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: May 1, 2013
RE: Maine DUR Board **Meeting minutes** from **April 9, 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

Ron Boynar, National Accounts Manager, Para Pro LLC presented **Natroba**, a new head lice product introduced in Augusta 2011 for infestations in four years and older. Boynar explained there were two phase-three studies by the Butler University College of Pharmacy comparing Natroba with Permethrin: 1) Permethrin with combing and 2) Natroba without combing in over 1000 patients. The study found that Natroba was twice as effective as Permethrin. Outcomes for Natroba were 85%/87% compared to Permethrin at 42%/44%. Permethrin was found to have resistance problems with more than 75% of patients retreated. Boynar pointed out Natroba is not acutely toxic to mammals; not systemically

absorbed – even with double doses; had no significant safety signals as early as six months of age, and had a Pregnancy Category B (all others have a Category C). He referred to the handout, Indiana Medicaid Study, a comparative analysis of three prescription head lice medications: permethrin, Natroba (Spinosad) and Ovide (malathion). They found that Natroba was more effective than malathion and permethrin. There were lower additional costs associated with treatment failure and retreatment, and there were no additional office visit claims. Boynar restated that more than 75% of patients have to be retreated with permethrin ($195.00 per patient). Natroba works the first time.

Dr. Robert Weiss asked if Boynar was aware of the contract that his company [Para Pro] gave Maine Medicaid, which states to use the generic before using other brand name drugs.

Boynar explained that he was here today to ask the Board to consider removing the two steps.

Michael Ouellette pointed out the utilization data is slightly different from the Indiana data and that it was worth taking another look at and comparing data – especially with retreatment.

Dr. Weiss felt the committee did not disagree that Natroba is a better product; the issue was with the contract.

Dr. Jeffrey Barkin pointed out in terms of cost effectiveness and outcome testing, the number needed to treat with Permethrin is 20 people to have one failure and expressed the need to factor this in.

Dr. Linda Glass explained there are additional office costs attached with Permethrin. We are seeing a lot more requests to by-pass this. This drug is safe.

Mr. Ouellette pointed out the SSDC states (which Maine is a part of) will meet in June to go over new offers for 2014. He felt this would be a good time to get information to all the states to try and get the restriction lifted off.

OLD BUSINESS

DUR MINUTES

MOTION by Dr. Glass to approve minutes for March 2013. All in favor [Waiting for phone votes].

PSYCH WORK GROUP MONTHY UPDATE

Lindsey Tweed discussed the need for DHHS to enact the most relevant or appropriate evidenced-based guidelines for bills. If better guidelines come along, than DHHS would have flexibility.

NEW BUSINESS

STATIN UPDATE

Dr. Weiss explained there had been the chronic process of trying to figure out why only one third of the people in Maine are treated with Statin, and only one ninth of the people in Maine are treated to the proper medical target.

Mr. Ouellette discussed the analysis of letters sent last year. He reported 718 letters were sent out on members indicating that either no labs had been done or no Statin was in place even though patients were high risk members. Letters were sent to 288 members in April and 430 members in May. The follow-up revealed that out of the 718 people, only 81 members had labs done, even though 200 members promised that labs would be "ordered soon".

Dr. Weiss re-emphasized that physicians are still treating patients inappropriately despite four months of identification and notification by the committee. The process has had no impact. People who were defined as having heart disease, stroke or diabetes by guidelines are supposed to be treated with Statin. In Maine, two-thirds were not. These numbers are not different from other states.

He felt one problem lies with everyone trying to be supportive, but it has no impact and physicians go back to doing what they did before. In addition, most physicians are trying to do too many things, so they do them poorly. Even the physicians who *are* using Statins, he added, often prescribe extremely dull doses of generic, so physicians are not titrating up. He indicated that the situation will not change unless something is done to force the change.

Mr. Ouellette reported other states are seeing similar results, particularly with atypical monitoring. They are getting the same type of response rates we are getting.

Dr. Weiss suggested one solution could be Mainecare, who is allowed to request specific charts. He explained that in the past they would identify a physician and talk to them to find out why this was happening. You could remind them of the guidelines and focus on problems. He suggested that Mike could identify some people to meet with face-to-face to see if the graph gets better.

Mr. Ouellette pointed out the same query was run using January – March of this year. The query identified more members in the two-month period than was identified one year ago: 718 compared to 856. Out of the 856 members, 150 patients from last year are still in analysis for this year. It showed that some people are just being left behind.

Mr. Tweed asked if there was success at the face-to-face intervention should the program be expanded?

Dr. Weiss felt that would be the idea.

Dr. Barkin asked if a lot of these patients were just not making contact or not returning phone calls?

Dr. Weiss reported they called 500 patients that were either poorly treated or not treated at all, and almost everyone had no idea that this was even an issue. They knew their cholesterol had been checked, but because nothing further was done they assumed they were ok.

Dr. Barkin pointed out the monitoring rate for treating psychiatric patients who are on atypicals for lipids is now higher than treating high-risk heart patients.

Dr. Glass felt part of the problem is the issue with: 1) fasting and 2) turn-around time. She pointed out they do them in the office so you have a captive audience. Before the patient leaves we know what they are – so if you have an issue you have it in "real time".

Dr. Weiss asked if the "turn-around time" issue is true, why would Doctors order blood tests to come back the next day if they are simply going to ignore them? There are Point-of-Service cholesterol tests that are easier, but this is such an overwhelming problem that even when someone *does* get the cholesterol panel done, less than 20% of people who have had the blood work get treated.

Dr. Glass suggested we let Doctors know that there are millions of these [Point-of-Service tests] that are available now that you can do in your office.

Dr Weiss explained hospitals will not do that in owned practices because the reimbursement for the formal blood test is greater than the Point-of-Service blood test. He felt they did not want to give up income.

Mr. Ouellette pointed out, with regards to "fasting" and "non-fasting" lipids, the State puts out a quarterly newsletter where an article could be incorporated suggesting the proper use of lipid testing in patients.

Dr. Weiss stated he would be willing to do that, but you would have to do a survey to see if anyone is reading it.

Mr. Ouellette pointed out it would be part of the education process so that when we are pulling chart notes, we can say that they have been informed.

Dr. Weiss suggested they start thinking about providers and sending someone to a few offices.

Dr. Barkin suggested to come up with something that stratifies by worseness or by volume what percentage of patients have this pattern in the Mainecare population over a certain age and come up with a relativity score. You can compare an individual to the average for the group.

Dr. Weiss agreed they could find 5 or 10 Doctors who have the most patients in this list, they could look at different ways of combining these ideas because the letters were ignored.

Dr. Glass felt asking people to process is the best place to start because of the issue with "fasting" and "non-fasting". Who is looking at the lipids when they come back? Who gets them? Does the physician get them and sign off on them?

Dr. Weiss pointed out at CMC, every lab test has to be signed by a physician.

Mr. Ouelette felt this was not happening in small practices.

Dr. Barkin asked about the work flow. As the one who is looking at a lot of these initiatives, he suggested the number one reason is "Not my patient".

Dr. Glass felt there had to be a work flow issue involved. The only way to know is to go in to the offices and see.

Dr. Weiss suggested a two-part, personal visit. The first part of the personal visit could address the work flow and why they think certain things are an issue, and the second part could be to give ideas on how to do it better, both on the work flow and in terms of treatment.

Dr. Barkin suggested publishing the rates of practices or do what we are already doing with the Benzo stimulant. You don't have to necessarily "publish" – just push the data to the offenders. He felt you should explore it first before you do anything too big because the sample size would be tremendous.

Dr. Weiss agreed they could start with that and suggested to pick 5 Doctors just as an experiment.

DUR LETTER UPDATE

Dr. Weiss explained this was an update for Benzo stimulants and antibiotic issues.

Mr. Ouellette reported that Stephanie approved 2 of the letters. They took the top 10% of Benzo combo prescribers. They identified 51 providers with 10+ patients that were on combo – Benzo stimulants and antibiotics at the same time. He reported that the letters have been generated, but have not been mailed yet.

Dr. Weiss asked how many total patients did Mainecare have who are on both Benzo and the stimulants?

Dr. Barkin reported there were approximately 700 and that number continues to grow. On Benzo and the stimulant, the model was a 60-day overlap in their practice and the average prescriber had 3 ½ patients. The number in children was very small and did not even bring single digits.

Mr. Ouellette reported the antibiotic letter encompassed 75 providers from the three different counties. Those letters are going to be mailed out this week.

Dr. Weiss reiterated they looked at the patterns of antibiotic utilization in certain pulmonary conditions and there was a big difference between geographies. Some people who had, for example, a cough in some communities got on antibiotics in extremely high number, and other people who had a cough were told they had a virus and did not get antibiotics. They are trying to write to them to see why this was happening.

Mr. Ouellette reported the letter states the precautions for using antibiotics for diagnosis when patients don't need antibiotic treatment and watching out for resistance. It also states if you have been identified in the top 10% and to take a look at your patients again to see if the co-prescribing is necessary.

PA CRITERIA

Mr. Ouellette reported there are thirteen drugs that are recommended by DUR for PA Criteria that they would like to put on the PDL:

Delzicol: A common name for mesalamine for GI-Inflammatory bowel agents. It is a capsule formulation and bioequivalent of Asacol 400mg tabs, which we currently have on the Preferred side. The only criteria would be that our standard PDL language be repeated every time:

> Preferred drug must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drug will be approved, unless an acceptable clinical exception is offered on the Prior Authorization form, such as the presence of a condition that prevents usage of the preferred drug or a significant potential drug interaction between another drug and the preferred drug(s) exists.

Pertyze: A common name for pancrelipase for GI-Digestive enzymes, which we currently have as Non-Preferred. The standard PDL language would be used as above.

Giazo: A common name for balsalazide disodium for GI-Inflammatory bowel agents. Only indicated for adult males as the safety/efficacy for use in females has not been established. It is the same active ingredient as Colazal, which we have as Preferred.

Quillivant XR: A common name for methylphenidate extended-release suspension, which we voted as Non-Preferred. It is only indicated for use in patients 6 years of age or older; the concomitant use with MAOI is contraindicated, and the maximum recommended dose is 60mg.

Juxtapid: A common name for lomitapid, which has all kinds of drug/drug interactions. It is contraindicated in pregnancy and in those with moderate/severe hepatic impairment and active liver disease; has a concomitant use of strong CYP3A4 inhibitors; would be contraindicated and we would put in edits to stop the drug from going through and also the other drugs from going through; weak CYP3A4, especially when you are looking at oral contraceptives, and making sure we are careful there. We are also looking at dose monitoring when changes occur with warfarin, simvastatin and lovastatin.

Eliquis: A common name for apixaban in the PDL category of Anticoagulants, which is Non-Preferred. Recommended dosing limits of 2 tabs/day; active comparators in FDA registration trials were aspirin and warfarin.

Dr. Weiss disagreed with the use of aspirin or warfarin in the profile because you are supposed to go right to Eliquis since it is better. It should be the same PA that you would use for Pradaxa or Xarelto.

Mr. Ouellette pointed out they are going to look at updating the PA form and bringing all three of them together on the same PA form.

Oxtellar XR: A common name for oxcabazepine extended –release in the PDL category of Anticoagulants, which is recommended as Non-Preferred. It is used as adjunctive therapy in adults and children 6-17 years; decreases the effectiveness of oral contraceptives [OCs], so we will put some edits in place with regard to OCs; a maximum daily dose of 2400mg, and DDIs with other anticonvulsants.

Forfivo XL: A common name for bupropion HCL extended-release in the PDL category of Antidepressants, which is recommended as Non-Preferred. It is approved for use only in adults; contraindicated with concomitant use of MAOIs; and has a dosing limit of 1Q per day.

Vascepa: A common name for icosapent ethyl in the PDL category of Lipid Drugs, which is recommended as Non-Preferred. Adjunct therapy for specific indication to reduce TG in those with severe hypertriglyceridemia (500mg per deciliter or more). We would look for the proper indication per lab values before we would allow an approval.

The next three are the new diabetic meds which are looking for Preferred agents:

Kazeno: A common name for alogliptin and metformin in the PDL category Diabetic-DPP-4 Enzyme inhibitor Combo, which is currently Non-preferred.

Nesina: A common name for alogliptin in the PDL category Incretin Mimetics, which is currently Non-Preferred. It has dosing limits of 1 tab per day.

Oseni: A common name for alogliptin and pioglitazone in the PDL category Diabetic-DPP-4 Enzyme inhibitor Combo, which is currently Non-Preferred.

Ilevro: A common name for nepafenac in the PDL category of OP-NSAIDS, which is currently Non-Preferred.

MOTION by Dr. Weiss to approve the ME DUR Recommendations for PA Criteria. All in favor [Votes obtained by e-mail give quorum to pass criteria] Motion passed.

HEPATITUS UTILIZATION AND ADHERENCE

Mr. Ouellette reported they were trying to re-run some utilization and adherence data and referred to the one-page analysis hand-out, which highlights the original analysis from January 2012. He explained that the analysis looks at the new drugs: *Incivek* and *Victrelis* and the utilization data compared to a variety of different dosing requirements using the triple therapy. The analysis highlights if they were using the drugs for the full duration or if they were using the other two products or doing some off-shoot of that.

When they looked at the analysis back in January 2012 they had patients that started with the new Hep-C drugs but never used the Ribavirin or other pegylated products. There was also high discontinuation due to a variety of different reasons: either they were not aware that the patient had discontinued the product or they had adverse reactions that had caused them to stop.

Dr. Weiss pointed out every time they look at this they are done poorly. There is almost no one on the bar graphs who is treated the way they are supposed to be.

Mr. Tweed felt these were very expensive meds that are used on a small number of people and that this seemed to call for a care manager.

Mr. Ouellette explained they had met with each of the different companies to talk about the adherence issues that we had seen and how they are prescribing. There is a heavy lean towards the Incivek product because of the ease of dosing.

Dr. Weiss felt this was interesting because in theory, this is done by gastroenterologists who know what they are supposed to do. In the past, this kind of utilization would be reinforced by drug reps because they would come in and talk about it. Now, most gastroenterologists will not see drug reps. There is nobody reinforcing directly to them.

Dr. Barkin pointed out you have pegylated interferon which is awful to take and patients hate it. Because its three drugs the compliance is going to be 12-15% - even if they did not have side effects. This is a very competitive drug class that is going to become more competitive.

Dr. Weiss asked if this was creating resistance by picking out certain viruses and then letting them live because you are not doing them. That is how bacteria became resistant.

Mr. Tweed suggested if you made some sort of financial model the inappropriate utilization may go down.

Dr. Weiss asked why you couldn't get a kind of unrestricted occasional grant from the manufacturer of Victrelis to try and help fund the care manager who goes in and sees these people. They did this many years ago and it is not illegal. It would help fund this position which 1) might stop the overutilization of very expensive drugs, and 2) might help use them properly. He suggested the need to think outside the box when trying to get into the limited number of doctors who do this.

Mr. Ouellette reported that they now have 178 members since they started in May 2011 that could be identified in the process. It doesn't mean they are currently taking it. That's what we want to find out – what they are currently doing. Overwhelmingly, the Incivek patients compared to the Victrelis patients are approximately 4:1.

Dr. Barkin pointed out that to show your benefit is to capture your cost on the medical side because appropriate use is going to drive down medical cost.

Dr. Weiss suggested Judy Butler (MERCK) talk to Mike and GHS about helping to create an unrestricted way to look at education so that it's not Drug Company related.

BUTALBITAL UTILIZATION AND MEDICATION OVERUSE

Mr. Ouellette reported they looked at the utilization pharmacy claims for January-March of 2013 and tried to figure out how many members they had and if they were taking these meds in any combination. They wanted to look at the members who were taking less than or equal to 18 tablets per month, greater than or equal to 60 tablets, greater than or equal to 120 tablets, and even greater than or equal 240 tablets. They looked at the unique diagnosis.

In addition, they wanted to look at other medications they may have claims for within their profile. Over that 2 month period they identified 798 members that were taking Fioricet or some version of Fioricet. There were 451 members taking less than or equal to 18 units per month, 262 members were getting up to 60 units per month, 66 members were getting close to 120 units per month, and 19 members were getting 200+ units per month.

Dr. Weiss pointed out one of the three components of this is Phenobarbital, which has the potential of being addictive.

Mr. Ouellette One of the big things is overutilization, which is obviously going to carry risk of tolerance, dependency or even rebound headache types of issues going on. Looking at some of these diagnosis types, the majority of the diagnosis types on the claims were either regular headache or migraine. Tension headaches were among the few diagnoses identified.

In another state they looked at the information rather than doing intervention. They sent out information letters like we normally do. Some ways to possibly intervene would be to 1) contact the prescribers to inquire about excessive use of butalbital containing analgesics and ask if the patient can be limited to a maximum of 18 units per month (most of these drugs are Preferred on the PDL list), and 2) put dosing limits on to force them to come through a PA model to find out why they are using such high quantities.

Dr. Barkin pointed out you have 85 unique members getting more than 60 doses a month – you could almost draw a line right there.

Mr. Ouellette reported that our utilization compared to other states is higher.

Dr. Barkin felt it would be helpful to break out who is prescribing the ones greater than 120 units.

Dr. Weiss explained there are not that many doctors prescribing this drug because it is extremely old fashioned and ineffective. You are not supposed to use this drug. We need to figure out who is using it and make it go away.

Dr. Barkin felt it would be nice to start with the unique DEA numbers to see who these people are.

Dr. Weiss agreed they could start with that.

ADJOURNMENT: 8PM

The next meeting will be held on **May 14, 2013**, 6:00p.m. to 8:00 p.m.

OTHER DISCUSSION

Mr. Ouellette reported on some drug changes that were taking place. He explained that last month when Delzicol came out they looked at pricing and what they had for availability for other products. They voted on making it Non-Preferred. Since then, drug companies have come to us with an offer to get it on a more favorable position on the PDL. In the meantime, one of our Preferred drugs have dried up on the market and they are going to stop producing Asacol.

He pointed out when they talked last month, Delzicol was running much higher for a script of 180 tablets. They have now come in with a supplemental rebate per prescription which is lower than some of the preferred products on the PDL. The State has not accepted the offer yet, but our recommendation to the State is to accept the offer and make it Preferred on the PDL.

Delzicol is the same product as Asacol - it has identical ingredients. The only difference is that Asacol is a tablet and Delzicol is a capsule. They will send something out once the State has decided they are going to accept the offer.

MOTION by Dr. Weiss to accept Delzicol as Preferred on the PDL. All in favor [10:00]. Motion Passed with votes received by e-mail from missing members.