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: September 12, 2013
RE: Maine DUR Board **Meeting minutes** from **September 10, 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
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

Dr. Tim Burner from Otsuka here to present Abilify Maintena. Today would like to discuss three main topics indication, registration trail efficacy and safety data and the unique pharmacological profile of Abilify maintena. It is an atypical antipsychotic indicated for the treatment of schizophrenia. The efficacy of Abilify Maintena was demonstrated in randomized withdrawal double blind placebo in adults. Compared to the placebo treated patient Abilify Maintena treated patients showed a statically significant longer time to relapse which was the primary end point. The key secondary end point was the percentage of patients meeting the exacerbation of psychiatric symptoms also was significantly lower in

the Abilify group. The safety profile is expected to be similar to the oral Abilify. The only commonly observed adverse reaction associated with Abilify tablets in patients with schizophrenia was akathisia. Abilify does a have boxed warning of increased mortality in elderly patients with dementia-related psychosis. The mechanism is unique it is proposed efficacy is mediated through a combination of partial agonist activity D2 and 5HT1A receptors and agonist activity at the serotonin 5HT2A receptor. Abilify Maintena is the first approved dopamine D2 partial agonist in a once monthly extended release injection. In closing Otsuka would like to ask that the State of Maine include Abilify Maintena on the preferred side of the PDL.

Patrick Jenson from Aegerion Pharmaceuticals would let to take just a few minutes to talk about Juxtapid because I know that the board is familiar with Juxtapid. Juxtapid is a microsomal triglyceride transfer protein inhibitor indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH) I know you guys are already familiar with our phase three study the primary end point was the reduction of LDL-C. I also know that you are familiar with our box warning and our REMS program. Because of the risk of hepatotoxicity associated with Juxtapid therapy, Juxtapid is available through a restricted program under the REMS. Under the Juxtapid REMS, only certified healthcare providers and pharmacies may prescribe and distribute Juxtapid. There is one piece of new information that I would like to make the board aware of and that is the EAS consciences statement published earlier this month. One of the major points that it brought out is that the genetic testing has a high false negative.

Mr. Ouellette asked what the LDL guidelines should be to initiate Juxtapid.

Mr. Jenson answered that it is a great questions. As I'm sure that many of you are aware there are no specific guidelines regarding the diagnosis of HoFH. I would say that looking at all the data that the 200 range would be the most appropriate. However, looking at recent data there are a number of treated LDL's that are at 150-190 so even the most recent data may be updated.

OLD BUSINESS

DUR MINUTES

The June 10, 2013 minutes were approved

PSYCH WORK GROUP MONTHY UPDATE

Dr. Tweed stated that they discussed LD 338 and since it is on the agenda it could be discussed at that point.

NEW BUSINESS

LD 338 DISCUSSION

Dr. Weiss stated that LD 338 is a potential law about antipsychotic drugs in children.

Dr. Tweed stated that it focuses on kids under 17 years of age. The LD states "Requires that the prescriber of atypical antipsychotic medication beyond the recommended period provide documented justification as to why the child should continue taking the medication". Where does the recommended period come from? The only place that I have ever seen it is the best practices guidelines. What the guidelines says is if the youth is doing well for 6months you should begin to taper unless there is another reason to not.

Dr. Weiss asked if this is a law currently a law or is being looked at to be a law. The Psych work group should get more answers regarding this and get back to us.

Mr. Ouellette stated that one of the reasons for bringing it to the board is to see if we need to make changes to the PA forms. Also, we are already doing metabolic monitoring which already includes ages 0-17.

Dr. Weiss stated that the only part of this resolve to him that needs to be answered is how long. The LD implies that there should be a limit of utilization. The psych work group could recommend to us that limit.

Dr. Barkin stated that since we already have metabolic monitoring we may be able to do it through that rather than doubling the amount of PAs.

Mr. Ouellette stated that after the psych work group's meeting with OMS that since we are already doing metabolic monitoring do we enhance what we are already doing. We could add a check box that they are doing the monitoring and or why we aren't.

Dr. Tweed that the intent of this law was to make sure that the guidelines were being done and that far out weight the concern of additional PAs.

Mr. Ouellette read to the board the current metabolic monitoring letter that is being sent out.

Dr. Braun asked does the DUR need to come up with a recommend period and if we are getting data what does that data say.

Dr. Barkin stated that the data is showing that the rate of monitoring has soared.

Mr. Ouellette added that we are getting a 45%response rate compared to when we started it was at 5%.

Dr. Weiss stated that you will get 100% eventually because if we don't get a response by week 21 then a PA will be required. And feels that what we are doing answers the questions in this resolve.

Dr. Tweed stated that is we were doing this from scratch. The logical way to do it would be to require baseline labs at 1month and annually after that.

Mr. Ouellette asked if it would be new users.

Dr. Tweed stated that he thought that it would be only new starters.

Mr. Ouellette stated that we have between 200-300 new starts but that is including everyone not just 17 and under.

Dr. Weiss added that one possibility is to re-do the PA and have it that a new PA would be due each year.

Dr. Braun asked how many new starts would that be.

Dr. Weiss stated that Dr. Tweed should bring back to the board his recommendation and it will be discussed at the November meeting

SUBOXONE/OPIOID UPDATE (KEVIN FLANIGAN OMS MEDICAIL DIRECTOR)

Mr. Ouellette stated that Dr. Kevin Flanigan wasn't able to attend but wanted to give the board an update on Suboxone two year limit and the 45 day opioid limit that have been in place. When this was first put into place the PAs went through the roof. When looking at the opioid limit it was set up to decrease utilization, set new parameters and try to trend some of the chronic users down in dose and MSE's .

Dr. Weiss asked if the 27,000 are pills or patients.

Mr. Ouellette answered that it's a patient count.

Mr. Ouellette stated that when looking at the day supply bands the use has decrease. The largest decrease is in the 15-29 days down 21% in narcotic utilization. When looking at the chronic users we are seeing less of a decrease. However, the overall impact was tremendous.

Mr. Weiss asked why it wasn't more.

Mr. Ouellette answered that if you had documentation as to why you need to stay on the medication on the PA then it would be approved to continue use.

Dr. Barkin added that anything under 30MSE will go through without a PA. Also, looking at the PA forms that are coming in you are seeing that proper monitoring, drug screen, contracts, PMP.

Mr. Ouellette stated that looking at the summary report on quarter one of 2012 the average quantity is 172.84 units, the average MSE 71.06, member count 23,660, total amount paid 1,312,479.00. Compared to the quarter four of 2013 the average quantity is 140.30 units, the average MSE 62.02, member count 16,805, total amount paid 855,022.00.

KETOCONAZOLE SAFETY REVIEW

Mr. Ouellette stated that a safety notice came out stating a potentially fatal liver injury, risk of drug interactions and adrenal gland problems. Currently ketoconazole is preferred on the MaineCare PDL. Looking at scripts being filled before the notice came out MaineCare was filling 50-60scripts compared to after the notice it is down to 20scripts. One recommendation is to move the oral ketoconazole to the non-preferred side of the PDL.

Dr. Braun asked if there has been any comparative data.

Dr. Barkin and Dr. Weiss both responded that no comparative data has been done but no other drug has received this warning.

Dr. Weiss asked if there were any other questions or comments if not they we would more it to non-preferred and off the PA as a first line medication.

Dr. Braun agreed.

OSTEOARTHRITIS GUIDELINES (HYALURONIC ACID DERIVATIVES)

Mr. Ouellette stated we have included in the packets the American Academy of Orthopedic Surgeons the Treatment of Osteoarthritis of the knee as well as the Hyaluronic Acid Derivatives PA form. This form is interesting because it is used on the medical side as well. The biggest thing in the guidelines is recommendation 9 stating they do not recommend using hyaluronic acid for patients with symptomatic osteoarthritis of the knee. This recommendation is listed as strong meaning the supporting evidence is high. One of the requirements we have on the PA form is they must have tried two of the other treatment options being used before they can get the other hyaluronic derivatives.

Dr. Weiss stated that the guideline is clear that it should not be used.

Mr. Ouellette indicated that most utilization is on the medical side of their benefit but we do see utilization on some patients.

The board discussed back and forth whether it was necessary even if patients were saying it helped.

Mr. Ouellette stated that the state had recently increased PT availability for members, confirmed by Ms. Yorks Wright that this would be viable alternative.

Ms. Paul indicated she would bring back to orthopedic physicians to get their input on the guidelines and will update the board at the November meeting.

HOFH PA REVIEW

Mr. Ouellette presented the board with 2 PA forms for recent HoFH drugs.

Dr. Weiss gave a recap of the drug class and PA requirements.

After board discussion and review the PA form was approved and will be added to the PDL.

NEW DRUG REVIEW

Simbrinza: Its common name is brinzolamide/brimonidine, in the PDL category OP-Carbonic Anhydrase Inhibitor/Combos. Simbrinza is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. This is a pregnancy category C medication. The safety and efficacy of use in those under the age of 2 years has not been established. It is recommended that it be placed on the non-preferred side of the PDL.

Abilify Maintena : Its common name is aripiprazole, in the PDL category Antipsychotics- Atypicals. Abilify Maintena is indicated for the treatment of schizophrenia. This is a pregnancy category C medication. The safety and efficacy of use in children under the age of 18 have not been established. It is recommended that it be placed on the non-preferred side of the PDL.

Tecfidera: Its common name is dimethyl furmarate, in the PDl category Multiple Sclerosis-Non-Interferons. Tecfidera is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). This is a pregnancy category C medication. The safety and efficacy of use in children under the age of 18 have not been established. It is recommended that it be placed on the non-preferred side of the PDL.

All board members reviewed and voted in favor of the recommendation to make all the above new drugs non-preferred.

SSDC UPDATE (OCTOBER MEETING)

Mr. Ouellette explained that the meeting for October will be the annual PDL meeting and will be from1-6pm. We will review significant PDL change sand vote on all recommendations. There will be a closed session to discuss the financial make up or the bids, then conclude with voting and open discussion.

ADJOURNMENT: 8PM

The next meeting will be held on **October 8, 2013**, 1:00p.m. – 6:00p.m.