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: February 18, 2014
RE: Maine DUR Board **Meeting** minutes from February 11, 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: Laureen Biczak, DO

CALL TO ORDER: 6PM

PUBLIC COMMENTS

John Peterson from Gilead here to present Sovaldi. Sovaldi is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen. There are six genotypes worldwide 78% of genotypes in America are genotype 1 so I will focus on that. Looking at dose and administration for Genotype 1 or 4 treatment Sovaldi + peg interferon + ribavirin for a duration of 12 weeks, for genotype 2 treatment Sovaldi + ribavirin for duration of 12 weeks and for genotype 3 Sovaldi + ribavirin for

duration of 24 weeks. Also in the indication if the patient is interferon ineligible you can consider using Sovaldi + ribavirin for a duration of 24 weeks. The 2014 AASLD/IDSA HCV Treatment Guidelines recommend Sovaldi as a component of the recommended regimens for all patients infected with GT 1-6, including sub-population. A couple of other highlights that I would like the board to consider is there are very few DDI, a high bearer to resistant and a very low discontinue rate. In closing please consider adding Sovaldi to the MaineCare PDL.

Mike Lombardo from Zimmer to speak on Gel One a single injection for osteoporosis of the knee. Please consider it adding it to the MaineCare PDL.

Mr. Ouellette asked if this is similar to the other products that are available.

Mr. Lombardo answered that form an efficacy stand point yes, from a side effect profile it hasn't had any reported sepsis and it is slightly cheaper. It also has its own J-code.

OLD BUSINESS

DUR MINUTES

The January 14, 2013 minutes were approved.

PSYCH WORK GROUP MONTHY UPDATE

Dr. Tweed stated that the psych work group discussed the new pa requirement for antipsychotic.

PA FORM FINAL REVIEW FOR ANTIPSYCHOTIC

Mr. Ouellette stated that along with the updated PA from a handout that summarized the current programs that are in place for antipsychotics.

Dr. Tweed stated that in reviewing the PA form there has been some discussion on whether we should collect the metabolic data since we will not being doing an annalists on the data.

Dr. Weiss added that we don't really need the data if they billed MaineCare for the test then we know they did it.

Dr. Tweed added that some do not require billing to MaineCare for example getting a patient BMI. But he agreed that something stated the provider attest that it was done.

Dr. Biczak asked what happens if they are not doing the test.

Dr. Weiss answered then a PA would be required.

Dr. Biczak added what happened if they don't get the PA.

Dr. Tweed asked for clarification on what happens when a patient goes to the pharmacy and a PA is required.

Mr. Ouellette explained that if a prescriber hasn't sent in the information a PA will be approved for one month giving them time to get the requested information in. This PA communication is sent out to the provider each month.

Dr. Weiss added that short of that we would have to not get the medication.

Dr. Tweed stated that they have thought a great deal about putting in a hard stop. What I think will happen is when the provider is notified so will his office. Reviewing the updates that have been made under medical necessity documentation for Aggression "third line treatment" may need some clarification we should list the first and second treatment.

Dr. Weiss stated that he disagreed that this is a PA form and it over complicates the form.

Mr. Ouellette stated that instead of listing it on the PA form we could have that information in the criteria section of the PDL. Then reference that on the PA form.

Dr. Tweed asked if listing the other medication tried is needed and if it's useful.

Mr. Ouellette answered that the information is helpful to have on the form for when a determination is being made. In some cases the patient may have tried other medications that we aren't seeing in the MaineCare profile for example if they are new to MaineCare or if they had a private insurance.

Dr. Tweed stated that there is no way to tell looking at the PA form if the provider is getting a baseline and again at three months. We need a way to document that they are doing both.

Dr. Weiss asked what is considered baseline.

Dr. Tweed answered that its best before the medication is started or within the first two weeks.

Mr. Ouellette suggested that if we remove the values from the form then we could do an audit letter verify that they are doing the follow up monitoring.

Dr. Biczak added that for the BMI we could add a baseline date and a current date.

Mr. Ouellette stated that the revisions will be made and send to the board to be voted on.

NEW BUSINESS

LYME DISEASE AND ANTIBIOTIC USE

Mr. Ouellette stated that included in the packet are a sample of patients profiles to review Dr. Biczak is going to present this information.

Dr. Bizcak stated that Lyme disease is the one of the few disease that they studied whether extended iv antibiotics are effective. It was proved to not be. What has happened is there is a group of people that think that there is a chronic undiagnosable form of Lyme disease that for which multiple antibiotics are indicated

Dr. Weiss stated that when looking at these profiles the ones that are concerning is when you see the antibiotics being prescribed by the same provider. This seems to be more of an issue with the providers not the disease.

Dr. Biczak stated that she would like to look into this further. Start looking at which physician fall into this and do chart review. Part of the issue is that MaineCare doesn't have a rule that really covers this because most of the medications are preferred and once the providers do need a PA they just change the medication.

Mr. Bondeson asked is it correct that for Lyme disease only 30day of antibiotic is indicated.

Dr. Biczak answered that is correct.

Mr. Bondeson then asked what is the rational for prescribing the medication.

Dr. Biczak stated that the provider believes that somehow we are hiding the fact that his patient has Lyme disease.

Dr. Weiss added that normally if you get a positive blood test then you have Lyme disease and are treated. These providers believe that even if the test is negative there are still people that have Lyme disease so he treats them. Unfortunately, sending them a letter or a PA isn't going to do much because they believe that they are right in prescribing.

Dr. Biczak stated that she doesn't have an easy answer for this. But feels that it is worth looking into further if it was a narcotic we would have no problem stopping it but it's an antibiotic and they are low cost drugs. With the DUR's input Dr. Biczak would like to see how big the problem is.

Dr. Weiss asked could we say if a patient is on an antibiotic for more than 60 consecutive days or 180 days, doesn't have to be the same one then a PA is required.

Mr. Bondeson asked how reliable the blood test is for Lyme disease.

Dr. Bizcak stated that it's disputed because the lab test can be negative in the first two weeks and if you get treated early it can stay negative. The issue is they have taken pieces of different guidelines and pulled them together to create their own guidelines.

Mr. Ouellette stated that one issue with putting a PA in place is the GPI's for these drugs are across a wide range.

Dr. Biczak stated that are current rules of requiring medical necessity would give of the ability to put a PA in place.

Dr. Weiss and Dr. Biczak both agreed that it is a good idea for Dr. Biczak to look into it more.

NEW GUIDELINES FOR CHOLESTEROL TARGETS

Dr. Weiss stated that a number of people disagree with these new guidelines one of them being the National Lipid Association rejects these guidelines because they believe in the numerical end points. It is a very simply guideline they no longer are looking for lab testing to be done after the medication has been started other than to prove compliance of the medication. In saying that it does make it easier to do an audit on since in the past we have had difficulty getting the lab results into us. Dr. Weiss stated that he can give us a list of the disease states and patients known to have those should be on Lipitor or Crestor and if they aren't then they are not reaching target.

Dr. Biczak asked does in state the recommended dose.

Dr. Weiss answered yes.

Mr. Ouellette stated that he will write up what GHS does and will send it to Dr. Weiss for review.

NEW DRUG REVIEW AND CRITERIA APPROVAL

Dr. Biczak presented an overview on the new drug review for Sovaldi. MaineCare will be looking at the guidelines and the data in which the guidelines are based. The guidelines do not state who should be treated when. They are very clear that there are certain people with lesser levels fibrosis who it maybe prudent to wait for a second direct agent. We are taking a very hard look at the data and will work through some recommendations based on genotype based on what the data supports most. For example the interferon free regiments are supported by relatively weak data some of the subgroups only included 14 people. We will be looking at the data very hard looking at both recommended regimens and the alternative regimens.

Dr. Weiss stated that now we are going to vote to add it to the MaineCare formulary as a first step.

Vote- Passed

BENZO/ STIMULANT/OPIATE UPDATE

Tabled until next meeting

DRUG PA CRITERIA APPROVAL

Adempas

- The indicated diagnosis supported by documentation from the patient's medical records
- Previous trials/failure of preferred medications
- Documentation regarding negative pregnancy tests and using contraception if of childbearing potential
- Monitoring of DDIs in patient profile

Brintellix

- The indicated diagnosis supported by documentation from the patient's medical records
- Previous trials/failure of multiple preferred medications and step medications
- Daily dosing limited to one tablet daily
- Monitoring of DDIs in patient profile

Fetzima

- The indicated diagnosis supported by documentation from the patient's medical records
- Previous trials/failure of multiple preferred medications and step medications
- Daily dosing limited to one capsule daily, allowing for titration
- Monitoring of DDIs in patient profile

Fycompa

- The indicated diagnosis supported by documentation from the patient's medical records
- Previous trials/failure of multiple preferred medications
- Monitoring of DDIs in patient profile
- Dosing limitations of one tablet daily

Gilotrif

- The indicated diagnosis supported by the documentation of the presence of EGFR exon 19 deletions or exon 21 (L858R) substitution mutations from the patient's medical records
- Prescribed by an oncologist
- Females of reproductive potential counseled on appropriate contraception use during treatment
- Daily dosing limited to one tablet daily
- Monitoring of DDIs in patient profile
- Three (or six) months approval, and re-approval will require documentation of response without disease progression and tolerance to treatment

Khedezla

- The indicated diagnosis supported by documentation from the patient's medical records
- Previous trials/failure of multiple preferred medications and step medications
- Daily dosing limited to one tablet daily
- Monitoring of DDIs in patient profile

Olysio

- The indicated diagnosis supported by documentation from the patient's medical records
- Previous trials/failure of preferred medications and no previous treatment failure of Olysio® or other HCV protease inhibitors
- Used in combination with peginterferon alfa and ribavirin for the appropriate length of treatment
- Monitoring of negative pregnancy tests and contraception use
- Monitoring of DDIs in patient profile

Opsumit

- The indicated diagnosis supported by documentation from the patient's medical records
- Previous trials/failure of multiple preferred medications
- Daily dosing limited to one tablet daily
- Documentation regarding negative pregnancy tests and using contraception if childbearing potential
- Verify in patients profile for strong CYP3A4 inducers/inhibitors
- Appropriate lab monitoring

Voted- Passed

ADJOURNMENT: 6PM

The next meeting will be held on **March 11, 2013**, 6:00p.m. – 8:00p.m at the Armory.