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: September 11, 2014
RE: Maine DUR Board **Meeting** minutes from September 9, 2014

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		
Linda Glass, M.D.	X		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

Chris Dube for MedImmune wanted to discuss the new guidelines for RSV. This is a significant change to the RSV guidelines and providers have not had an enough time to digest the information. The AAP guidelines opinion is that Pre-term infants without chronic lung disease born 29 – 35 weeks gestation have no substantial benefit from RSV prophylaxis. These guidelines, and criteria that go with it, go against current safety and efficacy profiles. The primary limitation with the new guidelines is that they did not follow the Institutes of Medicines guidelines for trustworthy clinical practice. Most importantly they did not look at the harms vs. benefits that would occur if such a guideline was put in place. Although the guidelines state that cost was considered, the net Medicaid cost after substantial rebates has risen less than 1% since 2005. In addition MedImmune has a proposal that would reduce the cost even more should the correct guidelines remain intact. Based on these comments and the lack of urgency around this with RSV season is several months away, MedImmune requests that any proposal

of adopting any updated RSV guidelines should be tabled until further information and supplemental data can be provided to the board.

Dr. Glass stated that it is not true that all of the children under 35 weeks would not get prophylaxis. The children that received oxygen would still meet the criteria to receive it. It is a big change and it surprised all the pediatricians.

Mr. Ouellette stated that we have more information on this as well.

Dr. Barkin asked Ms. Dube if Synagis lowers death rate.

Ms. Dube answered no it reduces hospitalization rates.

Bhavisha Desai from United Therapeuties- FDA approved in 2013, Orenitram (Treprostinil), is the first oral prostacyclin therapy option. The major mechanism of action is direct vasodilatation of the pulmonary and systemic vascular bed, inhibition of platelet aggregation and inhibition of smooth muscle cell proliferation. Orenitram is indicated for WHO Group 1 to improve exercise capacity. Orenitram is supplied as an extended release tablet and dosing is individualized according to a patient's clinical response, tolerability, and adverse events. It is indicated for two or three times daily dosing regiments and should be taken with food. Ms. Desai reviewed endpoints from three different trials, one of which showed improved exercise tolerance in treatment naïve patients. In patients with background therapy of endothelin receptor antagonist (ERA) or PDE-5 inhibitors, no improvement was shown. In an extension study patients were exposed to Orenitram for two to six years and showed a similar increase in exercise tolerability. Common adverse events were headache, diarrhea, and nausea. In trials 91 % of patients experienced and adverse event but only 4% discontinued therapy because of it.

OLD BUSINESS

DUR MINUTES

The May 13, 2014 minutes were approved.

PSYCH WORK GROUP MONTHY UPDATE

Dr. Barkin stated that the psych work group met last week. They had very little to talk about they are going to start looking at Suvorexant a new sleeping pill. No other update at this time.

MAINECARE UPDATE

Mr. Bondeson stated that the state is going to embark on creating a policy for 340B pharmacies.

NEW BUSINESS

RSV AAP GUIDELINE CHANGES

Mr. Ouellette stated that in the board members packets we have included the AAP guidelines, a write up from Dr. Biczak and Dr. Barkin of Synagis considerations that compares the changes and the Synagis PA form. One change for 2014 is that now all are recommended to have 5 doses. Reviewing the PA form the first few changes are just the start dates. These dates change ever year based on the RSV season. When you start looking into the medical necessity documentation section you will start to see the significant changes. The biggest change for simplicity is the number of infants that would only be allowed to get it for 12 months rather than for 24 months.

Dr. Glass stated that when you read the AAP guidelines the biggest issue is the focus on chronic lung disease (CLD). I think that there is a way to make that work. One of the things that concern me is the 35 week that has CLD one by all means shouldn't but does because of other issues. The definition of CLD listed is only one of them, another one that is widely used it the kids that needs chronic medication use diuretics, nebulizers. There are a ton of things that are going on that are affecting this. Looking at the form the first bullet is fine but we need to add one that is for any gestational age who are 12 month of age or younger who have CLD defined as chronic medication use. The congenital heart disease is going to be the hardest and we might want to add to that poor weight gain and failure to thrive because those are good indicators for CLD and congenital heart.

Dr. Braun asked want prompted the change in the guidelines.

Dr. Glass answered that when the AAP writes guidelines like this they have looked at longitude studies of hospital stay, length of stay, how much treatment was needed. They are saying that kids that come out of a neonatal unit and are relative health kids are not at significant more risk for RSV. If you have 33 week gestation and are health, only had oxygen for a couple days because they needed just a little bit are not at a higher risk. We have healthy kids coming out of the neonatal unit and are at no greater risk than a term. The academy is extremely safety related and I believe that there is a lot of thought and facts put behind it.

Mr. Ouellette asked on the third bullet on the PA form where it says congenital heart disease are you indicating that we should put a sub- bullet for failure to thrive.

Dr. Glass answered that yes she does feel that would be a good change.

Dr. Barkin asked if that would be picked up by bullet C "Cyanotic heart disease with palivizumab prophylaxis recommended by a pediatric cardiologist"

Dr. Glass reviewed that and agreed that it could fall under that. These children should be being seen by a pediatric cardiologist in conjunction with a PCP.

Dr. Barkin stated in review we will add a bullet D to the third one down stating poor weight gain, failure to thrive.

Mr. Ouellette added and we will add a bullet point to include '12months with chronic lung disease requiring medication therapy' once the change is made we will send it around to the board to review.

Dr. Braun asked how this works with patients that are traveling or moving from a different area that has a different start date of RSV.

Dr. Glass stated like most viruses they start on the west coast and spread across the US. That is why some states will have a different start date but FL for example wouldn't.

Dr. Braun asked how it would be handled for patients travelling.

Dr. Glass answered that we have never come across this issue. But we would not allow the patient to take Synagis with them because it has a high risk and needs to be given by the provider's office or a home health nurse. They would need to make their vacation plans around the dosing.

ATYPICAL PA UPDATE

Mr. Ouellette presented the process that GHS and OCFS created to comply with LD 338. GHS identifies members that would require a PA, from there we identified a process for the providers to summit the information and then remove the PA requirement. If we had a provider that resisted sending us the information that would be sent over to OCFS and they would reach out to the provider.

Mr. Ouellette presented charts that we have looking at data from Jan2014, Feb2014, March2014 because the providers have 20 weeks from the initial letter to send us the required information. In January 222 letters were sent, February 254 letters were sent and in March 243 of those roughly 25% of those are under 17. Looking into it further, for those 17 and under the first month we put the block into effect, we had a much larger response rate then the subsequent months. Because we didn't want patients going without their medication the process allows for PA's to be submitted giving the prescriber time to submit information. We are just now starting to get to the point where those providers that haven't sent us the requested info will be sent over to Dr. Tweed's group OCFS. Of the letters that were sent in January there are currently 25 members blocked. Of that, 17 are no longer filling an atypical. We do not know why they are no longer taking the atypical- if it's a direct correlation with the letter, compliance or some other reason. The 8 members left the have PA's that will expire soon and if the information is not received then they will be sent to OCFS.

Dr. Barkin stated that it would be interesting to know why the 17 members are no longer filling, if it is a thoughtful decision of the prescriber or if the provider is just giving up. Maybe we collect more data randomly to follow up and find out what the cause is.

Mr. Ouellette added that we can take a further look at those 17. It might be eligibility or primary insurance.

CHOLESTEROL COMMUNICATION UPDATE

Mr. Ouellette stated that we start out the statin letter to the top 20 prescribers and we have only gotten one comment back. They didn't have any concern about the guidelines but did state that it would be helpful if Crestor could be moved to the preferred side of the PDL. We were able to review that

request and this summer did move Crestor to the preferred side. With that change it should allow providers to switch patients to the more effective Crestor or Atrovastain. Timing had a lot to do with.

Dr. Barkin asked giving the low response should we leave it there or do something else?

Mr. Ouellette answered that it's still too early to tell. We should look at the data again early next quarter and at that point decide what we are going to do. It's not uncommon to receive little communication back when we send out letters.

Dr. Barkin suggested that maybe reach out to the provider by phone.

Dr. Braun agreed with reaching out to the 20 prescribers that were sent the letter.

Mr. Ouellette agreed that it is something to discuss when we review the data.

Dr. Barkin discussed some cost analysis showing MaineCare's cost for Synagis and then looking at the cost of hospitalizations.

Dr. Glass stated the data isn't showing everything because some kids will end up in the ICU and the numbers showing here are not an ICU cost.

Dr. Barkin stated that it would be very helpful to follow this as we go forward with the new changes.

PRO- DUR DATA REVIEW

Tabled until November

SSDC UPDATE

Mr. Ouellette gave an update on the SSDC. GHS is working to pull all the information together to present to Maine on October 14th. It will be very similar to meetings in the past. We will have discussion on each of the class reviews and time for the reps to present. The meeting starts at 1pm starting with public comments lasting for about 1hour and then the meeting will be put into closed session for the committee members to review the financials. We will try to keep it under an hour. Not every PDL category will be discussed. We will try to meet with as many Reps as we can before the meeting but our schedule is filling up fast.

NEW DRUG REVIEWS

Sitavig, common name acyclovir, in the PDL category Herpes Agents- the recommendation is for it to be non- preferred.

Zykadia, common name ceritinib, in the PDL category Cancer- the recommendation is for it to be non-preferred.

Luzu, common name luliconazole, in the PDL category Topical-Antifungals- the recommendation is for it to be non-preferred.

Zontivity, common name vorapaxar, in the PDL category Platelet Aggregation Inhibitors- the recommendation is for it to be non- preferred.

Hetlioz, common name tasimelteon, in the PDL category Sedative Hypnotics- Non-Benzodiazepines- the recommendation is for it to be non-preferred.

Aptiom, common name eslicarbazepin, acetate in the PDL category Anticonvulsants- the recommendation is for it to be non-preferred.

Tanzeum, common name albiglutidein, the PDL category Incretin Mimetics Inhibitors- the recommendation is for it to be non- preferred.

Entyvio, common name vedolizumab, in the PDL category Rheumatoid Arthitis- the recommendation is for it to be non-preferred.

Jublia, common name efinaconazole acetate, in the PDL category Antifungal, topical- the recommendation is for it to be non-preferred

Sivextro, common name tedizolid, the PDL category Lincosamides/Oxazolidinones/Leprostatics- the recommendation is for it to be non- preferred.

Vogelxo, common name testosterone, in the PDL category Androgens/Anabolics- the recommendation is for it to be non-preferred.

Jardiance, common name empagluflozin, in the PDL category Diabetic- Other- the recommendation is for it to be non-preferred

Orenitram, common name treprostinil extended-release, the PDL category Pulmonary Antihypertensives- the recommendation is for it to be non- preferred.

Otezla, common name apremilast, in the PDL category Psoriatic Arthritis- the recommendation is for it to be non-preferred.

Ragwitek, common name short ragweed pollen allergen extract, in the PDL category Immunotherapy- the recommendation is for it to be non-preferred

Grastek, common name short ragweed pollen allergen extract, in the PDL category Immunotherapy- the recommendation is for it to be non-preferred

Xartemis ER, common name oxycodone/APAP ER, in the PDL category Narcotics, Long-Acting- the recommendation is for it to be non-preferred

The boarded reviewed and discussed the drug reviews and they were all voted non-preferred. Xolair is listed because it has a new indication and the DUR board will be looking at the criteria for that in meetings to come

ADJOURNMENT: 6PM

The next meeting will be held on **October 14, 2014**, 1:00p.m. – 6:00p.m at the Augusta Armory.