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TO: Maine Drug Utilization Review Board  
 DATE: 5/11/11  
 RE: Maine DUR Board meeting minutes from 5/10/11

ATTENDANCE	PRESENT	ABSENT	EXCUSED
Robert Weiss, M.D., Cardiologist, Chair	X		
Laurie Roscoe, R.Ph., Martin's Point Vice Chair	X		
Amy Enos, Pharm. D. Waltz LTC Pharmacy	X		
John Salvato, M.D., Pediatrician	X		
Laureen Biczak, D.O., Infectious Disease, GHS			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		
Timothy Clifford, M.D., Family Practice, GHS	X		
William Alto, M.D. Family Practice, Dartmouth Family Practice Faculty			X
<b>Non -Voting</b>			
Jennifer Palow, Pharmacy Manager, OMS	X		

Guests of the board: Melissa Loring, Pharmacy Student

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CALL TO ORDER: 6PM

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PUBLIC COMMENTS

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Dr. Nadeau on Byetta: Dr. Nadeau spoke on increased access to GLP-1 agents. He recommended that the Department contract with members on lifestyle modifications if members granted GLP-1 therapy. He stated that insulins caused excessive weight gain.

Arlene Lee, Pharm.D. representing Daiichi Sanko, Inc. on Welchol (colesevelam HCl): Colesevelam HCl, administered alone or in combination with statin, is indicated as an adjunct to diet and exercise to reduce elevated LDL-C in patients with primary hyperlipidemia. Patients in study were followed for over 4 months, results show patients taking metformin and colesevelam average A1C reduction was - *Caring..Responsive..Well-Managed.. We are DHHS.*

1.1 vs. patients who were taking metformin and Placebo reduction was -0.8. Patients taking metformin and colesevelam LDL-C reduction was -21 vs. patients who were taking metformin and Placebo reduction was -5. Side effects are primarily GI related. Colesevelam recognized as a dual therapy in conjunction with metformin for patients who have baseline A1C of 6.5-7.5%. Joslin also supports colesevelam as treatment option for diabetes management. Also recommended to be used in conjunction with either metformin or sulfonylurea. USP has recognized colesevelam as a Dyslipidemic agent and Antidiabetic agent. Formulations available are tablets and oral suspension.

- Dr. Clifford asks when patent is due to expire. Ms. Lee responded that the patent expires in 2017.
- Dr. Weiss points out that this drug is comparable to Januvia, except colesevelam also lowers cholesterol.

Tony Morgado, Endocrinologist representing Novo Nordisk on Victoza: Requesting change in formulary status for Victoza, specifically in Prior Authorization requirements. New ACE guidelines place it further ahead than other guidelines in the past. Has proven efficacy in series of trials, HgbA1C reduction ranges from .8-1.5 depending on the study. In addition, very low rates of hypoglycemia, and no weight gain. The new ACE guidelines explore different combinations as to what agent comes after failure of triple therapy.

- Dr. Braun asks what kind of outcomes data there are not with regards to HgbA1C, for example mortality or morbidity? Mr. Morgado answers that they don't have any yet but there is a large trial (5,000 patients) underway now, looking at cardiovascular outcomes and many other factors.

Paul Stack, representing GSK: Benlysta is the first drug approved for lupus treatment in the last 50 years. Benlysta is an investigational human monoclonal antibody drug, B-lymphocyte stimulator specific inhibitor. Benlysta is indicated for the treatment of adult patients with active autoantibody-positive systemic lupus who are receiving standard therapies. Safety and effectiveness of Benlysta were evaluated in a Phase 2 and two Phase 3 randomized double blind trials in 2,133 patients with lupus. In the Phase 3 studies 1,084 with autoantibody-positive SLE, received Benlysta 1mg/kg or 10mg/kg or placebo. Only 10mg/kg dose is approved by FDA. In both trials significantly more patients achieved a response with Benlysta 10mg than Placebo, rates being 58 and 43 with Benlysta compared to 44 and 34 with placebo. Phase 3 trials showed with African Americans that the response rates with Benlysta were less than with placebo. Phase 2 trial showed black patients using Benlysta did not appear to have a treatment difference. Caution should be used in the African American SLE patient population.

## OLD BUSINESS

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### DUR MINUTES

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April minutes were approved with no corrections.

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### PSYCH WORK GROUP MONTHLY UPDATE

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There was a work group phone call, discussing the bill that went before Legislation, but they have nothing to bring to the Boards attention tonight.

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## STATIN INTERVENTION UPDATE: LETTER RESPONSES

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Mr. Ouellette presented some charts included in the packets, showing responses from letters sent out regarding (high risk) members who have not had any lipid testing in the past year. 74 responses were received, 59 were non-responsive. Of the responses, 42% were being treated to goal, 25% were not being treated to goal, 33% had no testing in the past year. Of the 27 patients who had no testing in the past year, 12 (44%) planned to test, 15 (56%) did not plan to test. Of those who did not plan to test, 5 (33%) was because patient was not compliant with testing, 7 (46%) had no explanation of why they weren't testing, 1 patient was deceased, 1 patient had left the practice, and 1 physician thought it was not his responsibility to test the patient.

- Dr. Braun pointed out that it's important to note 42% were at goal, that's better than 20 years ago when 10% were at goal, so there has been some progress.
- Dr. Weiss talked about developing a tool to help physicians pay attention to whether or not they are treating all patients, and whether or not patients are at goal.
- Dr. Tweed spoke about the need for a care management program on MaineCare's part.
- Dr. Clifford explains a little about how the state is looking for some topics for the Medication Therapy Management Program, where members are identified and possibly intervened directly with vs. intervening at the provider level. This topic might be a good example where we would try to contact members who have not been getting tested, try to encourage them to be tested.
- Ms. Roscoe asked who would be initiating these phone calls to members, GHS Pharmacists would be making these calls. Ms. Roscoe asked if it would be sufficient to send members a letter. Ms. Palow answered that in order for the program to be as effective as possible, they want to see the one to one contact, and would be much better for the member. In addition to phone calls, education mailings will be sent out.
- 3 questions to focus on:
  - Who is the target groups? Dr. Tweed suggested members who are getting meds but not getting testing, and members who are not getting their meds. Dr. Weiss suggested focusing on just members who are not getting their meds because they are at highest risk.
  - What is the intervention going to be? Phone calls will be scheduled quarterly or bi-annually.
  - What are the outcomes? Dr. Weiss recommended that after 4 months re-evaluate and see how many people are still not taking their meds. Dr. Weiss suggested someone write up the plan that was discussed so the DUR may vote on it.

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## ATRIAL FIBRILLATION: FURTHER ANTICOAGULANT DATA

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Dr. Clifford takes a look at the new AFIB diagnosis patients and when they've hit the system month by month from 2006-2010. When patients become officially AFIB by diagnosis, we then took a look at

how they behaved pre-diagnosis, a fair number already have some type of anticoagulant therapy going on. The analysis looked specifically at what number were on Warfarin in therapy both before and after the diagnosis of Atrial Fibrillation. Historically 20-30% were on Warfarin prior to the diagnosis in the medical claims system. Members with new AFIB diags jumped in 9/2010-10/2010, over half of them already on anticoagulants and high Warfarin use. Mr. Ouellette points out that was the point in which MIHMS went live. Dr. Clifford suggests there may have been people being treated for AFIB who are not accurately being picked up in the system as being AFIB due to lack of diagnosis on paid claims, the board discusses multiple other issues that may have led to this spike. Dr. Clifford stated that in the next analysis, Warfarin claims one month before the diagnosis will be eliminated. This problem will be solved but wanted to give the board a detailed view on what the issue is.

## NEW BUSINESS

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### NEW DRUG REVIEWS

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New Drugs: Members reviewed individual drug monographs.

- Axiron- motion to leave non-preferred, all in favor
- Benlysta- motion to leave non-preferred, all in favor. PA criteria will be voted on at a later date.
- Edarbi- motion to leave non-preferred, all in favor
- Makena- motion to leave non-preferred, all in favor
- Safyral- motion to leave non-preferred, all in favor
- Zymaxid- motion to leave non-preferred, all in favor

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### CLOSED SESSION

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Discussion on anticoagulant drugs and diabetic class will be delayed until June meeting when SSDC pricing data is available.

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### ADJOURNMENT: 8PM

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The next meeting is June 14<sup>th</sup> 6:00-8:00 pm.