



**MaineCare Services**  
 An Office of the  
 Department of Health and Human Services

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TO: Maine Drug Utilization Review Board  
 FROM: Shari Martin  
 DATE: October 15, 2009  
 RE: Maine DUR Board meeting minutes from October 13, 2009

Jeffery Barkin (Chair) called the meeting to order at 1 pm.

<b>ATTENDANCE</b>	<b>PRESENT</b>	<b>ABSENT</b>	<b>EXCUSED</b>
<i>Jeffrey Barkin, MD Psychiatrist, Chair</i>	X		
<i>Lisa Wendler, Pharm. D., Clinical Pharmacy Specialist, Maine Medical CTR, Vice-Chair</i>	X		
<i>William Alto, M.D. Dartmouth Family Practice</i>	X		
<i>Laureen Biczak DO, Infectious Disease, GHS</i>	X		
<i>Mark Braun, M.D., FACP</i>	X		
<i>Timothy Clifford, M.D., Family Practice, GHS</i>	X		
<i>Amy Enos, Pharm. D. Waltz LTC Pharmacy</i>	X		
<i>Jack Forbush, D.O., Family Medicine</i>			X
<i>Steven Gressit, M.D.</i>	X		
<i>Steven Meister MD, Pediatrician</i>	X		
<i>Mike Ouellette, R.Ph. GHS</i>	X		
<i>Laurie Rosco, R.Ph. Martin's Point</i>			X
<i>Robert Weiss MD</i>	X		
<b>Non - Voting</b>			
<i>Jennifer Palow, Pharmacy Manager, OMS</i>	X		
<i>Brenda McCormick, Director OMS</i>	X		
<i>Rod Prior MD, Medical Director OMS</i>	X		

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## Public Comments

The floor was opened to presentations by drug representatives regarding the inclusion of drugs on the Maine Preferred Drug List (PDL). Speakers are listed in order of presentation. Drugs under discussion by the Board for a change in their PDL status are marked with an asterisk and the number of the item in the voting session.

### **Erika Szabó, Lilly - Cymbalta (Anti-depressant) and Zyprexa (Anti-psychotics Atypicals)**

Information regarding Cymbalta's strengths and usage was given and reference made to studies that showed it as being favorable for patients with severe depression. Information regarding the Zyprexa's strengths and usage was given. It was argued that Zyprexa is associated with greater adherence in patients, meaning that patients stay on therapy longer and that total health care costs are therefore reduced.

### **Rocco Sullo, GSK - Avandamet (Diabetic) \*6 and Avandia (Diabetic) \*6**

Information regarding the drugs' strengths and usage was given. It was requested that they both be maintained on the PDL to provide a greater choice of treatment.

### **Paul Amato, GSK - Veramyst (Nasal Steroid) \*12**

Veramyst is approved for children as young as two. High compliance as the device fits into patient's nose, there is no alcohol and a low volume of mist. A study done comparing products showed savings of \$28-\$38 per patient per year. It was therefore argued that it should not be removed from the PDL.

Question from Dr Clifford: The study mentioned compared only brand agents. Why were low cost generics not included?

Mr Amato stated that the data collection method did not allow for comparison with generics.

### **Brian Korenda, GSK - Treximet (Migraine) \*19**

It was argued that Treximet should not be removed from the PDL as it gives a superior pain free response, significantly fewer patients on Treximet required rescue therapy and that 70% of all attacks were treated with one dose. It was also noted that chest discomfort was the only side effect found in a recent study.

### **Kate Worthington, Schering Plough - Peg-Intron (Hepatitis C) \*3**

It was argued that Peg-Intron should not be removed from the PDL for three reasons. Patients who have relapsed or were non-responders are now approved to be treated with Peg-Intron, which would reduce endoscopy and liver transplant expenses. Patients as young as three years old are now approved for treatment. It was noted that competing drugs did not have either of these approvals. Finally, new studies showed that after the first twelve week period the drug can be stepped down to a reduced dose without reduced efficacy for patients who were not able to be stepped down to the lowest dose. This would reduce costs

Question from Dr Meister: Young children are asymptomatic. What then is the benefit of treating them?

Ms. Worthington stated that this would reduce parental fear about their children playing with others.

Dr Meister noted that children's play is not how Hepatitis C is spread.

Ms. Worthington acknowledged the unlikelihood of the disease spreading in this manner and added that it would also prevent liver fibrosis and scarring which she stated had occurred in children as young as

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eight.

**Heather Thomson, Endo - Opana (Narcotic- Long Acting)**

It was stated that unlike Oxytocin, there is no PA waiver for Opana for dying from cancer or hospice patients for. She asked that the committee clarify the wording on the PDL and that Opana be allowed the same PA waiver to provide extra choice.

**Vik Patel, Amylin - Byetta injection (Incretin MMETIC)**

It was requested that the PA requirement for Byetta be removed or that the criteria be loosened. Patients using Byetta showed a slight weight loss and a decreased risk of cardiovascular problems.

Cardiovascular problems are the majority of mortality and cost with diabetes. It was argued that the current MaineCare PA was not consistent with other State's guidelines, other north-eastern states or the FDA's requirements. As only three out of ten patients had glucose control there was a need for agents such as Byetta.

**Judith Kando, Ortho-McNeil Janssen - Invega (Anti-psychotics Atypical)**

Although Invega has a high WAC price of \$2400, the cost over one year is similar to Risperdal which is used more often (Invega's yearly spend per patient of \$8700). Patients switched to Invega oral after expressing dissatisfaction with Risperdal had increased satisfaction with Invega. Invega should therefore remain as an option on the PDL.

**Arlene Price, Ortho-McNeil Janssen - Levequin (Antibiotic)**

Levequin is going off patent June 2011. Levequin requires only a short course, has high compliance and therefore reduces the risk of bacteria developing resistance. Requests that Levequin remain as an option on the PDL.

**Thomas Algozzine, Pfizer - Pregabalin**

Graphs were presented to the board showing that the cost per Rx for Gabapenti was lower than for Lyrica and cymbalta and that use of gabapentin for DPN and PHN treatments was growing in MaineCare. It was requested that restrictions be removed that prevent pregabalin being an approved treatment alternative for fibromyalgia, DPN and PHN on the PDL. It was further requested that the board consider adding failure of duloxetine or milnacipran to the step-edit criteria for use of pregabalin to ensure that failure of the only other approved treatments for FM and DPN are included in the criteria.

**Bruce Grothen, Merck - Emend (Anti-emetogenic) \* 11**

It was argued that Emend should not be removed from the PDL as it had an efficacy 20% higher in achieving complete response (no need for rescue medication and no vomiting) than similar drugs in a recent study.

**Jeff Holsen, Gilead - Ranexa (ranolozine) (Anti-hypertensive/cardiac) and Letairis (ambrisentan) (Pulmonary anti-hypertensive) \*10**

Information regarding the drugs' usage was given. It was argued that because of Ranexa's mechanism of action side effects and co-morbidity is reduced, allowing therapy to be optimized. It was requested that Ranexa be added to the PDL. Reference was made to trials that showed that Letairis improved exercise capacity and delayed clinical worsening. It was requested that Letairis be added to the PDL.

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## Other Business

### **Chronic narcotic use Prior Authorization (PA)/promotion of standard of care update**

Dr Clifford updated the board members on the progress of the chronic narcotic use PA. Patients requiring a PA will be determined by analysis; only patients newly requiring opioids for a ninety day period or more and who don't have an immediate life threatening illness will need a PA. The information required includes

- Chronic use necessity
- Drug history
- History of alcohol/substance abuse
- Copy of the narcotics contract if applicable

Patients would also be monitored using prescription monitoring reports. Certain patients would have additional monitoring in the form of urine drug tests or random pill counts. There would be a thirty day override available to allow a provider to prepare the PA; the goal is re-education, not stopping supplies. Mr. Ouellette pointed out that there was a possibility of patients having already broken existing contracts. Dr Barkin asked if the goal was to see there is a contract or to see if that contract was enforced. Dr Clifford replied that they expected the contract to address contract violations and for the physician to act as per contract. The first five contracts of a provider would be monitored to ensure that this happens. Various members of the board suggested that samples of a narcotic contract and/or a web address where samples could be seen should be given to providers. It was also suggested that the acronym PMP be spelt out in parenthesis after the acronym. GHS stated the form would be modified as suggested and brought to the November meeting.

### **Draft MaineCare Authorization Criteria for the 2009-10 Respiratory Syncytial Virus (RSV) Season**

Dr. Biczak said that there have been five major changes in the Redbook recommendations for RSV prophylaxis, and she recommended that Maine adopt these criteria. Epidemic season begins when more than 10% of tests for RSV are positive for two weeks in a row where more than five samples are tested, and historical data shows that for Maine this tends to start late and finish late. Administration of Synagis should therefore not begin until November 23 so that the effects will last until April. It was moved that the Draft Authorization Criteria presented to the board be accepted. The motion was made, seconded and passed.

**DUR Minutes:** Dr Barkin asked members to review the draft DUR meeting notes for June 9, 2009. A motion was made to accept the minutes as written. The motion was seconded and passed. Those homework items from this agenda that have not been addressed will be followed up in the November meeting. Dr Barkin then asked members to review the draft DUR meeting notes for September 8, 2009. A motion was made to accept the minutes as written. The motion was made, seconded and passed.

### **WIC Medicaid formula coverage update**

Dr Meister has met with Mike and Karen to go over the list of reasons for babies to get specialty formulas. He is now rewriting the med doc for WIC with Karen. They are aiming to get one form for WIC and a single PA to make it as simple as possible for providers to give exempt formulas if needed. Pharmacists will have descriptions of diagnosis for needing specialty formula and there will be reassessment at six months of age. It is anticipated that this will be ready for the end of the month. The

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plan is to pilot the program with a few practices in Augusta, Waterville and Winthrop and open it up to the entire state in January. Before then, there will need to be some education of nurseries in hospitals as 10-12 nurseries in the state do not currently carry the contracted formula. This could cause problems for the babies when they leave the nursery and will need to switch. In addition, MaineCare pays for formula in the nurseries as well. Board members were referred to pp. 26-28 of the current utilization packet to see the large range of formulas.

**Dr Barkin advised attendees that the board would now hold a closed session to discuss financial session from 2:30-3:30 at which time the room would reopen for voting.**

**Financials relating to proposed PDL changes (closed):** The members of the Board were informed of the financial impact of changes to the PDL.

<b>New Business</b>
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**Annual PDL Review and Vote**

Proposed motions are listed below. If relevant, any amendments from the original form given in the Agenda have been made so that the wording voted on is what is listed.

**1. Beta lactams – Augmentin XR non preferred.**

The motion was made, seconded and passed. One board member abstained.

**2. Antiretrovirals – providers with five or more HIV patients and PDL compliance to be exempt from PA requirement for all four of the antiretroviral drugs in the PDL.**

Dr. Biczak noted that antiretroviral therapy is more appropriate from providers who have five or more HIV patients. She would like to make it easier for high volume providers that have PDL compliance by making them exempt from requiring a PA. Providers who had a low volume of HIV patients (less than five) would still require a PA. The motion was made, seconded and passed

**3. Hepatitis C –Peg-Intron non preferred. Existing Peg-Intron patients to be grandfathered.**

The motion was made, seconded and passed..

**4. RSV – update criteria based on AAP guideline**

The motion was made, seconded and passed.

**5. DPP4 inhibitors – Onglyza non preferred**

The motion was made, seconded and passed.

**6. TZDs and related combinations – only Actos 15 preferred, Actos 30, Actos 45, Avandia, Duetact and Nateglinide non-preferred**

Dr Clifford noted that if analysis discovers Avandia users that have already tried Actos they will not require a PA to continue using Avandia. The motion was made, seconded and passed.

**7. Osteoporosis – Fosamax/D non preferred**

Mr Ouellette noted that many Vitamin D products are not rebate eligible, although some are. The motion was made, seconded and passed.

**8. Growth hormones – add Omnitrope to preferred**

The motion was made, seconded and passed.

**9. Zetia – Zetia splitting without PA**

Dr Weiss stated that there was no clinical situation needing 5 mg of Zetia. It is not supposed to be used a single agent and there is no outcome evidence in adding Zetia to a statin. Dr Clifford said that there was a limited study done by DA looking at splitting Zetia that showed no significant difference in the lowering of LDL between 10 and 5 mg dose. Dr Weiss questioned the rigor of this

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study, and said that there was still no outcome study. Statins do have benefit, and Zetia should be used as a last resort. He argued that the PA is protective of the patient and therefore recommended against this change. The motion was made, seconded and did not pass, with board members unanimous.

**10. Pulmonary hypertension/ERA – add Letairis to preferred**

Clinical PA still required. The motion was made, seconded and passed.

**11. Antiemetics – Emend and Granisetron to be non preferred except with PA that confirms patient is on a highly emetogenic regimen**

The motion was made, seconded and passed.

**12. Nasal steroids – Veramyst not to be removed from PDL now but to be revisited in the November meeting.**

Dr. Barkin noted that there had been a large number of letters received in favor of keeping Veramyst as preferred. Dr Clifford added that currently there appeared to be no significant clinical difference between Veramyst and other nasal steroids. An analysis would be set up to look at ancillary use of oral anti-histamines and ocular anti-histamines to see if there is any difference between Veramyst and Fluticazome patients. The information would be available for the November meeting. The vote could be contingent on revisiting the issue in the November meeting after looking at the results. Dr. Meister said that for children 3-6 years old allergic rhinitis can trigger asthma, which is a big public health issue in Maine. Veramyst is much better tolerated for those patients due to the smell and the lower mist volume. He suggested that for that age group there should not be a PA requirement for Veramyst. 3-8 year olds should also be a group investigated in the analysis. Dr Weiss said that those physicians who wrote in should be responded to and asked if there were any additional populations they wanted included in the analysis. The motion was made, seconded and passed.

**13. Inhaled steroids –Pulmicort inhaler non preferred**

The motion was made, seconded and passed

**14. Inflammatory Bowel Disease – Apriso preferred, Acasol 800 mg HD, Pentasa 500 mg and Lialda non preferred.**

Current patients of Lialda will be grandfathered. The motion was made, seconded and passed

**15. Antidepressants – add Lexapro preferred, Venlafaxine ER preferred (replacing all Effexor XR scripts), and Savella preferred for fibromyalgia**

Dr. Clifford gave some background on Lexapro. This had been preferred for several years, with tablet splitting added later. The State made good savings with this. Lexapro was made non-preferred in order to drive up generic SSRIs, but it was found that Lexapro being preferred retarded SNRI growth more than SSRI. Further, there is a significant cost difference between Lexapro and any SNRI even with supplemental rebate. Dr Barkin stated that there was no clinical difference in efficacy between Lexapro and generic SNRIs, which was confirmed by Dr Clifford. Lexapro also has tolerability advantages regarding nausea and sexual function. Tablet splitting will be in place again. There will be no grandfathering as a big part of the State's savings would be based on providers changing their patient's scripts in January. The motion was made, seconded and passed.

**16. Alzheimer's –Exelon non-preferred**

The motion was made, seconded and passed. Three board members abstained.

**i. Discussion of the value of the class**

Dr. Clifford began by saying that typically the advantage of this class is 2-3 points on a 70 point rating scale, showing statistical separation but no clinical benefit. Side effects include nausea on nightmares. They are also very expensive. Dr. Weiss said it was hard to take these drugs away as

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there are no other drugs that could be used and it could make the patient more manageable. Dr. Braun said that he used a fair amount in his practice, although it depended on the patient. It was not usually appropriate for patients in nursing homes, but could be a good outpatient drug. Some patients have a good clinical response and others none at all. There is not good data regarding long term efficacy. He sees a use for using it early on, although it is not clear if it changes anything long term. Dr. Barkin said that while this does help some patients by reducing the deterioration of memory, after six months if there is no effect it should be ceased as there are adverse effects and drug/drug interactions. Dr Braun said that sometimes when you stopped with this class you saw deterioration because the drug was masking something. There should be a re-evaluation within two weeks of stopping so that if the patient does worsen they can be put back on so that reversals are not permanent. Dr Clifford suggested that they should be stopped once anti-psychotic medication began, which Dr Braun agreed with, once it was certain that the reason for the anti-psychotic medication was not a transient one. Dr Clifford noted that there was a weak case for this class of drug at the population level, though there could be a case at the patient level. Dr Barkin said that given the medical and financial burden there perhaps should be a time period to determine if a patient is part of a subgroup that does respond. The data he reviewed showed no acceleration of non-reversible damage. He concluded by saying it was important to come back to this topic.

**17. Narcotics long acting – add Kadian (except 80 mg and 200 mg doses) to preferred.  
Oramorph moved to non preferred.**

*Board noted that there was a misprint on the voting slip; 20 should be 200.*

The motion was made, seconded and passed. Two members abstained from voting on Oramorph

**18. Biologicals – limit Enbrel to only 25 mg vials unless Amgen/Wyeth improved the financials for other Enbrel products (Enbrel 50 mg non preferred)**

The motion was made, seconded and passed. One board member abstained.

**19. Migraine – remove Relpax and Treximet to non-preferred leaving sumatriptan and Maxalt MLT as preferred triptans**

There will be no grandfathering. The motion was made, seconded and passed. One board member abstained.

**20. Anticonvulsants – add Trileptal suspension to preferred**

The motion was made, seconded and passed. One board member abstained.

**21. Topical Antibiotics – Altabax non-preferred status**

The motion was made, seconded and passed. One board member abstained.

**22. Pediculicides – Ulesfia non-preferred**

The motion was made, seconded and passed. One board member abstained.

**23. LHRH Analogs – Firmagon and Trelstar non-preferred**

The motion was made, seconded and passed.

**Adjournment:** A motion was made and seconded that the meeting be adjourned. All were in favor. The meeting was concluded at 4:40 p.m. The next meeting will be held on November 10, 2009. There will be no meeting in December, with the first meeting for 2010 being held January 12.

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