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: March 9th, 2011
RE: Maine DUR Board meeting minutes from March 8th 2011

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			
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., Sara Bell Pharmacy Intern

CALL TO ORDER: 6PM

PUBLIC COMMENTS

- Vic Pattel representing Amylin- Requests the board reconsider Byetta's non-preferred PDL status. Diabetes guidelines have been updated and Byetta is part of the standard of care. First line therapy recommended is metformin along with diet and exercise. Additional therapies depend on the patient's profile. For example, a patient that is overweight or obese, guidelines recommend an agent like Byetta because it does have a low risk of hypoglycemia and does help the patient lose weight. Therefore, Maine's criteria for Byetta is not consistent

with the guidelines. They have also looked into what the total cost of patients who have been on Byetta vs. Insulin, and they found that total cost was lower for patients who were on Byetta by ~$2500.00 over a year.

  - Dr. Weiss asks Mr. Pattel if he has data showing that Byetta should be used before insulin, or if it should be used with insulin. Mr. Pattel responded that right now Byetta is not indicated for use with insulin, it is to be used after failure of an oral agent.

- Rushmi Mathur medical science liaison representing Acorda Therapeutics- Ampyra is the first oral drug in its class approved for improvement of walking in patients with MS. This was demonstrated by an increase in walking speed. Dalfampridine, the generic name, is a broad spectrum potassium channel blocker. At therapeutic doses dalfampridine has been shown to block exposed potassium channels in demyelinated axons. There by reducing potassium leakage and increasing conduction of action potentials. This may result in improved nerve cell function. Efficacy was established in 540 patients, two phase 3 trials were 9 weeks and 14 weeks in duration. The primary end point was walking speed as measured by the timed 25 foot walk, research clinical outcome measure. In both of the phase 3 trials, a significantly greater portion of the patients taking dalfampridine 10mg twice a day had consistent improvement in walking, compared to placebo. Efficacy was shown in the 4 major types of MS. 63% of patients were on disease modifying therapy. The response rate was independent of baseline PDSS scores, and disease duration. Clinical meaningfulness of improved walking speed was assessed using a validated patient self assessment called the MSWS12. The MSWS12 is a twelve item scale that includes standing, climbing stairs, walking distances, walking speed and gate. Responders, regardless of treatment, had statistically significant improvement in their MSWS scores compared to non-responders. Therefore demonstrating clinical meaningfulness with the timed 25 foot walk.

  - Mr. Ouellette asks if it is unreasonable to expect a 20% improvement in the T25. Ms. Mather advises that the T25 is a research tool and not all physicians will use that in their clinical practice in assessing their patients. Mr. Ouellette asks what would be a good measuring guideline, where it's only a supplemental drug and what type of clinical outcomes should be looked at for continuation of therapy or discontinuation of therapy. Ms. Mather states that it depends on each patient and their individual baseline functioning.

  - Dr. Weiss points out that there are only "soft" endpoints for evaluation of efficacy and Ms. Mather agrees.

- Scott Steep representing Avanir- Nuedexta is used to treat Pseudobulbar Affect (PBA), a first in class product recently approved by the FDA. PBA occurs secondary to a variety of different disorders, predominant in the ALS population. This disorder is characterized by involuntary, sudden, and frequent episodes which are uncontrollable by the patient. Symptoms of PBA are hypothesized to be due to brain damage or injury. It was originally classified as emotional lability. Pivotal trial data demonstrated 83% reduction in episodes for patients, and 50% treatment reduction in patients who went through the final process. Over 51% of the patients who went through trials are in complete remission and were symptom free after 12 week period. There is no other treatment available for the 10% of special populations (including but

not limited to ALS, traumatic brain injury, and stroke) who have this disorder. Mechanism of action is a glutamate inhibitor, working on sigma1 and NMDA.

- James Stevenson a Neurologist from Belfast wanted to advocate for the MS drug Ampyra. Notes Ampyra has been used to treat MS for years, as a compounded medication. Stresses the benefit of improved walking speed among MS patients, patients felt better from a psychological and physiological standpoint. States only ~25% of patients will respond to Ampyra. Encourages consistency in improvement over time to be used as an outcome measure. Meaningfulness of this endpoint has been confirmed in trials. Supports appropriate use of this medication with consistency of response as an indicator of effect, suggests assessment at least monthly to ensure improvement over prior baseline is being obtained.

OLD BUSINESS

DUR MINUTES FROM JANUARY

February minutes were approved with corrections.

PSYCH WORK GROUP MONTHLY UPDATE

- Dr. Barkin noted that the PWG spent the last meeting discussing legislation that may be introduced that tightly regulates the prescribing of atypical & all anti-psychotics. The PWG is opposing the bill and has drafted and distributed a letter reflecting this position.

STATIN INTERVENTION UPDATE

- Dr. Clifford advised the board that in order to be able to collect meaningful data and to interact with physicians on a timely basis, incorporating all of the recent medical claims data is necessary to evaluate medical costs.
    - Dr. Weiss questions if the statin letter has been reformatted yet. Mr. Ouellette indicates that it has but the most recent data still needs to be evaluated before moving forward. By next month's meeting the letters will have been sent out and data will be being collected.
    - Dr. Weiss brings up Pradaxa cost data. Dr. Clifford indicates that the focus will be on inpatient hospital costs and outpatient laboratory costs for monitoring. Limitations on initial data analysis were described given the new claims processing system used by the state. Application of data collected will be an ongoing process but "first pass" will be presented at the next meeting.

DIABETES TREATMENT GUIDELINE EDITS / FOLLOW UP ANALYSIS

- The board reviewed a usage report provided in packets that describes how many diabetic drugs members are on over a period of time. Dr. Clifford noted that the analysts ignored whether a patient might have also been on insulin and only reported on the number of different oral therapy that a patient was on. Between January 2010 end of February 2011, 7,600 people who had any type of oral anti-diabetic drug, nearly 2/3 of them only had one oral drug. 28% of them had two. Only one patient had 7 different drugs.
    - Dr. Weiss added that the report shows 6% of the patients were on a 3rd oral drug but the report does not indicate if the usage was simultaneous or sequential.
    - Dr. Clifford added that there were multiple different scenarios on the report.
- Dr. Clifford went on to report that in any given month, the people who are on 2 oral drugs, how many went to 3 in the very next month. 2-4% of patients went from 2 to 3 oral drugs in the course of one month to the next. Analysts are working on a report on patients who are on 2 oral drugs, not on insulin, and who goes to a 3rd oral drug. Interesting to look at the number of patients who are on insulin and still taking significant numbers of oral products.
    - Dr. Weiss pointed out the issue with trying to figure out what to do after someone was on 2 oral agents and the worry of going to a 3rd oral agent instead of going to insulin. Pointed out that its only 2-3% of people total. Dr. Clifford affirmed that it is not a large amount of patients, and this is confirmation that it is safe to move to the next step which is to identify these members retroactively, and send out educational mailing to the physicians notifying them of the information the board is requiring. If the information requested has not been received in 30 days, a PA will be placed on that particular patient in order to get the information.
    - Dr. Weiss advised that from what he has read, if a patient is on 2 oral drugs and A1c is over 9, there is not much point in adding a 3rd oral drug. With an A1c less than 9 a third oral agent may be warranted if the patient is opposed to starting insulin. Dr. Clifford suggests an A1c value of 8.5 is discussed in literature.
    - Dr. Braun asked if the number of drugs on the report includes oral agents plus insulin, which was confirmed. Dr. Braun asked if it might be useful to look at those on insulin and multiple oral drugs to figure out why they are on so many oral drugs. Dr. Clifford said that in addition to focusing on patients moving from 2 to 3 oral agents that he will bring in a few patient profile samples to the next meeting, to see what patterns are most common.
    - Mr. Ouellette mentions that with the new contract for Medication Therapy Management (MTM) additional clinical data will be available through that program. It is similar to a case management program.
    - Dr. Clifford points out that by doing the reports based on monthly data sacrifices those patients having 90 day supplies filled. There is a trade off to narrowing the time span.

NEW DRUGS

The board discussed new drugs below. Dr. Clifford advised all comparators for these drugs are markedly less expensive. The board was given the opportunity to review the abstracts and financial data for each drug.

- Abstral- fentanyl sublingual tabs - Recommended PDL status non preferred
    - Board vote: All in favor
- Amturnide- aliskiren/amlodipine/hctz combo tabs - Recommended PDL status non preferred
    - Board vote: All in favor
- Axiron- testosterone topical - Recommended PDL status non preferred
    - Board vote: All in favor
- Fortesta- testosterone topical - Recommended PDL status non preferred
    - Board vote: All in favor
- Natroba- spinosad topical (pediculicide) - Recommended PDL status non preferred
    - Board vote: All in favor
- Nexiclon- clonidine extended release product - Recommended PDL status non preferred
    - Board vote: All in favor
- Zolpimist- zolpidem oral spray - Recommended PDL status non preferred
    - Board vote: All in favor

NARCOTIC ISSUES

- Dr. Clifford presented data for usage of Suboxone compared to other opioids. He points out Suboxone/Subutex uses up ~ 6% of the State's pharmacy budget, pre-rebate. This is not common among other states. Maine and Vermont are among the top states with high percentage of budget spent on Suboxone.
    - Dr. Weiss questions the reasoning behind this- is it because it's the best treatment or because too many physicians have been licensed to write for this product? He also questions what the value is in this; can the State afford to treat addiction at this

expense? Dr. Clifford talks about the infrastructure in place to deal with substance abuse using Suboxone, in the Northeast, that doesn't exist in other parts of the country.

- Mr. Ouellette informed the board that while attending the ADURS Conference, he noticed a lot of other States there were beginning to look at Suboxone the way Maine has been looking at Suboxone, seeing that it is starting to effect their budget, starting to put max daily quantities in place as Maine has been doing.

- Dr. Biczak points out the possible change in methadone costs as a result of increased Suboxone prescribing. Dr. Wendler adds that data on methadone cost as a percentage of budget would be helpful.

- Dr. Salvato shared a Pediatrics review with the board on the percentage of adolescents who were prescribed controlled substance went from 6% to 11%, and for young adults 8% to 16% mostly for headaches, back pain, a variety of symptoms that don't require narcotic pain relief. JACHO initiative to assure improved treatment of pain has influenced practice.

- Dr. Alto notes new published data that shows out of 400 pregnant women on buprenorphine or methadone, about half of their babies will have neonatal abstinence syndrome (NAS). Babies with buprenorphine will spend 7 days in hospital; babies whose mothers were on methadone will spend about 10 days at least in the hospital. Babies born to moms on oxycodone will spend even longer in the hospital and/or NICU (especially if physician is unaware of mother's usage). Money spent on drug cost is probably being saved when consideration is given to additional hospital cost for more time spent in the NICU.

- Dr. Barkin points out that the number of overdose stats are down considerably. He says that Maine has the highest amount of drug treatment of all states, and that this could be looked at as a success and not failure. This might represent a level of sophistication in the addiction community shifting away from methadone and identifying and treating opiate addicted patients. Recent approval, acceptance in the medical community and more and more physicians are becoming certified to prescribe Suboxone could be factors in the rise of utilization. From a public health perspective this may be considered a positive trend. Prescribing is hopefully being used judiciously with proper monitoring as a rule.

- Dr. Clifford discusses the issue of the rest of the budget. PDL categories year by year 2001 – 2010 claims and cost per claim. Also reports percent of total amount of budget year by year. Note the trends of different categories, which are highest and which should be a focus for cost containment. A new electronic version will be made available to the Board before the next meeting. This data has been contaminated by some Part D wrap claims, thus a new version will show pure Medicaid claims.

- Ms. Palow poses the question if any data has been collected on how many members are being weaned off of the Suboxone and if there will be a downward trend in Suboxone usage.

- Discussion continued regarding Suboxone use among Medicaid and non-Medicaid patients. Also the long term outcomes of children born to mothers addicted to Suboxone and methadone. Dr. Weiss suggests a representative audit of each prescribing physician, possibly 5 patients per physician to see how they are monitored and how many are weaned off. Mr. Ouellette points out that there are programs currently in place, IBM, that monitor these members. Dr. Weiss expresses concern that Suboxone prescribing may be occurring haphazardly.

- Dr. Clifford suggests possibly inviting Dr. Publicker to debate the data surrounding Suboxone Medicaid use. Currently physicians are monitored using PA requirements for identified patients.

- Dr. Alto notes he has a 2/3 retention rate of patients on chronic Suboxone use. Only 2 patients have successfully weaned and abstained from opioid use afterwards. Average dose was 25mg four years ago, so it has reduced over time. Possibly due to max dosage limits applied.

- Dr. Clifford proposes a better plan would be to prevent narcotic addiction rather than try to restrict Suboxone use further. Discussed the Medicaid members who have been prescribed narcotics over one year. Data is categorized by days' supply of narcotic within a year, by age group, and how duals (over age 65 and/or disabled) compare to Medicaid only. Report does not distinguish where the narcotic was prescribed. Discussion of Mercy Hospital attempting to wean all patients off narcotics in their pain program. Dr. Weiss encourages discussion about initiatives to address these high numbers of narcotic use, could Board consider meeting with Dr. Hull at Mercy to get more information about his program. Dr. Wendler agrees that it would be helpful.

- Dr. Salvato suggests limiting the dispensing quantity on prescriptions not written by the patients primary care, should be a limited time assigned to treating pain.

- Dr. Barkin suggests putting a PA in place to restrict opioid prescribing, making those with CA/HIV etc. exempt from the PA process.

- Dr. Biczak points out that the IBM and chronic narcotic programs are fairly new to Medicaid and have not been in place long enough to see good effect. Target is preventing addiction and chronic use not weaning established chronic users off.

- Dr. Alto notes fewer patients seem to be doctor shopping for narcotics and more appear to be buying narcs on the street. Based on data collected from admission interviews. Also notes an increase in street price since the max daily dosage limits have been instituted.

ADJOURNMENT: 8PM

The next meeting is April 12th 6:00-8:00 pm.