TO: Maine Drug Utilization Review Board
DATE: 11/08/11
RE: Maine DUR Annual Board meeting minutes from 11/08/11

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<th>ATTENDANCE</th>
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<td>Robert Weiss, M.D., Cardiologist, Chair</td>
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<td>Laurie Roscoe, R.Ph., Vice Chair</td>
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<td>Amy Enos, Pharm. D. Waltz LTC Pharmacy</td>
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<td>Laureen Biczak, D.O., Infectious Disease, GHS</td>
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<td>Lisa Wendler, Pharm. D., Clinical Pharmacy Specialist, Maine Medical CTR</td>
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<td>Lindsey Tweed, M.D., Psychiatrist</td>
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<td>Mark Braun, M.D., FACP, Internist/Geriatrician</td>
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<td>Mike Ouellette, R.Ph., GHS</td>
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<td>Rebecca M. St. Amand, R.Ph., Staff Pharmacist Community Pharmacy - Pittsfield</td>
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<td>Timothy Clifford, M.D., Family Practice, GHS</td>
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<td>Kevin Flanigan, M.D., Medical Director, OMS</td>
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<td>Jennifer Palow, Pharmacy Manager, OMS</td>
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Guests of the board:

CALL TO ORDER: 6PM

PUBLIC COMMENTS

- Michelle Manzo from Alkermes on Vivitrol—no potential for abuse or diversion issues unlike methadone or buprenorphine. Further detail on the effects demonstrated in the clinical studies please see full prescriber information. In summary Vivitrol was evaluated 624 alcohol dependent patients outpatient at a dose of 300mg. It was seen that the patients drank less than before. For the opioid depends 250 detoxified opioid depend the percentage of patient going opioid free was significantly more then those who took the placebo. Most common adverse effects for alcohol dependence included nausea, vomiting, injection site reaction. The most common adverse effect for opioid dependence included injection site reaction and nasal faringits. For full safety information please see the full prescribing information.
Rishit Patel from UCB Cimzia is the only PEGylated anti-TNF (Tumor Necrosis Factor) on the market. Pegulation enhances both viability of the product as well as allowing for reduced dosing frequency. Cimzia was approved April in 2008 for reducing signs and symptoms for Crohn’s disease and maintaining proper response to adult patients with mild to severely active disease. In May of 2009 approved for adult pts with RA. For Crohns, recommended initial adult dose is 400mg at weeks 0, 2weeks and 4weeks for those pts that get an appropriate response the 400 every four weeks. For RA it is similar to the Crohns at 400mg 0/2/4 and either a 200 every other of a 400mg every four weeks. Can be used as a monotherapy or with methotrexate. Supplied as either powder for solution to be prepared and administered by a healthcare professional or in a single use prefilled syringe. The efficacy of Cimzia in Crohn’s was reviewed.

OLD BUSINESS

DUR MINUTES

October minutes were approved with correction of Sharon Treat’s affiliation.

PSYCH WORK GROUP MONTHLY UPDATE

Discussion on the two year limit on Suboxone. It was decided that it was not a topic for the Psych Work group because it was primarily a cost saving intervention. Did an update of the HHS committee report on use of antipsychotics in youths.

NEW BUSINESS

EVIDENCE BASED PRESCRIBING PRACTICES DISCUSSION

Ann Woloson the executive director of Prescription Policy Choices. Would like have the committee use evidence based resources when making recommendation for considering drugs for preferred status for Mainecare. Prescription Policy Choices is nonprofit, nonpartisan organization with the goal of improving access to effective, safe and affordable prescription drug in Maine and the US. They have no industry funding and are primary funded by private foundations and consumer advocacy organizations including the Maine Health Care Access Foundation, Nathan Cummings Foundation, Endowments for Health, Consumer’s Union, and a handful of other smaller foundations.

PPC promotes public policy in an effort to improve access to affordable prescription drugs. PPC works with consumers, providers and payers to promote evidenced-based prescribing. One of the things PPC promotes for prescribers is Non-biased prescriber education/academic detailing to give a balance to the information provided by the drug representatives. Some of the materials PPC promotes for consumers are Consumer Reports Health Best Buy Drugs for patients to be able to see...
what medications are available. We also work with Payers and looking at how they pay for drugs and how they do cost sharing in an effort to promote evidence based drugs. Has been following the Maine DUR process for many years now and feels that overall it is a good process. The Board meets regularly in public meeting, involves reviewing a variety of data and comparative drug reviews in making PDL recommendations which is supplemented by member expertise and ad hoc committees. The Maine DUR works well to maintain access, while balancing costs. Would like to provider more information and resources for the DUR to use.

- The first recommendation is to encourage use of new and exciting independent, evidence-based information resources in PDL recommendation/decision making. Feels that this is important because there has been a huge investment as a result of the ARRA (American Recovery and Reimbursement Act) $1.1 billion for comparative effectiveness research to NIH, AHRQ and DHHS.
- Let’s start with Rapid (Regional Adaptation for Payer Policy Decisions) the reason that feels that it is important is that it gets input for 6 new England states, maine medical directors and Dr. Flanigan can take the needs of the DUR and ask the group to do an analysis. It’s a free resource that the DUR can use since Maine’s medical director Dr. Flanigan is participating
- Next is Patient Centered Outcomes Research Institute (PCORI). PCORI is a newly established federal CER entity to fill research gaps identified by public Pharmacy Directors (PDs) and translate new and exciting CERs to meet the needs of PDs and policy makers. Grants may become available to help states interested in incorporating CER in patient centered outcome research. Grants will be coming out quarterly. Ann states she is willing to help with the grant process.
- AHRQ Effective healthcare Program systematic comparative effectiveness reviews of new and existing research on the effectiveness and comparative risks of different health care interventions. It also provides relevant evidence to inform real-world health care decisions for patients, providers, and policymakers

Dr. Weiss stated that although the information very interesting and useful it does not impact prescribing habits. Over the years we have done several studies and they have been published out of the DUR and it has not changed the prescribing habits of the prescribers. Doctors know the information but aren’t doing it.

- Ms. Woloson stated that is why PPC is attacking the problem from all three sides prescriber, payor and patients.
- Dr. Weiss states that it’s not just the patient that wants the drug that they saw in an ad since for example 30% of patients with heart disease that should be on a statin are not.
- Dr. Braun asked since the guidelines are insufficient in changing behavior what would be a more useful way to change prescribing?
- Dr. Clifford clarifies that with the PDL formulary function we can favor one drug over the other and increase utilization but we can’t make sure that doctor is using the drug correctly.
- Dr. Weiss stated that ultimately using the drug correctly is more important to patient care.

Ms. Woloson suggestion on is to get Maine’s prescribers to participate in academic detailing program. When you look at strong academic programs for example, Pennsylvania does show changes in provider habits, quality of care and cost saving. Think about including participation in academic detailing in perhaps the primary care incentive payment.
Dr Weiss spoke about that in central Maine 80% of providers no longer see detailers of any kind. In southern Maine the percent is even higher. Maine Med doesn’t permit them into the doctors’ offices. Ms. Woloson responded that some education is needed.

Ms. Roscoe explains it is hard for this committee to look at the drug and say is it safe, is it effective, is cost effective. Even if it isn’t cost effective the Board looks to see if the drug is needed to treat disease, to stay healthy, in order to justify it that way. The Board tries to put as much on the formulary as possible. Various needs are carefully balanced, some inexpensive drugs are weaned out since they are ineffective or less effective than other choices. We need to avoid limiting the choices to prescribers too severely. Who are we to take the choices away from the prescribers? It’s tough because we are already so limited by cost.

Ms. Woloson noted that Medicaid puts out a newsletter that might be a way to get out education.

Dr. Weiss responded that we have already done that. Dr. Weiss explains that he went around and talked to people after and although everyone said they read it but when you checked nobody was doing it. We need to find a way to translate guidelines into action.

Ms. Woloson stated that she is aware of the struggle with cost containment issues. The question in her mind is how can you look at evidence based prescribed drugs that worked well for most the population. How can you make use of the resources to contain cost but also keep your benefits? One of the reports that Ms. Woloson provided included an article where researchers did a comparison of six plans in Minnesota. Some of the plans were private some were public. They looked at evidence based when the recommended drugs and they found that if evidence based drugs replaced brand name drugs at 100% and 85 % usage there were savings to be found. That is what sparked my interested in this issue. Is there a way to incentivize providers to use evidence and work with consumers at the same time? My company learned that Avandia remained as a preferred drug after some of the information about the safety problems came out and after talking to Dr. Clifford I have a better understanding of why, mostly because the patients that stayed on it weren’t responding to other medications. I haven’t done an analysis on whether they were responding to the Avandia or if those patients had health problems due to being on the Avandia that ended up costing the state more money. My point if those patients had been switched over to something that had been proven to be just as effective and safer the state Medicaid based on our analysis would have saved over a short period of time $150,000. I know that’s not a lot of money and it a short time period but I wondered why that drug had remained preferred.

Dr. Weiss says that the DUR deals with that every meeting. We have switched patients to different drugs based on evidence or cost and the doctors don’t always like it but we have done it. We have had patients come in and complain to us about switching their medications. I think we do that already and do it well.

Ms. St. Amand - Stated that last meeting the Board was talking about Yaz it was non-formulary last year. The price came down so we made it formulary but there are clinical side effects. It is concerning that we aren’t going to take that choice away from the doctors even though we know there are side effects.

Dr. Weiss doesn’t think that is very common.

Ms. St. Amand responded that if it’s an expensive drug and has side effects we are very good at taking it off the formulary but if it inexpensive and has side effects we may err by keeping it on as a choice to the providers.

Ms. St. Amand commented that Yaz may not be the best example there are many other options in this category.
Dr. Clifford -Drugs are by their nature all dangers to some people, that the risks are all relative. One of the big problems we have is the committee has time constraints. It an advisory committee; four
times a year the meeting are primarily PDL-formulary issues. The other four to five times it is trying to
meet on DUR issues. This is a very limited amount of time. But the biggest problem isn’t that we don’t
have access TO enough good resources clinical or economical. Our problem is to condense the data into
summaries that the committee can use. let’s look at for example, atypicals. They have been 12%
or 14% of the drug budget for the last several years. And now we have three going generic and more
importantly we aren’t going to be constrained by any grants or rebate contracts we will be able to
manage cleanly. In the past the Psych Work Group and the committee have been taking a look at the
metabolic profiles. Jeff is going to be talking more about this later in the evening. So we want to be
doing something more aggressive about trying to force the providers into being more mindful of what
atypicals can do. Dr.Barkin will really get into this later but we are going to be proposing collect raw
data and that brings me to maybe these would be something that we could develop together it very
useful data for Medicaid program.

Ms. Woloson answered that there are other issues for example the atypicals with young children.
There is a risk of diabetes if they are on them for a long period of time six months or longer. The DUR
has already taken great steps to take care of this issue for children under five. Medicaid should look
at these children to see if they are benefiting from these drugs. Maybe some are but if they are not
benefiting they may be developing diabetes.

- Dr. Weiss responded that there are a limited amount of resources to do all the projects. One
  project we started was to try to look at why 70% of people who have Cardiovascular disease
  are not on a statin. That’s a much bigger bang for your health care buck but the question is
  how to generate the time or the money to do it.
- Ms. Woloson says that’s a good perspective for her to have.
- As for the atypicals, Dr. Barkin in the legislator last session instead of have a law on how to
  use atypical has been resolved which has been bounced back to the psych work group which
  now if being writing into something that makes sense and can adoptive and discuss how to
  hard adopt these things.

Dr. Clifford states that we have another example. We have a really brief summary in 2009-2010 we
took a look at the highest risk cardiovascular disease patients. We took a look at them to see what
percent were on statins and getting lipid tested. We looked at it again in 2010 and we wanted to be
more aggressive in this area. Our target group was age 19-64 because we have very few under age
19 and over 64 we lose them to Medicare Part D. We have over 13,000 statin users out of that only
3,400 that were high risk and not using statins. We had sent letters off asking doctors what were the
lipid levels on these patients. We got sort of lukewarm results back. There were some valid reason
on why they might not be on therapy but lots fell through the cracks. Doctors would state that they
were not their patients etc.. things like that. So we still have a huge question mark on why these
patients aren’t on statins.

- Dr. Weiss states this goes back to there isn’t a doctor in the state of Maine that doesn’t know
  the guideline that a patient with heart disease needs to be on a statin. So giving them new
  guidelines in not the bunch line what this says is that 50% of people that should be on a statin
  aren’t even if you are off a little bit. It really embarrassing but it’s not just here it nationwide. In
  North Carolina they did a much bigger study and they got the same numbers.
- Dr. Clifford added the state is moving forward with Medication Therapy Management(MTM)
Mr. Ouellette explained the first phase of MTM is basically education to providers sending them out adherence reports. A lot of providers A: don't know that there patient isn’t taking the statin that they prescribe or B: that the provider isn't following up with the patient. A lot of times when we have done this is the past its has been an eye opener to the provider, It tends to be a blind faith that the patient is doing what they say. You always want to trust the patient but patients don’t want to tell their doctors that they aren’t taking their medication. The second part will include an education piece that will send out education materials to the patient and the providers and pull in lab data incorporated into the new application just built. We can then report back to the committee on changes with the population.

Dr. Weiss thought that it is interesting but don’t goes far enough. He feels that is still going really soft. We are trying to jog the memory of people who already say they know. It’s not enough there has to be some sort of way in real time identifying a patient that has heart disease that sees the doctor isn’t on the medication and you call the doctor. There has to be a real link between this.

Dr. Clifford suggest now let’s try to go from a different direction. What if we started to PA doctors on new starters on statins. If we caught everyone starting on a statin we could assess their cardio risk right off bat and determine if they are high risk or not and then follow up on that.

Ms. St. Amand asked lets say they get an approval for six months. Then make sure that they are tested and they aren’t going to get there statin until we get there labs?

Dr. Clifford answered it could go like that but it would be a little strange to take away the statin.

Dr. Weiss responded what I would do it if you have a diagnosis of diabetes, peripheral vascular disease, or coronary artery disease cross link to see if there was a statin in their medication list and go after them if there isn’t. That way it isn’t penalizing the people that are using it correctly but identifies those that aren’t.

Dr. Clifford states if we do go after them and only used the medical claim data we would weeks and months behind but if we build up a list of proxy medications for the POS to assume the presences. Diabetes would be easy. We could take a lot of the anti platelets agents, antihypertensive. You could build up a pretty good list.

Dr. Weiss states you won’t get a 110 but you would get more then 10

Dr. Braun asked What would be the delay in medical claims?

- Mr Ouellette Stated that medical claims and pharmacy claim are two totally different systems.
- Dr. Clifford added the claim are getting done more timely but it depends on a lot of different things.
- Dr. Weiss responded that he likes claims data better, they are cleaner.
- Mr. Ouellette added state’s pharmacy claims are real time.
- Dr. Weiss states that looking at pharmacy data for diabetics is easy but with other diagnoses it might not be. At least with claims data at least when you get it a month later it’s still what it is.

Dr. Braun suggest what if you went back to 2010 data take a whole year off you still has most of those patients in the system

Dr. Clifford answered let’s say that we can detect the highest risk heart disease patients. From a PA point of view what are we going to do because we can’t threaten them with needing to do a PA to get there statin because the problem is they are on statins

Dr. Weiss asked Does Medicaid has the right to get there records, right?
Dr. Clifford answered yes, Medicaid does have the right to demand records. But that’s different than the PA process.

Ms. St. Amand asked so this is just checking to see if they are on a statin? Not to see they are taking it correctly or if it’s working.

Dr. Weiss responded yes just to see if they are on a statin we are so far away from checking to see it it’s working. The last time we looked 50% of people were on a statin and out of the others only 50% had a lipid panel.

Dr. Braun added one of the troubles I have as a provider is let’s say I had 100 patients in this category and Mainecare called and said show me the data. I says yes because I have a registry I can show you the data there it is. But one, what is the incentive to doing this? It takes a lot of time to do that let’s say that I don’t have a registry to do that and now I have to build all that in and I don’t have any incentive to do it. I think that there is a real crisis as a system to almost try to take it out the hands of the doctor. Like you said Bob we want to do the right thing. We know what to do but the system almost isn’t there to help us do it.

Dr. Weiss stated that you do not need to monitor 100 out of 100 charts. If you look at two charts that would make the provider nervous enough to check the rest. Providers do not like to outliers they do not want to be identified as doing it worse than the next guys.

Ms. St. Amand stated that doctors change behavior by giving them incentives. I have worked for doctors and until we gave them strong incentives they didn’t do it.

Dr. Braun stated one thing that hasn’t ever been tried is to tell the patients that they need to ask their md why they aren’t on a statin. I have had patients come to me before with something whether I have talked to them about it or not. I think it could be very effect.

Discussion on how to best go about this continued between all board members. Dr. Clifford summarized that the consense is that the to focus on the high risk untreated statin patients. Everyone agreed.

Ms. Woloson closed with some cost saving suggestions.
Dr. Barkin stated a brief overview of evidence based medicine that the clinical team at GHS team uses. Also would like to discuss that guidelines for Atypicals and why they are so under used. The monitoring information is available. There are clear guidelines for when patients need to monitored baseline at two weeks, four weeks. We put together a table of the data provided by the prescribing information of each product looking at weight gain. What can we do to monitor it? The weight gain needs to be tracked. Should it be a comparative effort to show your rate of monitoring or should it be a hard PA stating your pt has been on the med we need to see the the glucose or lipid panel.

Dr. Clifford explained all new users would need a PA. In three months with the PA renewal will need to include the the labs in order to get a PA refill.

Ms. St. Amand asked at what level are we talking about? When a new user comes into the pharmacy and I go to fill it will it pay? Then when the 3 months is up it will reject PA required?

Mr. Ouellette answered it will reject PA required

General discussion by all board members on to best implement this process.

Dr. Clifford added if we find out that the baselines are not being sent in or the baselines aren’t done being done timely then lets toughen up the PA by shortening the time that they get the intial PA. I would prefer that the first PA be education and the second would be the baseline labs. It would be first time users or when they switch to a different atypical.

Dr. Tweed felt this can be productive but we need to work out the details.

Mr Ouellette stated that we have been doing a similar program with Chronic Narcotics and the specialist do not send in the monitoring guidelines because they feel like they know there patient better and shouldn’t have to send that information in. So how is that going to change for the statins or atypicals?

Dr. Clifford stated lets go back to you start on the atypical you can go ahead and fill it but at the end on the 30 days we need to to have the baseline labs sent into us or you will not get a refill. This will require us to do weekly reports and then notify the doctors after.

Dr. Weiss stated that on the table is when a member gets a script then within 30days the patient will have to get a lipid panel.

o Dr. Clifford added that the earliest we would plan to start doing this would be April.

Dr. Weiss- All in favor of implementing as close to what we stated above for the atypicals for new starters.

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OPIOID ANALYSIS

Dr. Clifford stated the state is trying to make progress with narcotic abuse and narcotic treatment. We have a group of the Mainecare population that are high users and we are trying to see what happens over time, the natural history, do they ever go away? We are also looking at Suboxone and Medical cost. What are the effects of the state trying to do an initiative where it was trying to encourage non pharmaceutical pain treatments. This will be discussed more over ensuing meetings.
The next DUR meeting will be held January 10th 2011 6:00-8:00pm