification on the psych work group role. It was originally formed as an advisory board to the DUR. But we are being asked to do reviews and report that are unrelated to the DUR.

Mr. Ouellette agreed that the Psych work group was formed as an advisory committee to the DUR. Mr. Ouellette still sees the board as that. However, do to notoriety other people within the state but out of OMS have begun to give direction to the PWG. Mr. Ouellette's feeling toward that is that everything should be funneled through OMS and the DUR.

Dr. Tweed stated maybe it's just as simple as the PWG is advisory to OMS as well as the DUR. Dr. Tweed added that is the way that Dr. Flanigan had explained it.

Ms. Yorks-Wright added it would be good to get Dr. Flanigan's prospective.

Mr. Bondeson asked if the PWG as a subcommittee is in the bi- laws and if not should it? If it was formalized in the bi-laws then that would make it clear. It is almost as if the PWG is being recognized as separate.

Mr. Ouellette stated that he will review the DUR bi-laws and bring that information back to the board

PA FORM REVIEWS

Mr. Ouellette stated that for the Platelet Aggregation Inhibitors we just needed to add a check box "Ticagrelor + Aspirin for at least 1year" under the recommended treatment for condition Acute coronary syndromes.

Dr. Weiss motioned to vote on that change.

Voted- Passed

Mr. Ouellette stated that on the Byetta/Victoza form we added Bydureon to the PA form.

Dr. Weiss motioned to vote on that change.

Voted-Passed

BEERS CRITERIA AND MAINECARE SULFONYLUREA DATA

Dr. Weiss stated for those that don't know the BEERS criteria is for the drugs in the elderly one of the things that we picked out is sulfonylureas in the elderly. In reviewing the guidelines the sulfonylureas are being pushing down partially in the elderly.

Mr. Ouellette discussed the utilization data of Chlorpropamide, Glimepiride,Glipizide, Glyburide Micronized, Tolazamide, Tolbutamide and Metformin HCL for state fiscal year (SFY) 2012 and 11months

of the SFY 2013 that was pulled to review. For each of the medications the report was broken down by age brackets and claim count and member count.

Dr. Weiss stated looking at this data its approximately10, 000 patients on sulfonylurea. Looking at just over 60 you are looking at approximately 5,000. That is a lot of people.

Dr. Braun added that we shouldn't just be looking at if they are on a sulfonylurea but what sulfonylurea they are on.

Mr. Ouellette agreed. The BEERS criteria looked mostly at Chlopropamide and glyburide.

Dr. Weiss asked if they looked at glipizide.

Mr. Ouellette answered no

Dr .Weiss stated that he wasn't aware of much of a difference between Glipizide and Glyburide.

Dr. Braun clarified that there is a significant difference in the half life.

Ms. Paul added especially in patients with renal failure.

Dr. Weiss stated that the trouble he has with this is that he can't think of a practical of dealing with it. I don't see how we are going to educate providers to switch sulfonylureas. Shouldn't we be discouraging the whole class not because of the side effect profile but because of the efficacy profile. It's rated 5th now.

Dr. Braun responded that he doesn't agree.

Dr. Tweed added that we can't get people to do stuff but we can get them to stop stuff.

Dr. Weiss stated that we could put a PA on it to shut it down or we could say that we aren't covering for anyone over "X". But the goal then shortly after would be to get them to stop using this class because it's not recommended but either of the two endocrine societies.

Mr. Ouellette doesn't completely agree with stopping the entire class. We could easily put in age edits but I would like to send out an educational letter before shutting off all those patients.

Dr. Weiss made a motion that after sending out the educational we make glyburide require a PA for anyone over 65 and no grandfathering.

Voted- Pass

DRUG CRITERIA REVIEW

1. Pomalyst
    - Provider must be certified with Pomalyst REMS Program

- Female patients of reproductive potential must have 2 negative pregnancy tests and use 2 forms of contraception
- Complete blood counts weekly for first 8 weeks, then monthly
- DDI with strong inhibitors of CYP1A2 and CYP3A4 drugs
- Have received at least 2 prior therapies, including lenalidomide and bortezomib

2. Kynamro
    - Clinical PA for appropriate diagnosis
    - Appropriate lab testing prior to starting (ALT, AST), phosphatase and total bilirubin
    - Monthly liver-related tests for first year, then every three months
    - Restricted through REMS Program

3. Invokana
    - Type 2 diabetes
    - Available to patients who are unable to tolerate any preferred medications
    - Dosing limits

4. Prolensa
    - Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred will be approved, unless an acceptable clinical exception is offered on the PA form

5. Gattex
    - Diagnosis – adult with SBS who are dependent on parenteral support
    - Appropriate colonoscopy and lab assessments 6 months prior to starting Gattex

6. Fulyzaq
    - Diagnosis – non-infectious diarrhea in patients with HIV/AIDS on anti-retroviral therapy.
    - Prior trials of preferred, more cost effective anti-diarrheals
    - Dosing limits

7. Inclusig
    - Clinical PA to verify appropriate diagnosis
    - Prior trial of TKI therapy
    - Appropriate lab monitoring
    - DDI with strong CYP3A4 inducers

8. TOBI Podhaler
    - Clinical PA for appropriate diagnosis
    - Limited to patients with significant impairment from using nebulized version of medication

All drug criteria was voted on and approved.

BUTALBITAL LETTER

Mr. Ouellette presented a draft version of a letter to be sent out to prescribers of patients on Butalbital. Total number of patients is 798 and those on 61 units or more is 85 members.

Dr. Braun stated that he does like much of what is written. The first lines need to be why we are sending this letter. Then it should say "We have identified 85 members with more than 61 unites of Butalbital and one or more of your patients have been identified." This should be in bold. Also the last sentence "We recommend that you review your patients' utilization and respond to this letter with necessity for chronic utilization" is unclear. How should I respond? Who do I respond to? Then have the background information.

Dr. Weiss added that he liked the suggestion of Dr. Braun. Doctors don't like to be outliers. It could be very easy for the doctor to not read this letter unless the doctor feels like it is specifically looking at them.

Mr. Ouellette asked the board what kind of respond we are looking for. In most cases it is only one or two patients per doctor.

Dr. Weiss added that it shouldn't be that hard to get an answer.

Dr. Braun added do we want them to respond by sending a letter, by decreasing the dose with their office.

Mr. Ouellette added or do we want to know why they are at the dose that they are.

Dr. Weiss answered that we should have at the end of the letter that Dr. Barkin will contact them to discuss this. That way it is not the doctor's burden to respond.

Dr. Braun agreed that it is a great idea.

Mr. Ouellette stated that he will make the changes and talk to Dr. Barkin about it. Mr. Ouellette also wanted to briefly touch on some SSDC updates. Meetings are taking place and the final outcome will be in October for Maine. The DUR doesn't meeting in July or August so the next meeting won't be until September. The September meeting will include some clean up items, PDL criteria changes and updates on our letter writing that we have done on the benzos /stimulants and the butalbital. Per the request of Dr. Weiss and Dr. Tweed we will provide updates on the initiatives that we have done.

ADJOURNMENT: 8PM

The next meeting will be held on **September 10, 2013**, 6:00p.m. – 8:00p.m.