MaineCare Services
An Office of the Department of Health and Human Services
Paul R. LePage, Governor Mary C. Mayhew, Commissioner

Department of Health and Human Services
MaineCare Services
Pharmacy Unit
11 State House Station
Augusta, Maine 04333-0011
Tel. (207) 287-7131; Fax (207) 287-8601
Toll Free (866) 796-2463; TTY (800) 423-4331

TO: Maine Drug Utilization Review Board
DATE: 4/19/11
RE: Maine DUR Board meeting minutes from 4/12/11

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 Coppi, R.Ph.		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		
Non -Voting			
Jennifer Palow, Pharmacy Manager, OMS	X		

Guests of the board: Jeff Barkin M.D., Ed Bosshart PharmD., Melissa Loring Pharmacy Intern

CALL TO ORDER: 6PM

OLD BUSINESS

DUR MINUTES

March minutes were approved with no corrections.

STATIN INTERVENTION UPDATE

- Mr. Ouellette explained that the statin data was generated from patients with at least a 270 day supply, current therapy and no lipid testing in the past year. Patients were selected who were receiving prescriptions from primary care doctors, excluding those who had the majority of prescriptions with facility/hospital DEA numbers. This analysis found 160 members, involving 65 physicians, to which letters are being sent now. We should receive back from the doctors lipid results if done, and reasons why they weren't done if not. We will keep track of and follow up with any physicians that don't respond to the letters.
    - Dr. Braun wondered why the analysis was only limited to patients with 270 days of therapy instead of 365. Mr. Ouellette explained that when looking back 365 days, the analysis picked up inconsistent prescriber data and it was difficult to identify who was the current prescriber. Some of this inconsistency related to the conversion from the old medical claims system.

DIABETES TREATMENT GUIDELINE EDITS / FOLLOW UP ANALYSIS

- Dr. Clifford presented the board with the sample member drug profiles that were requested at the last meeting, all of which were simultaneously taking insulin and at least one oral agent. The goal was to get a feeling for the appropriateness of different combinations of diabetic drugs seen in practice.
    - Patient 1 was on Lantus, Novolog, and glipizide. Question was raised that the Novolog claim was run as a 10 day supply, yet only filled approximately monthly, and that could potentially indicate that there was titration occurring and that the doctor may eventually discontinue the oral drug. Dr. Clifford explained that days supplies on such medications for which doses may change are often are dosed "as directed" are not always accurate.
    - In addition to the insulin + sulfonylurea, there were patients taking Actos + insulin and metformin + insulin. Dr. Clifford identified one of the more common trends as metformin + long acting insulin.
    - Another example involved metformin + Humulin R for shorter acting prandial coverage.
        - Dr. Weiss observed that the above was an unusual treatment strategy, and was not a preferred option in either of the guidelines discussed at the last meeting. Dr. Clifford stated that in this research he found that this strategy was not uncommon, and may be used for patients who have less of a problem with overnight control but more trouble after eating.
    - Dr. Weiss pointed out that the summary data presented last meeting identified some patients on 3 oral agents plus insulin, but looking at these specific profiles, he noticed that a larger trend involved only 2 oral agents, suggesting that the large pooled data had picked up patients that were at one time on a third oral agent but it was later discontinued.
    - Dr. Weiss commented that most of the combinations in these profiles seemed reasonable, but the data did not answer the question of whether limits should be put in place to steer

prescribers towards the guidelines. For example, when a patient is on 3 oral agents and then starts insulin, how long do we allow the 3 agents before requiring them to cut back to 1 or 2 agents + insulin?

- Dr. Clifford stated that one of the goals discussed last meeting was to identify those patients who were already on 2 products and attempting to add a third, and to redirect them towards insulin instead of the third oral product.
- Question was raised that many of these patient profiles presented included 2 or 3 psychotropic medications. Dr. Clifford stated that it was becoming more common for psychiatrists to co-prescribe metformin with psychotropics.
- Dr. Weiss stated that the main objective of this exercise is to create a system of MaineCare guidelines regarding how long a patient can remain on 3 oral diabetic agents before it is suggested to start insulin.
    - Original idea was to not even allow a third agent, but the two sets of guidelines presented at the last meeting differed on that point, so possible solution is to allow a third agent, but if A1c didn't meet a set goal in a certain amount of time then MaineCare would no longer approve that third oral drug.
    - Dr. Clifford recommended the more lenient cutoff of A1c at 9% initially, with the potential to get more aggressive later on.
- Dr. Weiss asked if Mr. Ouellette would be able to create a system where patients on 3 oral agents would have to submit an A1c, and if it was above 9% then it would be suggested to start insulin and discontinue the third agent. Mr. Ouellette stated that the system could scan profile for certain drugs, and when 3 or more were used then a PA would be required, forcing submission of the A1c.
    - Dr. Clifford raised the point of programming difficulties with the combination oral drugs, and stated that the system could be initiated with just single agents at first, but it may take some time to get it working perfectly with all of the combination drugs.
    - Mr. Ouellette then brought up another potential issue where a patient has an existing PA for a non preferred agent that would override these new edits.

NEW BUSINESS

ACETAMINOPHEN TOXICITY

- Dr. Clifford states that the FDA plans to halt the manufacture of high-dose acetaminophen-containing products. Two the most affected products will be hydrocodone and oxycodone combinations, and he examines the cost effects on MaineCare when these products are no longer available.
- Some comparative pricing:
    - Lower APAP doses (~325mg): 14-15 cents per unit

    - Mid-APAP doses (~500mg): 3-12 cents
    - High APAP doses (650-750mg): 4-50 cents
- So if the higher APAP products such as hydrocodone/APAP 7.5/750 or hydrocodone/APAP 5/500 (costing 3-4 cents per tab) are no longer available, patients will be shifted towards higher priced 325mg strengths, and potentially take twice as many.
- Dr. Weiss questioned if it would be possible to approve oxycodone or hydrocodone alone and then giving APAP separately, however, it was stated that hydrocodone is not available alone and oxycodone alone is even more expensive.
- Dr. Clifford proposes quantity limits on combination hydrocodone and oxycodone products to keep patients under 4g APAP/day. Limit 325mg to 12/day, 500mg to 8/day, and the higher strengths to 5 or 6 per day.
    - Dr. Weiss counters that just because patients are limited based on month supplies, there is no control over whether they take the whole prescription in the first 2 days. Dr. Clifford points to other states that have imposed such limits. He admits there is a lack of data on whether such limits reduce overdoses or liver toxicity, but points to utility of getting physicians used to writing prescriptions that are dosed within guidelines. He goes on to state that the proposed removal of the higher doses is intended to prevent APAP toxicity, and these limits will help prevent people from just using more of the lower strengths to compensate.
- Dr. Weiss asked if it was possible to make patients split the higher dose tabs for a cost savings, but Dr. Clifford said that the higher strengths will soon be discontinued anyway per the FDA.
- Ms. Roscoe noted that regardless of cost savings, such limits make clinical sense and should be in place anyway.
- What to do if patients are on multiple strengths? Dr. Clifford states that it would require a huge program to constantly run in the background to add up all cumulative APAP doses from different products, but that the vast majority of APAP in the Medicaid population comes from hydrocodone and oxycodone combination products, so just these proposed limits alone will have a big impact, and a potential next target could be the butalbital products.
- Dr. Biczak brought up the need for education of prescribers about new dosing limits, especially given the extremely high volume of prescriptions for these products. Update will be included in the next 2 newsletters.
- Ms. Roscoe questioned the ability to do a query to identify patients that are on excessive doses of APAP and alert physicians. Dr. Clifford concurs that this would be a good way to look for APAP risk across various classes of drugs.
- Dr. Salvato commented on the epidemic of overprescribing and utilization of opiates, and suggested that physicians may appreciate these limits of the overuse of such drugs.
- Dr. Alto questioned if APAP may be even better absorbed nasally, and whether 4g may actually be too high of a limit.

- In summary, proposed daily limits as described in the handout will begin on all hydrocodone and oxycodone combination products by the end of the summer, and doctors will be notified in the next two newsletters.
    - Board vote: All in favor

ANTICOAGULATION USER BASELINE MEDICAL COST ANALYSIS – PRADAXA AND WARFARIN

- Dr. Clifford presents data attempting to classify patients by CHADS score and what they are on for anticoagulation therapy in order to conduct a cost analysis. 80% of patients in this Medicaid AFib population had a CHADS of 2 or higher. Fairly consistently across CHADS scores, 40% of people were receiving no anticoagulation. When anticoagulation was used, data was presented within each CHADS score on what the predominant anticoagulant drug was in a one year time frame. Credit was given to either the drug that the patient was most recently on, or when more than one drug was used, to the more potent drug. No trend was seen in that as the CHADS score increased, the patient was no more likely to be anticoagulated. Among those who were anticoagulated, there was generally a trend downward in warfarin use as CHADS increased.
    - Dr. Weiss points to failure of the system to educate doctors to treat according to guidelines, in that as CHADS score increases the patient's risk increases, and anticoagulation should be prescribed based on these scores.
    - Dr. Clifford points to some of the weaknesses of the analysis:
        - No control for comorbidities that could increase as you go up in CHADS, and potential other indications for aspirin.
        - Analysis based on diagnosis of AFib, but there is no way to know if the patient still has the disorder.
        - Does not identify patients who were initially started on warfarin, but then later stopped or became noncompliant. Dr. Clifford suggests looking at newly diagnosed patients and what they are initially prescribed, and then following their trajectory over a few years. Dr. Weiss believes that such an analysis may not be worth doing because the numbers are already so poor that such an analysis won't improve them significantly.
    - Dr. Weiss points out reasons for hesitation to use warfarin: perceived patient risk, intensive monitoring. Wonders if a drug that doesn't require blood tests would make doctors more likely to treat AFib. Interested in the cost-benefit difference between dabigatran and warfarin, and how it could be fit into this data.
    - Some preliminary cost data: 1442 people on warfarin (not restricted to AFib), generated $10.2 million in hospital cost ($600pmpm) and 1.7 million in lab costs ($100pmpm).
        - Dr. Weiss pointed to a recent article in a Cardiology journal that outlined a cost benefit in reduced hospital costs by using Pradaxa compared to warfarin.
    - Dr. Clifford outlines the next steps for this analysis. Plan is to go back several years to see if 2010 is really representative of the baseline. Bidding for supplemental rebates just opened up for the next contract year and are due in April, so at the meeting in May, we will be able to look at what the net cost of Pradaxa will be.

- Average determination time in hours: overall is pretty consistently under 3 hours from start to finish. If more PAs were put in effect, it could result more staff demands. Federal requirement for determination in at least 24 hours, but in practice, people expect it in 3-4 hours.
- Dr. Weiss asks in certain cases where PAs are approved 95% of the time, is it worth the time spent on determination just to eliminate claims for that 5%? At what point is it not cost-effective to even bother with requiring a PA?
    - Dr. Clifford responds that there is a huge deterrent effect by just having a PA in place, because many doctors won't even bother submitting it or trying to prescribe that drug.
    - By comparison, other states that have no PA in place in a particular category are far worse off than states like Maine that have a high approval rate in that particular category.
    - However, there may still be room for elimination of some categories where approval is near 100% and the drug is inexpensive.
- Dr. Clifford points to the PPI class, in which there were 3800 PAs in Q1 2011. However, many PPIs have gone generic recently and have dropped significantly in price. For the fall, Dr. Clifford is considering making the preferred PPIs all generic, and potentially doing away with the PA, because H2RAs are only slightly cheaper at this point.
- Ms. Palow pointed out that despite pushback regarding the volume of PAs required, GHS examines PA volume per prescriber and when a threshold is met that prescriber can become exempt from PAs. Also there will be a new system coming out this summer that will serve as a PDL look up tool for prescribers: what needs PA, what doesn't, what is preferred, etc.
- Dr. Weiss asks why some drug classes that are entirely generic still require PA? (i.e. nitrates, diltiazem)
    - Dr. Clifford responds that in these classes, the brand still exists in addition to generics. Criteria states that if the patient has had a legitimate trial of the generic, and they and the doctor state it doesn't work, then the state must pay for brand. Comments made that insurers often must go to hearing regarding denied brands and often lose if the patient had indeed failed on generic and showed evidence of benefit on the brand. Question posed to Martin's Point representative, who stated that carrier simply does not pay for brand, or is able to tier copays so that more of the cost is passed to the patient.
    - Also, there are lots of drug-drug interaction PAs submitted that will show up in various generic categories.
- When asked about desired PA turnaround time, Dr. Clifford stated a goal of under 3 hours.
    - In the future, as everything becomes electronic it should become even faster.
    - Turnaround time starts when fax comes into PADSS until time of determination/notification fax sent to physician.
    - Dr. Weiss asked if there were any specific medications for which GHS might want to set an even shorter turnaround goal, such as medications that people might need right away, such as anticonvulsants or antipsychotics. Dr. Clifford said that it may not be necessary to set up

specific goals and ways of handling such medications because if something really needs to be fast tracked, the doctor or pharmacy will usually call the help desk and put a rush on it, so these can be handled on a case by case basis and overrides can be given over the phone until all the paperwork can be completed. Further, there is the ability at the pharmacy level to give a 3 or 4 day supply on weekends/afterhours.

PDL CATEGORY COST REPORTS

- Several reports were presented outlining various yearly metrics over the past 10 years, such as average cost per claim, total cost per category, etc.
    - Dr. Weiss noted that in terms of number of claims, SSRIs and narcotics lead the list in terms of sheer numbers, but fortunately the majority are generic.
    - 10 years ago, ACE inhibitors took up 2% of the budget, but now that they are all generic they only take up 0.1% of expenditures, despite still being widely used. Dr. Weiss questions if we will stop pushing people towards ACE inhibitors once all the ARBs are also generic, and Dr. Clifford agreed. Similarly, anticonvulsants and PPIs have fallen significantly in terms of percent of expenditures due to recent generic transitions.
    - Antipsychotics have remained a large percentage of expenditures for the past several years.
    - Narcotics:
        - Dr. Tweed questioned if diversion of narcotics falls within the scope of the board, considering it could be regarded as a "side effect." What are some things we could do to prevent it? Dr. Clifford states that it is definitely something the board could try and address. Some things that could have an effect are which drugs are preferred or nonpreferred, what PA criteria are in place, analyses we could do to look at prescribing patterns. For instance, we could be on the lookout for people getting huge numbers of short acting drugs, or those who are getting large amounts of lower strength drugs when they could just as well be treated with fewer units of a higher strength.
        - Of note, Suboxone is the biggest cost driver in Medicaid.
    - Leukotriene receptor antagonists (Singulair), in looking at paid amount by category by year, currently cost 4.3 million dollars per year (2% of budget), and has been doubling in cost over the past several years, in part because there are no other competing meds in the class. Also it is an overly expensive drug and may be improperly utilized and prescribed.
        - Dr. Weiss mentions that the board has in the past tried to better define who takes and should take Singulair.
        - Mr. Ouellette states that over the same time frame where costs have increased, GHS has loosened up PA criteria for Singulair.

        - Dr. Clifford states that Singulair might be an easier target to find out what is going on because it is essentially just one drug in the class, versus some of the other classes that have multiple drugs within them.
    - Dr. Biczak looked at RSV use as we have gotten more serious about using it according to guidelines. We have fought the cost down significantly over a time where the cost of the drug has increased significantly by only allowing it according to strict guidelines.
    - Stimulants represent another class of growing costs.
        - Dr. Weiss made the point that we may be able to make inroads with pediatricians for controlling costs of stimulants as well as RSV prophylaxis and Singulair. However, rising stimulant use could also represent increasing use among adults, and Mr. Ouellette stated that GHS works with other states that limit the use of stimulants to adolescents less than a certain age.
        - Dr. Clifford states that we might want to expand on some of the stimulant data, pulling out where most of the money is going, looking at total doses, short acting plus long acting, non-stimulants plus stimulants, what combinations are out there, etc. Keep in mind that short acting products are more prone to diversion.
        - In addition to total percentage of budget, the cost per claim of stimulants is also rising.
    - Dr. Weiss asks some questions regarding MaineCare's coverage of nicotine replacement products. He states that anyone who is not on MaineCare can still get NRT through the state for free, so questions if MaineCare could just not cover NRT and have all patients go through the other state program to save MaineCare money.
        - Response is that Medicaid is required to cover such products, and also that the state tobacco program reimburses MaineCare for some of the cost as well.
    - Dr. Weiss asked about rising expenditures for growth hormone. Dr. Clifford states that PA criteria is fairly tough and that prescribing is restricted to certain providers.
    - Dr. Alto wondered what is making up the bulk of the vaginal contraceptive category. Huge jump in 2010 as compared to the previous year. Dr. Clifford and Mr. Ouellette wonder if some other product has been improperly coded in the system as a vaginal contraceptive, and plan to look closer at what products are being counted under the category. (After researching contraceptive category, increase due to Mirena IUD).
    - In looking at the insulin costs, it is important to note that when the dual eligibles were no longer counted in this population as of a few years ago, we lost many of the older diabetics so expenditures on insulin fell. However, the prevalence of diabetes is increasing and the medical community is pushing for earlier treatment, so the costs associated with insulin are creeping back up. Mr. Ouellette also states that in the past few years, manufacturers have come out with various pen devices that cost more than vials, although GHS attempts to control this with PAs. Dr. Clifford states he believes that Levemir vials are miscoded in the system as penfills.
    - Question raised by Dr. Alto on impotence drugs and erectile dysfunction. Dr. Clifford responds that the federal government has told Medicaid not to cover these drugs UNLESS they are used

for non-erectile dysfunction purposes, so for sometime MaineCare was paying for the drugs for those other indications such as pulmonary hypertension until the specifically branded drugs such as Revatio came out and they could be coded under a totally different category.

- Dr. Weiss brings up idea for new Welchol indication.
  - Lowers A1c by 0.6%, which is the same as Januvia.
  - Trying to figure out new algorithm for different diabetes classes. Dr. Weiss suggests that Welchol and Januvia be in the same "step." Welchol has additional value in its LDL-lowering capabilities.
  - Board then needs to look at what the cost effect and rebate potential of that would be. The company that makes Welchol is beginning to market it for diabetes because due to its cost, it is not commonly used for its original cholesterol indication.
- Dr. Clifford summarizes which classes the board would like to look into further: anti-asthmatics, LTRAs, within diabetic class look at Welchol versus DPP4, stimulants, vaginal contraceptives

ADJOURNMENT: 8PM

The next meeting is May 10th 6:00-8:00 pm.