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: 02/15/13
RE: Maine DUR Board Meeting minutes from 2/12/13

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

Guests of the board: Carla Quinlivan, Goold Health Systems

CALL TO ORDER: 6PM

PUBLIC COMMENTS

John Holtz from Pfizer- Here to present information on Xeljanz. Xeljanz, an inhibitor of Janus kinases (JAKs), is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs).Xeljanz has an extensive safety data base, we have shown that our safety signals are similar to other agents in this area. The area in which we stand out in is herpes zoster infections we have some extra information on that if you are interested. Xeljanz is a small molucle has a half –life of about 3.5 hours. Coverage of the inhibitor concentration 50% of the JAK enzymes are interested for about 12 hours each day with that coverage we are able to show efficacy in methotrexate

inadequate responders. Xeljanz also has a study in inadequate responders of the agents that MaineCare currently has on formulary and we have shown significant efficacy and similar safety in that patient population as well.

Dr. Weiss asked what drugs do you think are your competitors and can you show that you are better than any of those because we can show that you are more expensive.

Mr. Holtz answered that are competitors are the ANTIF- agents. We have on phase three trail that has an active comparative Humira. It was not powered to compare Xeljanz to Humira but rather Xeljanz to placebo and Humira to placebo. In that study Humira preformed pretty much what it has done historically maybe a little worse. Xeljanz showed it had efficacy similar to Humira.

Dr. Weiss asked if your drug is five times more expensive than your competitor why would pick your drug.

Mr. Holtz answered that is you look at the injectables verse the oral agents that you have on formulary right now there are issues with patients going on and off the injectables. Xenjanz has 3years of published data that shows efficacy even if the patient needs to stop for a short time then go back on it.

Dr. Braun asked if the drug was small.

Mr. Holtz answered yes.

Kylie Paulson from Bristol Meyer Squid- Here to present information on Orencia for Rheumatoid Arthritis. Both the intravenous and subcutaneous are indicated for moderately to severely active RA in adults. Orencia IV is also indicated for moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 6 years of age and older. ORENCIA may be used as monotherapy or concomitantly with methotrexate. Orencia is a first line biologic you do not need to fail other biologics or anti-TNF agents prior to its use. Orencia has a unique mechanism of action; it's different than any other RA biologic on the market. It's a selective T-cell co-stimulation modular and leads to inhibition of pro inflammatory cytokines that are detrimental to RA. These include TNF and MMP and CRP. It's the only current biologic that comes in two formulations both intravenous and subcutaneous. This allows the prescriber and patient to choose what the best treatment option is for the patient based on their lifestyles. It also may address compliance issues. With Orencia there is no dose escalation the subcutaneous is a fixed dose 125mgs per week the IV is weight based dose of approximately 10mg per 1kg. The efficacy has been studies extensively in trails with over 1400 patients. Looking at the safety and tolerability of Orencia it's remained unchanged in the full prescribing information over time. There is no black box warning. When you look at real world health outcomes data it has shown that when Orencia is used as the first or second biologic used retain really high retention rates.

Dr. Wiess asked if it is better than any other drug.

Ms. Paulson answered that they have done two trails with active comparator arms one was not a true head to head. We have done a head to head study Orencia verse Humira in which case the efficacy was comparable. Both were on a background of methotrexate the only statically powered end point was we saw was injection site reactions. Humira had statically more reaction than in the Orencia arm. There was also a difference in safety not in terms of numbers but in serious infections. Seven patient experienced

serious infections in the Orencia arm with no discontinue rate verses nine in the Humira arm and five of the nine had to discontinue.

Dr. Braun asked if your drug is five times more expensive than your competitor why would pick your drug.

Ms. Paulson answered the number one answer would be looking at real world data and you look at health outcomes data switching of RA patients is most expensive cost. When looking at claims data Orencia has the lowest switch rate compared to all the other biologics.

Tom Algozzine from Novartis- Here to discuss Gilenya. We have a 12 month clinical head to head study against Avonex demonstrated a 52% relative risk reduction in annualized relapse rate. This is the only oral agent that head to head data again an interferon that shows a statistical difference in annual relapse rate. Taking the data further then is the study they switched people from Avonex to Gilenya while there was a benefit of switching people to Gilenya they did not catch up to those that had been on it from the start. This raised the questions how cost effective is it to go on Gilenya earlier rather than later. Using Maine WAC cost the delayed treatment cost $21,000 dollars more. The utilization of most of the compounds that treats MS patients in MaineCare are pretty flat Gilenya included in that. With that for MaineCare patients and providers to offer equal access to the only oral agent that demonstrated decreased relapse rates. Think about how it might affect overall cost not just the pharmacy cost.

Dr. Braun asked what the side effects were.

Mr. Algozzine answered Slow heart rate (bradycardia or bradyarrhythmia) when you start taking Gilenya. Gilenya can cause your heart rate to slow down, especially after you take your first dose. You will have a test to check the electrical activity of your heart (ECG) before you take your first dose of Gilenya. You should stay in a medical facility for at least 6 hours after you take your first dose of Gilenya. After you take your first dose of Gilenya your pulse and blood pressure should be checked every hour and you should be watched by a healthcare professional to see if you have any serious side effects. If your heart rate slows down too much, you may have symptoms such as: dizziness, tiredness, feeling like you heart is beating slowly or skipping beats

Dr. Weiss added that what they do in the Lewiston area is when a neurologist wants to put a patient on this med they come into his office and they administer the medication. The patient spends the day in the waiting room so that they can be monitor. It's done this way because it's not worth the cost of going to an infusion center.

Arlene Price from Janssen- Here to discuss Xarelto. In November we received approval for deep vein thrombosis (DVT), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE. Our data from the Einstein trials demonstrated the effectiveness of Xarelto compared to enoxaparin followed by warfarin. Also in data presented in the Ash meeting we also demonstrated cost effectiveness compared to enoxaparin followed by warfarin resulting in a three day less hospitalization stay. When we look at Maine data going back to an analysis that the DUR did it was found that 80% of patients with the diagnosis of atrial fibrillation had CHAD score of greater than 2 or more and of those patients only 40% were on some kind of anticoagulant. I know that there had been discussion on whether or not a simpler regiment without monitoring would give a better result of patients going on an anticoagulant that are at risk of stroke. As far as the cost effectiveness there is less hemorrhagic stroke seen with Xarelto compared to Warfarin also in terms of adherence because Xarelto is a once daily dose.

Dr. Braun asked if there was any data in geriatric patients.

Ms. Price answered yes in each of the major trails there has been a geriatric group. One of the advantages of Xarelto compared to Pradaxa in the elderly populations is that we have a shorter half life so you don't see the same kind of accumulation. This results in a lower incidents rate of bleeds in the elderly populations.

Dr. Weiss stated that there are no head to head studies proving that as a fact. Also it's difficult to say that the half life is shorter because Xarelto is a once a day dosing but it doesn't make sense because drugs with a longer shelf life are at twice a day dosing.

Ms. Price answered that Xarelto is a once a day dosing based of the studies that were done Xarelto was able to maintain a peek that was able to give the efficacy.

OLD BUSINESS

DUR MINUTES

January minutes were approved.

PSYCH WORK GROUP MONTHY UPDATE

Dr. Tweed discussed and provided a drafted regarding the co-prescribing of Benzodiazepines and Stimulants. The Psych Work Group recommends sending this letter out to the top 10% of prescribers.

Dr. Weiss asked how many cases of co-prescribing were there. Because it wasn't a small number, that's what started this. Is this something that we need to vote on?

Dr. Tweed answered yes.

Mr. Ouellette asked if the Psych work group felt that the letter was to strong in singling out prescribers.

Dr. Tweed answered no but there was discussion that a chart review should be mentioned in the letter. After discussion that was taken off the table. This is just a letter stating where the provider falls. Dr. Flanigan was involved in the Psych work group meeting and it was his feeling that if it is something that the DUR votes to do that it would need to be presented to Mainecare for approval before moving forward.

Mr. Ouellette asked after looking at the data we noticed that most of the providers are nurse practitioners. Is there something else going on where we need to provide education.

Dr. Tweed agreed that it is something worth looking into. He can discuss it with the NP that is on the Psych Work group

Dr. Braun stated that the first line of the third paragraph should be moved to the beginning of the letter because it grabs the provider's attention. Also we should provide something more useful to the practitioners then we recommend that you review your cases. I don't feel that is good enough.

Dr. Weiss agreed that the third paragraph should be the first. If you show that a prescriber is an outlier then they are more likely to work toward getting more inline.

Dr. Braun suggests that we put specific in the letter as to what they need to do.

Dr. Weiss stated that the letter needs to stay at one page.

Dr. Braun added that he will bring home the letter and rework it and bring it back.

Dr. Tweed stated that one thought is the prescriber gets the letter and sees that they are in the top 10% percent and that causes self reflection on their prescribing habits. Another hypothesis is that it would be helpful to include treatment guidelines.

Dr. Weiss added that the first part of the letter is about diversion and that's not really what the letter is about. The real problem is the inappropriate uses of both drugs at the same time.

Dr. Tweed responded that is where it gets messy because there are no problematic interactions between benzos and stimulants. There are people that do need to be on both. However, this was selected because of the people that are abusing and diverting its seen that these classes of medications clustered together.

Dr. Braun and Dr. Weiss both agreed that above statement from Dr. Tweed should be added into the letter.

Dr. Tweed stated that he will rework the letter and email it to the board members. Once approved by the DUR then it will be given to OMS for approval.

Mr. Ouellette added that after this letter is send out we should go back and look at these providers to see the impact. Where there is a high number of NP's on the list should we send out a communication to the Nurse Practitioner Association.

Dr. Tweed answered that first if we can look at the NP's and see if they are all working within the same office that might explain it. If they are not there is a NP on the Psych Work group and he could bring the information to her to see what she thinks.

Dr. Weiss added that it will be interested to see if the NP's are in areas where there aren't Psychiatrist and then might benefit from education.

NEW BUSINESS

DUR ORGANIZATIONAL DISCUSSION

Mr. Ouellette explained that Jennifer Palow is no longer working for the state. Jan Yorks-Wright was in attendance last meeting as well as tonights. They are in the process of redefining roles at OMS as they just hired Roger Bondeson. At this point we are unsure who will be attending the DUR meeting as a representative of OMS in the future.

DRUG CRITERIA FOR JANUARY DRUG APPROVALS

Mr. Ouellette stated that all the drugs that were voted on during January's DUR meeting were voted non-preferred. For tonight's meeting the board needs to review and vote on the PA criteria for those drugs.

Dr. Weiss asked about Xeljanz for RA is it set up so that it can be used after Methotrexate with no need to do another drug in between.

Mr. Ouellette answered that is correct but some RA drugs are required to go thru both Methotreaxte drugs and Humira.

Dr. Weiss added that the DUR should look into this class of medication because Orencia presented information that in a head to head study they had a better outcome then Humira.

Dr. Braun made a motion to accept all PA criteria.

All in favor

ATYPICAL MONITORING UPDATE

Mr. Ouellette stated that for those of you that are new to the board about a year ago we send out letters to prescribers requesting them to summit metabolic monitoring on their patients that are on atypicals. One of the charts provided is a summary of the responses, in the first 6months the response rate are very low 2% to 19%. For the ones that we had no responses after 20weeks a block was put into place requiring a PA. At that time you can start to see the increase in response rate from 30% to 38%.

Dr. Braun asked what is the likely hood that the numbers will increase is.

Mr. Ouellette answered that based off of previous analysis that have been done it usually doesn't get much higher than 45%. The response that are coming back vary anywhere from just a weight to all the information.

Dr. Weiss stated that there needs to be a plan B because currently we aren't going to get even close to 50% response rate. There needs to be something more. Although not sure what that is yet.

Mr. Ouellette added that the pharmacies do work as an advocate for us to get the information in from the prescriber. The other charts are responses by county the first one based off the county that the patient lives and the second chart is based off county by provider.

Dr. Weiss stated that he thinks that unless we get all the appropriate monitoring we should continue to block the drug for the patient.

Dr. Tweed responded that one problem with doing that is some of the patients have schizophrenia and denying a medication at the pharmacy could then in fact cause a volatile reaction from the patient that would be more harmful then the metabolic issues.

Dr. Glass added that as far as the pediatric side of this issue atypicals are prescribed when I child is on the Autistic spectrum. Getting blood from these patients are extremely difficult and taking the patients off the medications will also creates an extremely volatile situation. While we need to enforce the monitoring we also need to be cognate of the issues.

Dr. Tweed added that we could put those issues on the PA.

COUNTY DATA ANALYSIS

Mr. Ouellette discussed the charts provided to the DUR board. The first one is looking at Aroostook, Cumberland and Oxford counties and looking at different diagnosis and seeing if they received an antibiotic, bronchodilator or steroid. This is a more in depth look then what was done last month because we wanted to see if the scripts were given with 14days of the diagnosis.

Dr. Weiss asked do you think that there is correlation to age of the providers. That the older prescribers use more antibiotics than the younger prescribers, looking at the top ten prescribers they are older.

Ms. Paul added that in Aroostook county most of the providers are nurse practitioners.

Dr. Weiss stated that we can see that there are differences but what can we do about it. Is it educational or should we do something else.

Mr. Ouellette stated that he did randomly pick a provider and looked at the provider's patients. Most of them were children and looking some of the patient you could tell were asthmatic while others just had an antibiotic.

Dr. Weiss suggested that maybe we do something similar to benzos-stimulant letter. Write a letter regarding the high use of antibiotics and send it to the top 10% of prescribers.

Mr. Ouellette added that he wasn't sure that it would be as effective.

Dr. Braun stated that it might as effective as we are going to get. At this point patients are trained to call and ask for antibiotic.

Dr. Weiss asked who is going to draft the letter.

Mr. Ouellette asked do we use the recent CDC letter as a template.

Dr. Weiss answered that we could but we need to make sure that we add a line stating that they are receiving the letter because they are at the top ten percent of prescribers.

Mr. Ouellette agreed to draft a letter and bring it to the next meeting.

QUARTERLY PA REPORTS

Dr. Weiss stated that in the last quarter 27,000 PA's were processed. Approximately 10% of them are denied.

Mr. Ouellette added that one of the reports shows number PAs by drug, last quarter Omeprazole was at the top. You might wonder why Omeprazole is so high but it's because we have a 60 day limit on all PPI's.

Dr. Weiss noticed that in most categories we approved more than we deny other then nicotine patches/tablets. Why is that?

Mr. Ouellette answer that is because Mainecare doesn't cover those products they need to go through the Maine Tobacco Hotline. The average determination time is between 1 to 2.5 hours depending on the complexity. But looking at the Narcotic-Misc category you can see the significant increase in PA's.

Dr. Weiss amount of hours spend just on narcotics are huge.

Mr. Ouellette added that since the new narcotic and Suboxone limits were put into place we went from doing on average 400 to 500 a day to 800 to 900 per day.

Ms. Yorks-Wright added that in requiring the PA for Suboxone we have found been able to find when it is being used for off label use that Mainecare doesn't cover.

Mr. Ouellette asked have we had any hearing on the Suboxone yet.

Ms. Yorks-Wright answered that we have only had one hearing requested.

Dr. Weiss asked why we don't eliminate the PA requirement on the ones with 100% approval.

Mr. Ouellette answered because on those we are looking for the drugs to be used for certain indications and if we remove the PA requirement the medication would start to be used for off label use.

ADJOURNMENT: 8PM

The next meeting will be held on March 12, 2013 between 6 to 8 p.m.