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
Toll Free (866) 796-2463; Fax: (207) 287-8601
TTY Users: Dial 711 (Maine Relay)

TO: Maine Drug Utilization Review Board
DATE: April 23, 2015
RE: Maine DUR Board **Meeting** minutes from April 14th, 2015

ATTENDANCE	PRESENT	ABSENT	EXCUSED
Robert Weiss, M.D., Cardiologist, Chair	X		
Linda Glass, M.D.		X	
Lisa Wendler, Pharm. D., Clinical Pharmacy Specialist, Maine Medical CTR	X		
Mark Braun, M.D., FACP, Internist/Geriatrician	X		
Mike Ouellette, R.Ph., GHS			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, Ed Bosshart, PharmD

CALL TO ORDER: 6PM

PUBLIC COMMENTS

Medical Liaison from Pfizer presented Duavee. Duavee is used post-menopausal for women with a uterus to reduce moderate-to-severe hot flashes and to help reduce the chances of developing osteoporosis. 54% rate of amenorrhea with Prempro versus 88% with Duavee. There is a 2 year bone marrow density study involving Raloxifene. This study showed that Duavee had a significantly better outcome in lumbar spine bone marrow volume than Raloxifene at all of the time points measured.

Medical Liaison from AstraZenca presented Movantik. Movantik is the first once daily oral therapy in its class indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain. Opioids bind to mu receptors in CNS and mu opioid receptors that are found in the GI tract. This can inhibit multiple aspects of normal bowel function and result in a unique form of constipation which is

referred to as OIC. In fact, OIC is the most common adverse event seen in patients who are taking opioids for chronic non-cancer pain. Lack of consensus guidelines on the recognition and treatment of OIC and is often managed just like general constipation (lifestyle modifications as well as laxatives). Data from the US cohort of an observation study of patients with chronic non-cancer pain and OIC demonstrated 2/3 responded to laxative therapy, whereas 1/3 did not respond despite using 2 laxatives for at least 2 weeks from at least 2 different classes. This nonresponsive group would be the target population for Movantik. Additional evidence demonstrates that OIC may impact health related quality of life, work related outcomes, and pain management. Movantik is the pegylated derivative of naloxone which is restricted in its ability to cross the blood brain barrier. When administered at recommended doses the CNS penetration is considered to be negligible which in turn does not limit the analgesia that is experienced from an opioid. Efficacy and safety of Movantik have been confirmed through a phase 3 clinical trial program. This included 2 double blind placebo controlled 12 week efficacy and safety trials and a 12 week safety trial extension, a 52 week open label randomized controlled safety and tolerability trial as well. In these trials, Movantik 25mg resulted in a significantly higher rate of response compared to placebo including a sub group of patients who were laxative users with ongoing OIC symptoms prior to enrollment. The median time to first post dose spontaneous bowel movement was 6 and 12 hours in the 2 studies with Movantik 25mg compared with 36 to 37 hours with placebo. The most common adverse reactions were abdominal pain, diarrhea, and nausea. The rate of abdominal pain was quite high. This is something you'd expect in those that have had a sleepy bowel for as long as these OIC patients have had. For more information please refer to Movantik's prescribing information. AstraZenca request that Movantik be placed on the preferred side of the MaineCare PDL.

OLD BUSINESS

DUR MINUTES

The Mach 2015 minutes were approved.

PSYCH WORK GROUP UPDATE

No update at this time

MAINECARE UPDATE

No update at this time

NEW BUSINESS

AMIODARONE DDI

Dr. Barkin presented data on Amiodarone DDI. In review, of this Amiodarone has a half-life of 26- 107 days. Should we do a retro Dur edit to lookback for possible drug to drug interactions (DDI)?

Dr. Weiss stated that the pharmacies do try to look for these DDI when they can. Anything more than 3 or 4 months back will have no impact.

Dr. Barkin asked if the board should do a lookback of patients that were on Amiodarone that have recently stopped or only those that are currently on it.

Dr. Weiss responded that it's not of grave concern and that it would depend on how much time the board wants to focus on this because you can't look at everything. Most of the drugs listed as having a potential DDI are not used.

Lisa Wendler added that Azithromycin is commonly used.

Dr. Weiss agreed however in most cases it is not seen in time because Azithromycin is usually a short script amount.

Board Decision: No action required

GARDASIL- 9

Mr. Bosshart stated that Gardasil -9 is an updated Gardasil that now includes vaccine that provides protection against 9 strains of Human Papilloma Virus (HPV). Currently under MaineCare policy is no PA needed if all the following criteria are met:

- Member is nine (9) through 26 years old* ,Member is male or female
- Vaccine is administered in a covered place of service*

For members ages nine (9) through 18 years old, Gardasil is covered under the Vaccine for Children (VFC) Program administered by the Maine Centers for Disease Control and Prevention and should be billed with an SL modifier.

- This is not a covered service for members age 27 years and older, even if the series began before the member's 27th birthday.

The recommendation is to continue with the current criteria for the Gardasil- 9

Board Decision: The Board unanimously approved the above recommendation.

NEW DRUG REVIEW

Glyxambi common name empagliflozin/linagliptin indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2diabetes when treatment with both is appropriate. Not recommended for use in type 1 diabetes and has a pregnancy category C. Renal function should be assessed prior to treatment and periodically thereafter. It is recommended to correct volume depletion prior to treatment. If GFR is less than 45 consistently discontinue treatment. Major adverse drug reactions include urinary tract infection, nasopharyngitis, and upper respiratory infection. Combination product is more expensive than the individual ingredients.

Recommendation: The recommendation is for it to be non-preferred.

Rytary common name levodopa & carbidopa, extended- release in the PDL category Antiparkinson Agents. It is indicated for the treatment of Parkinson's disease, post-encephalitic Parkinsonism, and Parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.

Recommendation: The recommendation is for it to be non-preferred.

Rasuvo common name methotrexate in the PDL category Rheumatoid Arthritis. Criteria for Rasuvo will be treatment failure or intolerance to other forms of preferred methotrexate.

Recommendation: The recommendation is for it to be non-preferred.

Movantik common name naloxegol in the PDL category GI Anti-Flatulents/GI Stimulants it's indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. There were 2 randomized double blind studies that were 12 weeks long and they were well powered. Only Bisacodyl Laxative was allowed in these studies. Primary end point for response was defined as greater than 3 spontaneous bowel movements per week. With a baseline change of greater than 1 bowel movement per week for greater than 9 out of the 12 study weeks as well as 3 out of the last 4 weeks. Its been calculated that number of patients to treat to retrieve that primary endpoint were 9 with the 12.5mg dose and 7 with the 25mg dose in the first study. In the 2nd study, a replication study, was not quite as robust in terms of results. The number of patients to treat was 17 for the low dose and 10 for the higher dose. First line treatments dietary modifications, such as increased intake of fluids and dietary fiber, may improve bowel functions.

Recommendation: The recommendation is for it to be non-preferred.

Pazeo common name olopatadine in the PDL category Opthalmic Anti- Allergics. Pazeo is indicated for the treatment of ocular itching associated with allergic conjunctivitis.

Recommendation: The recommendation is for it to be non-preferred.

Duavee common name estrogens, conjugated & bazedoxifene acetate in the PDL category Estrogen Combo's the recommendation is for it to be non-preferred. Duavee used for the treatment of moderate to severe vasomotor symptoms associated with menopause and for the prevention of post-menopausal osteoporosis. Pregnancy Category X. Used once daily. Not recommended in those with renal impairment and contraindicated in those with hepatic impairment. Metabolism affected by CYP3A4 inhibitors/inducers.

Recommendation: The recommendation is for it to be non-preferred.

Lenvima common name lenvatinib in the PDL category Cancer. Treatment of locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer.

Recommendation: The recommendation is for it to be non-preferred to verify diagnosis.

Ibrance common name palbociclib in the PDL category Cancer. The recommendation is for it to be non-preferred to verify diagnosis and to make sure it is taken with Letrozole. Indicated for the treatment of estrogen receptor (ER)–positive, human epidermal growth factor receptor 2 (HER2)–negative advanced breast cancer (in combination with letrozole) in postmenopausal women as initial endocrine-based therapy for metastatic disease. Dose reduction or discontinuation may be required based on adverse reactions or toxicity.

Recommendation: The recommendation is for it to be non-preferred to verify diagnosis, drug interactions, and to make sure it is taken with Letrozole.

Prezcobix common name darunavir ethanolate & cobicistate in the PDL category Antiretrovials.

Recommendation: The recommendation is for it to be non-preferred.

Evotaz common name atazanavir & cobicistat in the PDL category Antiretrovirals.

Recommendation: The recommendation is for it to be non-preferred.

Vitekta common name elvitegravir in the PDL category Antiretrovirals. Integrase inhibitor.

Recommendation: The recommendation is for it to be non-preferred.

Board Decision: The Board unanimously approved all the above recommendation.

FDA SAFETY ALERTS

Chantix (varenicline): Drug Safety Communication - FDA Updates Label to Include Potential Alcohol Interaction

FDA Drug Safety Communication: FDA warns of serious slowing of the heart rate when antiarrhythmic drug amiodarone is used with hepatitis C treatments containing sofosbuvir (Harvoni or Sovaldi) in combination with another Direct Acting Antiviral drug

Zyprexa Relprevv (olanzapine pamoate): Drug Safety Communication- FDA Review of Study Sheds Light on Two Deaths Associated with the Injectable Schizophrenia Drug

Nationwide Alert: DEA Calls Opioid a Serious Public Health Threat
Fentanyl laced with heroin is a safety concern. This makes it 100 times more powerful than morphine and 30-50 times more powerful than heroin. It is very easy to get an acute opiate overdose. There are issues seen with law enforcement ceasing fentanyl laced with heroin and getting it on their hands causing an acute opiate overdose. Seeing fentanyl end up in heroin and heroin being sold as heroin but it has fentanyl.

Board Decision: No action required

ADJOURNMENT: 8PM

The next meeting will be held on **June 9, 2015** 6:00p.m. – 8:00p.m at the Augusta Armory.