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
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TO: Maine Drug Utilization Review Board
DATE: 3/25/13
RE: Maine DUR Board Meeting minutes from 3/12/13

ATTENDANCE	PRESENT	ABSENT	EXCUSED
Robert Weiss, M.D., Cardiologist, Chair	X		
Amy Enos, Pharm. D. Waltz LTC Pharmacy	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	
Steve Gefvert, D.O.		X	
Lourie Paul, NP	X		
Linda Glass, M.D.	X		
Non –Voting			
Jan Yorks-Wright, Pharmacy Supervisor, OMS	X		
Kevin Flanigan, M.D., Internist, Medical Director, OMS			X
Roger Bondeson, Director of Operations, OMS	X		

Guests of the board: Jeffrey S. Barkin MD, DFAPA, Linda Bolland, PharmD

CALL TO ORDER: 6PM

PUBLIC COMMENTS

Carl Possidente from Pfizer- Here to present Eliquis is a factor Xa inhibitor anticoagulant indicated to reduce the risk of stope and systemic embolism in patients with nonvalvular atrial fibrillation. The recommended dose is 5mg orally twice daily. Evidence for the efficacy and safety of ELIQUIS was derived from ARISTOTLE, a multinational, double-blind study in patients with nonvalvular atrial fibrillation (AF) comparing the effects of Eliquis and Warfarin on the risk of stroke and non-central nervous system (CNS) systemic embolism. Eliquis treatment resulted in a significantly lower rate of all-cause death than did treatment with Warfarin. The results for the primary efficacy endpoint were generally consistent across most major subgroups including weight, CHADS, prior Warfarin use, and level of renal

impairment. Eliquis was superior to Warfarin for the primary safety endpoint of major bleeding with a 31% relative risk reduction. Resulted in a significant lower rate of all cause mortality rate with a P value of 0.046 versed Warfarin primarily because of the reduction in cardiovascular death. Looking at cost avoidance analysis Eliquis was estimated to give medical cost avoidance was estimated at $485 verses Warfarin. By reducing the incidences of stroke and lower risk of bleeding then Warfarin. Turn your attention to the box warning. Discontinuing ELIQUIS places patients at an increased risk of thrombotic events. An increased rate of stroke was observed following discontinuation of ELIQUIS in clinical trials in patients with nonvalvular atrial fibrillation. If anticoagulation with Eliquis must be discontinued for a reason other than pathological bleeding, coverage with another anticoagulant should be strongly considered. We would like to request that based off of this information Eliquis be put on the MaineCare PDL.

The next drug Mr. Possidente would like to touch upon briefly is Quillivant XR. It is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). It is the first once daily extended release oral suspension approved for the treatment of ADHD. Quillivant XR does have a boxed warning for abuse and dependence similar to other methylphenidate products because of its high level potential for abuse and dependence. It's important to assess abuse prior to prescribing and monitor signs of abuse while on therapy. We request that based off this information Quillivant XR be added to the MaineCare PDL.

Dr. Weiss asked why we should add Eliquis when we already have two non-Warfarin products on the PDL.

Mr. Possidente answer that the best answer would be even though there are no head to head comparative studies I would refer you to the Aristotle trail that showed superiority in efficacy outcomes, safety and mortality.

Dr. Weiss added that in the three non Warfarin drugs this is the only drug that showed decrease in mortality.

OLD BUSINESS

DUR MINUTES

February minutes were approved.

PSYCH WORK GROUP MONTHY UPDATE

Dr. Barkin stated that the psych work group continued to look at the initiative metabolic monitoring. What we are seeing is monitoring points are coming up. The LD's that are on the agenda were also discussed.

NEW BUSINESS

ADURS CONFERENCE UPDATE

Mr. Ouellette explained that the ADURS conference is an educational conference where representatives for all 50 states meet to discuss successes and challenges of the states of have with their DUR interventions, PDL changes. Also gives the states a chance to see what is working in other states to see if and how they can implement them in their state. Some of the topics that were discussed were increased safety of psychotropic medications in children, potential intervention with the hemophiliac medications because of the high cost associated with those drugs. One thought is to contract with a specialty pharmacy to help lower cost.

Dr. Blank asked how contracting with a specialty pharmacy helps lower cost.

Mr. Ouellette answer that but doing that you can get a different rate for reimbursement, plus many will do monitoring for you so that there is less waste of the drug.

Another big topic was Medicaid fraud and abuse, dealing with refill too soon, dosing issues, medication therapy management. Each of the states presents a brief presentation of what they are doing within their state. Most states discussed opiods, suboxone limits, and high cost drugs and how they are affecting the budget, stimulants in the adult populations, atypical.

LD UPDATES

Dr. Barkin discussed Legislative Document No. 802, in that it states that beginning January 1, 2015, the MaineCare program may not provide coverage for buprenorphine and naloxone combination drugs for an individual for the treatment of addiction to opioids. Also beginning January 1, 2015, the MaineCare program may not provide reimbursement for methadone for the treatment of addiction to opiates as defined in Title 17-A section 1101, subsection 7. After reading document carefully though it excludes suboxone it has no mention of subutex whether that was intentional or not it is unclear.

Dr. Weiss asked if this was passed in the last legislature.

Dr. Barkin answered no this is a current bill in the legislature.

Dr. Weiss stated that there are always thousands of bills that are written very few of them get to committees and even less get to the floor why are we looking at these.

Dr. Barkin agreed but felt that it was good to be aware of what updates are out there because this committee does not have input to legislative initiatives.

Dr. Braun asked if we have an obligation or option to respond to these.

Mr. Ouellette stated that to make a recommendation as a board it would need to come under the direction OMS as to whether or not we should chime in.

Dr. Tweed suggested that since the DUR is an advisory board to OMS, the board could recommend that OMS take a certain position on these different LD's.

Mr. Ouellette stated is why we are bringing these pharmacy related bills to the board so that the DUR is aware of what OMS is looking at in regards to some of the bills they are facing.

Dr. Weiss added that he agreed with what Dr. Braun was saying that we need to do more than just listen to the information.

Dr. Braun stated that since we are an advisory board and if we have some thoughts in regards to these bills that are relevant OMS would be interested in hearing them.

Dr. Barkin responded that Ms. Yorks-Wright and Mr. Bondeson from OMS are here and are hearing your thoughts and perspective.

Dr. Weiss stated that if the state stops paying for Methadone treatment as recommend in LD No.802 the affect would be people going back on heroin. Dr. Weiss feels that it is something that the committee should say something about it may never come up but the idea of not covering Methadone is pretty bizarre.

Dr. Braun added that it truly depends what OMS wants to do about this.

Dr. Tweed adds that more he thinks about it the DUR board advises OMS, they then take a position and forwards that on to the governor's office and they make the finally call.

Dr. Barkin as the president of the states psychiatric board and practicing psychologist thinks that it would be very dangerous to stop covering products that are for opioid addictions. In terms of a public health it would require a large number of detox beds and armed guards at pharmacies.

Dr. Braun made a motion to formally recommend that LD No. 802 not be passed.

Dr. Weiss asked if anyone would like to add to that.

Dr. Tweed stated that he objects clinically and economically it is bad for patients care, will cause high costs, increase abuse of Subutex and will lead to increase crime.

All in favor- passed

Dr. Barkin presented LD No. 338, in this bill it states that the department of Health and Human Services shall amend its rules pertaining to the use of atypical antipsychotic medication by a child under 17years of age enrolled in MaineCare to require that the prescriber of atypical antipsychotic medication beyond the recommended period provide documented justification as to why the child should continue taking the medication and to require that the prescriber perform a timely assessment and ongoing monitoring of metabolic and neurologic variables of the child in accordance with the American Academy of Child and Adolescent Psychiatry's Practice Parameter for Use of Atypical Antipsychotic Medications in

Children and Adolescents. With this bill and the next one that we are going to discuss we as a board have already looked at these concerns. The psych work group has discussed this one, it's a good idea to monitor antipsychotic for children under 17 two, its gets a little dicey because they are legislating practice guidelines. As a practical matter if I am treating a patient and using evidence based guideline that's different then the AACAP's and there is a negative outcome and get sued. Am I in trouble that I didn't adhere to a legislative guideline? As it turns out treatment guidelines don't define the standard of care in medical malpractice. MaineCare has already addressed these concerns with a PA in place for all children under five and already require metabolic monitoring. The concern is the legislation of specific guidelines.

Dr. Weiss agrees that guidelines are suggested plans of care and shouldn't be used as mandates and motions that we vote.

All in favor- passed

Dr. Barkin presented LD No. 716; this bill is very similar, this bills guidelines from the American Academy of Pediatrics for stimulants that need to be followed. The second part is prescribing Stimulants and benzodiazepines in conjunction.

Dr. Weiss stated that the actual issue regardless of the topic is that you shouldn't be allowed to legislate guidelines from anyone onto anyone because that is not how doctors practice medicine.

Dr. Weiss motions the committee feels that regardless of if these are good idea or bad ideas that the legislature shouldn't legislate guidelines as laws. They are meant to be suggested patterns of behavior.

All in favor- passed

STATIN UPDATE

Mr. Ouellette stated that the last time that the DUR talked about the statin letters that were sent out was in September 2012. Provided in the DUR packets are two handouts the multi page document was the results from our survey letter.

Dr. Weiss added that only about a 3rd of the patients that were defined as high risk were on a statin. Over a thousand letters were sent out and only 421 were returned.

Mr. Ouellette stated that it was continued to be broken down by questions on the letter. For example, Do you agree patient is at high risk? 46% answered yes, 37% gave no answer and 17% said no.

Dr. Weiss added to summarize this most of the patients were at high risk and most of the people were not taking statins.

Dr. Tweed asked what the definition of high risk was.

Dr. Weiss answered patients with diabetes, heart disease, and stroke.

Mr. Ouellette stated that the one page document is an update of those members.

Dr. Weiss added that he through research that he has reviewed over 2,500 patient charts and less than 50% were at goal.

Dr. Braun asked if anyone at the ADURS conference talked about statins.

Mr. Ouellette answered no that everyone was talking about opioids, atypicals and suboxone.

Mr. Braun added that the data that we have is unclear because we have a lot with no answers giving and what we do have is not very reassuring.

Dr. Weiss stated that now that we have data. And the data is as good as it's going to be. Now we need a plan for what we are going to do with this data to correct the doctor behavior.

Dr. Braun stated that it comes down to a systems problem the cardiologist says it's the PCP then it's the patients, pharmacies and so on. Within his own practice he would love to see good data that he could act on.

Dr. Weiss stated that we could pick 10 physicians that have high utilization and low outcomes and do chart reviews.

Dr. Barkin responded that a chart review may not be necessary. We could take a look at who is prescribing and do a look back to see who is doing lipid testing take the top 10% of physician that are prescribing statins but aren't performing lipid testing and send them a letter.

Dr. Weiss disagreed because we have already sent letters and that did nothing.

Mr. Ouellette stated that what we can do for the next meeting is identify providers through pharmacy and medical claims that we would identify ones that would be high prescribers.

BENZO-STIMULANTS LETTER

Dr. Tweed stated that this is a revised letter after bring it in front of the board last meeting. Dr. Braun had asked that we add some material on how to avoid diversion. We were unable to find any real documentation.

Dr. Weiss stated that the letter captures everything that was discussed at the last meeting and that it will be interesting to see if it gets the attention on the prescribers.

Mr. Ouellette stated that the next step is to send this letter out to the top 10% of prescribers that we have identified through our analysis and send this out.

All in favor of sending this letter out- passed

DRAFT LETTER FOR ANTIBIOTIC USE

Mr. Ouellette presented a draft letter for review and discussion to be sent out to high antibiotic prescribers.

Dr. Weiss stated that this is a good first educational letter

Dr. Glass stated that sinusitis needs to be removed from the letter.

Dr. Braun stated that the beginning of the letter needs to really hook prescribers and that you have to read half way done the letter before knowing what the point of the letter is. He stated that the last paragraph may be better suited to be the opening one.

Dr. Weiss agreed with Dr. Braun in suggesting that the last paragraph be moved to the first and instead of saying "The MaineCare Drug Utilization Review (DUR) Committee, in conjunction with MaineCare… that we should remove "in conjunction with MaineCare."

Dr. Weiss stated that if the letter is going to be sent to prescribers in certain counties then it could say something to the effect of "This committee has found doctors in Aroostook County use more antibiotic then those in other counties.

Mr. Ouellette agreed that the letter could say that based off of the analysis we saw different variations between counties.

Mr. Ouellette stated that he would make chances to the letter and email it out to the board members.

NEW DRUG REVIEWS

Delzicol common name mesalamine, delayed-release in the PDL category GI- Inflammatory Bowel Agents the recommendation is for it is to be Non-Preferred.

Mr. Ouellette added that is a capsules, delayed release: 400mg. The recommend dose is 800mg (two-400mg capsules) TID for 6weeks. Two Delzicol 400mg capsules have not been proven to be bioequivalent to one Asacol HD 800mg tablet.

All in favor- passed

Pertzye common name pancrelipase, delayed- release in the PDL category GI- Digestive Enzymes the recommendation for it is to be Non-Preferred.

Mr. Ouellette added that this drug is used for the treatment of exocrine pancreatic insfficiency due to cystic fibrosis or other conditions. It is not interchangeable with other pacrelipase products.

All in favor- passed

Giazo common name balsalazide disodium in the PDL category GI- Inflammatory Bowel Agents the recommendation for it is to be Non-Preferred.

Mr. Ouellette added that the drug is only indicated for the of ulceraltive colitis in male patients 18 years of age and older. The effectiveness of treatment of female patients has not been demonstrated in clinical trials. Also, the safety and effectiveness of use beyond 8 weeks have not been established.

All in favor- passed

Quillivant XR common name methylphenidate extended-release suspension in the PDL category Stimulant- methylphenidate-Long Acting the recommendation for it is to be Non-Preferred.

Mr. Ouellette added that the safety and efficacy of use in children under the age of 6 has not been established.

All in favor- passed

Juxtapid common name lomitapid in the PDL category Lipid Drugs the recommendation for it is to be Non-Preferred.

Mr. Ouellette added Juxtapid is indicated to be used for those with homozygous familial hypercholesterolemia (HoFH). The safety and efficacy has not been established in those with hypercholesterole who do not have HoFH. The recommended starting dose is 5mg once daily titration should be done gradually based on safety/tolerability. It is recommended to be on 5mg dose for at least 2 weeds prior to titrating to 10mg after that, there should be at least 4 weeks elapsed prior to any additional dose increases with a maximum of 60mg daily.

All in favor- passed

Eliquis common name apixaban in the PDL category Anticoagulants the recommendation for it is to be Non-Preferred.

Mr. Ouellette added Eliquis is indicated for patients with non-valvular atrial fibrillation also the safety and efficacy of use in children under the age of 18 have not been established. It is a film-coated tablet.

All in favor- passed

Oxtellar XR common name oxcabazepine extended-release in the PDL category Anticonvulsants the recommendation for it is to be Non-Preferred.

Mr. Ouellette added Oxtellar is indicated for the adjunctive therapy of partial seizures in adults and children 6-17 years of age. It's an extended-release tablet the recommended initial dose for adults is 600mg per day. Subsequent titration are recommended on a weekly basis for achieve the recommended dose of 1,200-2,400 once daily.

All in favor- passed

Forfivo XL common name bupropion HCL extended-release in the PDL category Antidepressants, Selected SSRIs the recommendation for it is to be Non-Preferred.

Mr. Ouellette added it is an extrended-release tablet comes in a strength of 450mg

All in favor- passed

Vascepa common name icosapent ethyl in the PDL category Lipid Drugs the recommendation for it is to be Non-Preferred.

Mr. Ouellette added it's a soft-gelatin capsule: 1gm and the recommended dose of 4mgs per day, given as 2 capsules twice daily with food in combination with appropriate nutritional intake and physical activity.

All in favor- passed

Kazano common name alogliptin and metformin in the PDL category Diabetic-DPP-4 Enzyme Inhibitor Combo the recommendation for it is to be Non-Preferred.

All in favor- passed

Nesina common name alogliptin in the PDL category Incretin Mimetics the recommendation for it is to be Non-Preferred.

All in favor- passed

Oseni common name alogliptin and pioglitazone in the PDL category Diabetic-DPP-4 Enzyme Inhibitor Combo the recommendation for it is to be Non-Preferred.

All in favor- passed

Ilevro common name nepafenac in the PDL category OP-NSAIDs the recommendation for it is to be Non-Preferred.

All in favor- passed

ADJOURNMENT: 8PM

The next meeting will be held on April 9, 2013 between 6 to 8 p.m.