MaineCare Services
An Office of the Department of Health and Human Services
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**TO:** Maine Drug Utilization Review Board
**DATE:** January 21, 2014
**RE:** Maine DUR Board **Meeting** minutes from January 14, 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 | | |
| Rebecca M. Thibodeau, R.Ph., Staff Pharmacist Community Pharmacy – Pittsfield- Co-Chair | | 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, DFAPA

## CALL TO ORDER: 6PM

## PUBLIC COMMENTS

Arlene Price for Janssen here to present Olysio it is a hepatitis C virus inhibitor indicated for the treatment of chronic hepatitis C as a component of combination antiviral treatment regimen. Olysio efficacy has been established in combination with peginterferon alfa and ribavirin in HCV genotype 1 infected subjects with compensated liver disease (including cirrhosis). Olysio must not be used as monotherapy. Screening patients with HCV genotype 1a infection for the presence of virus with the NS3 Q80K polymorphism at baseline is strongly recommended. Alternative therapy should be considered for patients infected with HCV genotype 1a containing

the Q80K polymorphism. Dosing for Olysio is one 150mg capsule taken once daily with food. Olysio should be administered with both peginterferon alfa and ribavirin. The recommended treatment duration of Olysio with peginterferon alfa and ribavirin is 12 weeks, followed by either 12 or 36 additional weeks of peginterferon alfa and ribavirin depending on prior response status. The most common reported adverse reactions (greater than 20% of subjects) in subjects receiving the combination of Olysio with peginterferon and ribavirin and occurring with at least 3% higher frequency compared to subjects receiving placebo in combination with peginterferon alfa and ribavirin during the first 12 weeks of treatment were: rash (including photosensitivity). Olysio has a Drug interaction when co-administrated with moderate or strong inducers or inhibitors. In summary when you compare Olysio to what is currently available we do see improved SRV rates, low rates of anemia and given the simplicity of the regiment it helps improve the patient adherence. Please consider Olysio for preferred on the PDL.

Ms. Paul asked if there was a head to head study done.

Ms. Price answered no there has not been a true head to head done. They are in the process of doing a head to head now.

Mr. Ouellette asked when that data would be available.

Ms. Price answered later this year.

## OLD BUSINESS

### DUR MINUTES

The November, 2013 minutes were approved.

### PSYCH WORK GROUP MONTHY UPDATE

Dr. Tweed stated that the Psych Work Group discussed the LD 338 and the Antipsychotic PA form needed for this. Dr. Tweed provided the board with a draft version with the PA form with some changes that the Psych Work Group added. The main changes are for Aggression we need to make sure that the prescriber attesting that it is being used as a third line treatment. We will need to rearrange the order of how things are listed on the PA form so that it is clear that the requirements are not just for if the patient is under age 5. Need to be able to divide out the base line and the 3 month data because we will never deny out for not getting the baseline because they cannot go back and get it. On an earlier daft there were spaces for the prescriber to list other medications that have been tried as well as data that has been collected including BMI, cholesterol etc. The Psych work felt that since we will not be analyzing that data it didn't serve a good purpose to collect it. Office of Child and Family Services (OCFS) will be doing some sort of chart review. Also, added in AMES because it is listed in the law. The law requires us to monitor the side effect of the medication but we do not want to kick someone off an antipsychotic. We have been discussing how to deal with this if the prescriber does not submit the required information with the PA at the 20 week mark. If that is the case the member we receive one more month of medication and the OCFS will reach out to the prescriber on contractual bases.

Mr. Ouellette stated that a procedural process will need to be put into place to send the information over to OCFS and some sort of feedback loop under then email so that nothing getting missed.

Dr. Tweed stated that OCFS is going to be highly motivated in reaching out the prescribers.

Dr. Braun had some comments regarding the PA form. First the heading should read Form members under 17. Second the first highlight section should be changed from "member under 17 years of age require" to "for members under 17 years of age we require" or "the law requires". Because this is being required to be done by law there should be a reference to that one the PA form. Also in this section it states a "timely assessment" that is unclear to what are expectation is.

Dr. Tweed stated that a base line is 3 months but yes that is a good point.

Dr. Braun added that if the last section about the attestation is only for the annual PA then it either needs to be clearer or put into a second PA form.

Mr. Ouellette stated that one concern is that we have multiple PA forms currently we have 32 different forms. If we can wrap it all into one form it may be a better option than two different forms. We could add "For continuation therapy sign here".

Dr. Barkin added that we could electronically do the ones for the one year mark.

Mr. Ouellette responded that he would need to look into what data we have in order to do that.

Dr. Braun asked if the abnormal involuntary moment scale is commonly understood and maybe we can put a reference for that on the PA form. Also, does there need to be more clarification on the BMI.

Dr. Tweed answered that both are available online and we could put a link to it on the PA form. Following on with Dr. Braun's comments to change the heading to for members under 17… and then a large header stating at the 20 week mark and then on the back annual review.

Asked how often do they recommend AMES for these kids?

Dr. Tweed answered that it isn't really clear, in most cases it's every time the patient is seen. We are going to be requiring it less then that at the baseline and three months.

Dr. Braun added that if a draft is done he would be happy to review it.

## LD 338 UPDATE ANTIPSYCHOTICS AND CHILDREN

Discussed in the Psych Work Group Monthly Update.

## PA FORM REVIEW FOR ANTIPSYCHOTIC

Discussed in the Psych Work Group Monthly Update.

## LD 716 UPDATE STIMULANTS AND BENZO'S

Dr. Barkin stated that this would be discussed separately for the provided in the packets include LD 716, graphs of usage in each county as well as the raw data. Dr. Tweed will be discussing LD 716.

Dr. Tweed stated the LD 716 has been through numerous versions from when it was initiated. It ended up they were directed to do a work group. The following recommendations were the result of the work group. Most recently Dartmouth did availability of services for child they used quality indicators. When a youth (6-16) is started they need to be seen back with the first month and seen a total of three times in the first 10 months. Maine scored within the 30-35%. In talking with the Maine Health Coalition they are going to start incorporating MaineCare data. The hope is to publicize how low the quality care is and to raise that so at the very least providers are seeing their patients back.

Dr. Barkin discussed the co-prescribing of stimulants and benzo's. Provided in the packet is an analyst that the board has seen before showing co-prescribing with an overlap of 60 days by year and by age band. Also included is a list of the prescriber by DEA. Dr. Barkin has reached out to the top offenders and after speaking with we are seeing a decrease in their members. For example one provider that Dr. Barkin spoke with went from 84 members in SFY 2013 to 10 in SFY 2014. To be clear this is state fiscal year that runs from June to July so for 2014 it is only half the year but even at that it is a significant change.

Dr. Barkin added a couple things still bother him with is the trend upwards across the age bands. But even more than that is the second chart showing co-prescribing of benzos with stimulants/opiates with a 60 day overlap and the next one looking at multiple benzos with stimulants/opiates with a 60 day overlap. This is a combination that could be deadly. The good news is that we have been able to go after the top prescribers and change their behavior. What he would suggest is to look at the benzos, stimulant and opiate combination and see who is driving it because it may end up being that it is multiple prescribers.

Dr. Braun asked if there was any intention to reach out to the different groups for example the NPs.

Dr. Barkin stated that NP's do not have a listsev.

Dr. Braun asked do we have any information that this data is bad.

Dr. Barkin answered that there is no study that shows that these drugs are necessarily bad and not sure how quantify good or bad.

Dr. Braun stated that he brought it up only because to convince a prescriber to change his or her prescribing style it may take more than just the DUR or Psych Work Group feels you have a problem.

Dr. Barkin stated that when we sent the letters out and contacted that prescribers that were prescribing benzos and stimulants the feedback was mixed some were defensive some stated they were trying to change their ways.

Dr. Braun added that what he would like to do is encourage good behavior and be positive and try to lead them in the right direction so that they can make better choices in what to do.

Dr. Barkin stated that as far as the next step is to see who is prescribing to see if it's all coming from one or multiple prescribers that may not be aware of what the other are doing.

Dr. Tweed asked if this included Methadone.

Dr. Barkin answered that this report did not included Methadone.

Dr. Tweed stated that the presumption is that the patient getting all three of these is a higher risk of being a diverter.

Dr. Barkin added that there is nothing evidence based that would suggest to patients to be on all three of these types of medication and seeing an increase in this over the years.

Dr. Braun added that is it very hard to get patients off these medications once they are on them.

Dr. Barkin would like to do what the board did with the benzos/stimulants to this group.

Mr. Ouellette added that because what the DUR needs to do and report on for CMS we may want to look into the patients as well.

Dr. Tweed and Dr. Braun agreed that notifying the prescribers that their patient is getting scripts from other prescribers may be helpful.

Dr. Barkin stated that he will identify the prescribers that are doing it and bring that information back to the board.

Dr. Tweed and Dr. Barkin felt that it might be something that we want to present at the NP annual conference

Ms. Paul added that the annual conference is in April. Most likely when looking at where the different NPs are located it's going to be where they don't have psychiatrist.

Dr. Barkin stated that we need to do reach to them.

## NEW BUSINESS

### LYME DISEASE AND ANTIBIOTIC USE

Mr. Ouellette stated that with the new PCM program we are looking into the drug Mepron which peeked our interest in why we were seeing prolong courses of the therapy this led us to look into some other diagnosis Lyme, Anaplasmosis, Babesisois, Ehrlichiosis and other. After talking with Dr. Biczak our infectious disease doctor at GHS even though it's not huge dollar amounts, the use of chronic anti-infectives is something that we should look into more. The analysis provided to the board today shows the diagnosis and SFY broken down into age band. Also provided are total counts of member with

diagnosis verse without diagnosis. Also average cost of members with and without diagnosis and total spend with or without diagnosis. The purpose of this is to look into it further by looking at this patients to see why this medication are being prescribed and see if they are being prescribed appropriately. For example with the PCM program looking at Mepron we have been able to identify inappropriate use and have been able to get prescribers to reduce the dose or discontinue use. The other thing is to look at what kind of prescribers are writing primary cares or specialist.

Dr. Braun asked for clarification on the charts provided.

Mr. Ouellette stated that they looked at the entire Mainecare population comparing those with one of the diagnosis to those without that have been prescribed an anti-infective.

Dr. Braun felt this analyst is hard to wrap your head around.

Dr. Barkin added another way of looking at it is why is someone on an antibiotic chronically with one of those diagnoses and without and then what is the cost.

Dr. Braun stated that he would rather focus on getting compliance on Hepatitis C protocols.

Mr. Ouellette stated that he agreed that there is much more dollars being spend on Hep C but looking into this the cost it is higher than expected. It may be worth finding out why that is. As we look at this more with Dr. Biczak we will give the board an update.

## NEW GUIDELINES FOR CHOLESTEROL TARGETS

Tabled until next meeting

## NEW DRUG REVIEWS

Adempas common name riociguat in the PDL category Pulmonary Antihypertensives the recommendation is for it to be non- preferred.

Mr. Ouellette added that it is a film coated tablet, recommended to obtain pregnancy test females of reproductive potential prior to starting therapy, monthly while on treatment, and one month after discontinuation of treatment.

Brintellix common name vortioxetine in the PDL category Pulmonary Antidepressants, Selected SSRIs the recommendation is for it to be non- preferred.

Dr. Barkin stated there is no evidence at this time to support that Brintellix® is more efficacious or safer than the currently available, more cost effective medications. Therefore, it is recommended that Brintellix® remain non-preferred

Fetzima common name levomilnacipran extended-release in the PDL category Antidepressants, Selected SSRIs the recommendation is for it to be non- preferred.

Dr. Barkin stated that there is no evidence at this time to support that Fetzima® is more efficacious or safer than the currently available, more cost effective medications.

Fycompa common name perampanel in the PDL category Pulmonary Anticonvulsants the recommendation is for it to be non- preferred.

Mr. Ouellette added this drug is for adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy. Use with oral contraceptives may render them less effective; therefore, additional non-hormonal forms of contraception are recommended. The starting dose should be 2mg per day and titrated until target dose is achieved, up to a maximum recommended dose of 6mg in those with mild impairment and 4mg in those with moderate hepatic impairment. There is a box warning regarding the increased risk of serious life-threatening psychiatric and behavioral reactions, including aggression, hostility, irritability, anger, and homicidal ideation and threats.

Gilotrif common name afatinib in the PDL category Cancer the recommendation is for it to be non-preferred.

Mr. Ouellette added Gilotrif is **f**or the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test .

Khedezla common name desvenlafaxine extended release in the PDL category Antidepressants, Selected SSRIs the recommendation is for it to be non- preferred.

Dr. Barkin added that no head-to-head comparator studies were found on this drug.

Olysio common name simeprevir in the PDL category Hepatitis C Agents the recommendation is for it to be non- preferred.

Mr. Ouellette added it **must not** be used as monotherapy. There is no evidence at this time to support that Olysio® is more efficacious or safer than the currently available, more cost effective medications

Opsumit common name macitentan in the PDL category Pulmonary Antihypertensives the recommendation is for it to be non- preferred.

Mr. Ouellette added that it has drug interactions when use with strong CYP3A4 inducers, such as rifampin, with macitentan should be avoided. The concomitant use of strong CYP3A4 inhibitors, such as ketoconazole, should also be avoided. Recommended dose is 10mg daily. It has a box warning regarding the risk of embryo-fetal toxicity and thus should not be given to a pregnant female due to the risk of fetal harm.

Zorvolex common name diclofenac in the PDL category NSAIDs the recommendation is for it to be non-preferred.

Mr. Ouellette added if is for the treatment of mild to moderate acute pain in adults. The concomitant use of aspirin with Zorvolex® is not generally recommended due to the potential of increased GI adverse reactions. Coming is 18mg and 35mg capsules the recommended dose is take 18mg or 35mg TID on an empty stomach. As other diclofenac products contain a salt of diclofenac (ie diclofenac potassium or

sodium), Zorvolex® contains the free acid; therefore, it is not interchangeable and not substitutable with diclofenac products of similar dosing strengths.

All in favor to make all non-preferred- passed

## ADJOURNMENT: 6PM

The next meeting will be held on **January 14, 2013**, 6:00p.m. – 8:00p.m at the Armory.