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:** January 10, 2017
**RE:** Maine DUR Board **Meeting** minutes from December 13, 2016

| ATTENDANCE | PRESENT | ABSENT | EXCUSED |
|---|---|---|---|
| Linda Glass, MD | | | X |
| Lisa Wendler, Pharm. D., Clinical Pharmacy Specialist, Maine Medical CTR | | | X |
| Mike Antoniello, MD | | | X |
| Kathleen Polonchek, MD | X | | |
| Kenneth McCall, PharmD | X | | |
| Steve Diaz, MD | X | | |
| Erin Ackley, Pharm. D. | X | | |
| **Non –Voting** | | | |
| Mike Ouellette, R.Ph., Change Healthcare | X | | |
| Jeffrey S. Barkin MD, DFAPA Change Healthcare | | | X |
| Jacquelyn Hedlund, MD, Change Healthcare | X | | |
| Jan Yorks-Wright, Pharmacy Supervisor, OMS | X | | |
| Roger Bondeson, Director of Operations, OMS | X | | |
| Christopher Pezzullo, State Health Officer DHHS, DO | | | X |

**Guests of the Board: Ed Bosshart, PharmD**

## CALL TO ORDER: 5:30PM

Dr. Pezzullo called the meeting to order at 5:30 PM.

## PUBLIC COMMENTS

Chris Dube, AZ: Highlighted the attributes of Zurampic®.
Randy Perrin, Sarepta: Highlighted the attributes of Exonoys 51®.
Shaffee Bacchus, J & J: Highlighted the attributes of Invokamet XR®.

## OLD BUSINESS

### DUR MINUTES

The October DUR meeting minutes were accepted as printed

### MAINECARE UPDATE

No update at this time

## NEW BUSINESS

### PCM REPORT- HEPATIS C

Change Healthcare

- Adherence is commonly measured by Medication Possession Ratio (MPR)
    - The days supply of medication divided by the number of days elapsed
    - A marker of good adherence is an MPR $\geq$ 0.80, meaning member has medication on at least 80% of days
- Our July 2016 PCM report showed that about 96% of our Hepatitis C patients showed good adherence (MPR $\geq$ 0.80)
    - 357/371 patients
        - 14 members non-adherent
            - Members did not complete treatment and did not follow up with the PCM program, the pharmacy or their providers – often after the first 14 day supply. These patients are considered "Lost to followup"
                - 2 members followed up as having resumed alcohol use
        - Choosing not to take the medication, or resuming past lifestyle behaviors suggest that these members were not truly prepared to undertake treatment. The PCM program/involved Hepatitis C PA form aim to ensure that members and providers are fully ready for treatment and often defer out treatment if a member does not demonstrate proper readiness (less than 6 months of drug abstinence/sobriety, etc)
        - Communication is sent to prescribers and pharmacies so that all parties are aware when a member is not adherent to Hepatitis C treatment
            - If/when a followup request is made for Hepatitis C treatment in the future, more careful consideration is given as to whether this member has demonstrated a change in readiness
                - In this case we try to get contact information and reach out to the member prior to PA approval to discuss the importance of adherence and assess patient readiness.

**Board Decision:** No action required

## USE OF ANTIPSYCHTICS IN MAINE REPORT

Change Healthcare presented data on the usage of antipsychotics. The data was separated by county, age and gender. In review of the data it was noted that higher usage was found in rural counties and young men.

**Board Decision:** No formal action required

## RETRO-DUR INTRODUCE:CO-PRESCRIBING OF STIMULANTS, BENZODIAZEPINES AND "Z" DRUGS

Stimulants have been shown to markedly improve the symptoms of ADD and ADHD. Many people with these disorders also experience anxiety requiring treatment, either behavioral psychotherapy, pharmacologic treatment, or both. In addition, sleep disorders are relatively common in this group. While SSRIs and SNRIs are recommended to address anxiety in these patients, benzodiazepines can be used to treat acute episodes while waiting for SSRIs or SNRIs to "kick in" since it take up to 12 weeks to achieve effectiveness.

In the general population, so called "Z" drugs (zolpidem, zaleplon, and zopiclone), are widely prescribed for sleep disorders, most commonly chronic insomnia. Sleep disorders are common among patients with numerous psychiatric diagnoses including mood disorders, anxiety disorders, attentional disorders, and autism. As a rule, stimulants, benzodiazepines and Z drugs should not be used in combination due to overlapping CNS effects, including worsening anxiety and mood, confusion, lethargy, obtundation, bradycardia, respiratory depression, agitation and aggressive behavior. In children, the recommendation is to treat anxiety and sleep disorders initially with behavioral therapy, followed by antidepressants (SSRIs), if needed. Benzodiazepines and Z drugs are not recommended for children.

**Recommendation:** Identify members with diagnoses of ADD, ADHD, and ASD, stratified by age, and identify use of stimulants, "Z" drugs and benzodiazepines concomitantly for greater than a 30day period of overlap. Age stratification will be age bands 0-10, 11-20, 21-30 and 31 and over. Additionally, data may identify prescribers to evaluate whether there is a need for an education program around the use of these drugs generally, or if there are a limited number of prescribers not following guidelines.

**Board Decision:** No formal action required.

## NEW DRUG REVIEWS

**Emverm®** (mebendazole); **PDL category**- Anthelmintics

Emverm® is indicated for the treatment of *Enterobius vermicularis* (pinworm), *Trichuris trichiura* (whipworm), *Ascaris lumbricoides* (common roundworm), *Ancylostoma duodenale* (common hookworm), *Necator americanus* (American hookworm) in single or mixed infections. There is

no evidence at this time to support that Emverm® is safer or more effective than the currently available, more cost effective medications.

**Recommendation:** Emverm® be non-preferred.

**Jentadueto XR®** (linagliptin & metformin extended-release); **PDL category-** Diabetic- DPP4 Enzyme Inhibitor Combinations.

Jentadueto XR® is indicated for use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate. Jentadueto® XR should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Furthermore, it has not been studied in patients with a history of pancreatitis; and, it is not known if patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Jentadueto® XR. There is no evidence at this time to support that Jentadueto® XR is safer or more effective than the currently available, more cost effective medications, including the use of each individual ingredient together. There is no evidence at this time to support that Jentadueto XR® is safer or more effective than the currently available, more cost effective medications.

**Recommendation:** Jentadueto® XR be non-preferred.

**Onzetra® X sail** (sumatriptan succinate); **PDL category**- Migraine- Selective Serotonin Agonists (5HT)-Tabs/Nasal.

Onzetra® X sail is indicated for acute treatment of migraine with or without aura in adults. It is not indicated for the prevention of migraine attacks, and safety and efficacy of use have not been established for the treatment of cluster headaches. Onzetra® Xsail should only be used if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Onzetra® Xsail, it is recommended to reconsider the diagnosis of migraine before treatment of subsequent attacks.

**Recommendation:** Onzetra® X sail be non-preferred.

**Sustol®** (granisetron); **PDL category**- Antiemetic-5HT3 Receptor Antagonists/ Substance Neurokinin.

Sustol® is indicated for combination with other anti-emetics in adults for the prevention of and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens. There is no evidence at this time to support that Sustol® is safer or more effective than the currently available, more cost effective medications.

**Recommendation**: Sustol® be non-preferred.

**Inflectra®** (infliximab-dyyb); PDL category- Rheumatoid Arthritis.

Inflectra® is indication for:

- Crohn's Disease (CD): To reduce signs/symptoms and inducing/maintaining clinical remission in adults with moderate to severe CD who have had an inadequate

response to conventional therapy AND to reduce the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adults with fistulizing CD

- Pediatrics Crohn's Disease: To reduce signs/symptoms and inducing/maintaining clinical remission in pediatric patients ≥6 years of age with moderately to severely active CD who have had an inadequate response to conventional therapy
- Ulcerative Colitis (UC): To reduce signs/symptoms, inducing/maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adults with moderately to severely active UC who had an inadequate response to conventional therapy
- Rheumatoid Arthritis (RA): In combination with methotrexate to reduce signs/symptoms, inhibit the progression of structural damage, and improve physical function with moderately to severely active RA
- Ankylosing Spondylitis (AS): To reduce signs/symptoms
- Psoriatic Arthritis (PA): To reduce signs/symptoms of active arthritis, inhibiting progression of structural damage, and improving physical function
- Plaque Psoriasis (PP): Chronic severe PP for adults who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. Should only be administered to those who will be closely monitored and have regular follow-up visits with physician.

There is no evidence at this time to support that Inflectra® is safer or more effective than the currently available, more cost effective medications, including Remicade®.

**Recommendation**: Inflectra® be non- preferred.

**Probuphine®** (buprenorphine); PDL category- Opioid Dependence Treatments.

Probuphine® is indicated the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine-containing product (i.e. doses of no more than 8mg per day of Subutex® or Suboxone® SL tab equivalent or generic equivalent). Probuphine® should be used as part of a complete treatment program to include counseling and psychosocial support. Due to the lack of studies suggesting improved safety or efficacy over existing, more cost effective therapies, it is recommended that Probuphine® be made non-preferred and be available to those who are unable to use more cost effective, preferred products. In addition, if used, it should be documented that both the provider and patient are registered as part of the Probuphine® REMS program.

**Recommendation**: Probuphine® be non-preferred.

**Criteria: 1)** Add comment Both provider and patient need to be registered as part of the Probuphine REMS program. **2)** Remove Suboxone Tabs and correlating comment The manufacture will be discontinuing the tablets by the end of quarter one 2013

**Exondy® 51** (eteplirsen); PDL category- Muscular Dystrophy Agents.

Exondy® 51 is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. This indication is approved under accelerated approval based on an increase in

dystrophin in skeletal muscle observed in some patients treated with Exondys® 51. A clinical benefit of Exondys® 51 has not been established. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials. The indication was approved under accelerated approval based on an increase in dystrophin seen in some patients. The clinical studies for Exondys® 51 included extremely small sample sizes and a clinical benefit of treatment, per the 6MWT, was not established. It is therefore recommended that Exondys® 51 remain non-preferred and require clinical prior authorization to verify diagnosis and use of a stable dose of a corticosteroid for at least 6 months.

**Recommendation:** Exondys®51 be non-preferred.

**Criteria**: 1) Add new Muscular Dystrophy Agents category. **2)** Add comment Clinical prior authorization to verify diagnosis and use of stable dose of corticosteroid for at least 6 months.

**Otovel®** (ciprofloxacin & fluocinolone solution); PDL category- Ear.

Otovel® is indicated for the treatment of acute otitis media with tympanostomy tubes (AOMT) in pediatric patients (aged 6 months and older) due to *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, and *Pseudomonas aeruginosa*. While there is evidence that Otovel® is more effective than each individual ingredient alone, there is no evidence at this time to support that Otovel® is safer or more effective than the currently available, more cost effective combination medications

**Recommendation**: Otovel® be non-preferred.

**Bromsite®** (bromfenac solution); PDL category- OP-NSAIDs.

Bromsite® is indicated for the treatment of post-operative inflammation and prevention of ocular pain in patients undergoing cataract surgery. Bromsite® is an ophthalmic NSAID indicated for the treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery. While other topical NSAIDs and bromfenac ophthalmic agents are available (e.g. Prolensa® 0.07% and bromfenac 0.09% products), this is the first topical NSAID FDA approved to prevent ocular pain after cataract surgery. There is evidence that Bromsite® is safe and effective for the prevention of ocular pain as compared with placebo.

**Recommendation**: Bromsite® be non-preferred.

**Zurampic®** (lesinurad); PDL category- Gout.

Zurampic® is indicated in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone. Zurampic® is not recommended for the treatment of asymptomatic hyperuricemia and should not be used as monotherapy. There is no evidence at this time to support that Zurampic® is safer or more effective than the currently available, more cost effective medications.

**Recommendation**: Zurampic® be non-preferred.

**Criteria:1)** Add comment Zurampic should be used in combination with a xanthine oxidase inhibitor, including allopurinol or febuxostat.

**Byvalson**® (nebivolol & valsartan); PDL category- ARB and Beta-Blocker Combination.

Byvalson® is indicated for the treatment of hypertension, to lower blood pressure. It may be alone or in combination with other antihypertensive agents. While there is some evidence support that Byvalson® is more effective than its individual ingredients when used as, there is no evidence at this time to support that Byvalson® is safer or more effective than the currently available, more cost effective medications or the combination of its individual ingredients or other combination products.

**Recommendation**: Byvalson® be non-preferred.

**Criteria**:**1)** Add to criteria DDI: Byvalson will be non-preferred and require a prior authorization if it is currently being used in combination with drugs known to be significant CYP2D6 inhibitors (e.g. quinidine, propafenone, fluoxetine, paroxetine).

**Relistor**® (methylnaltrexone); PDL category- GI, Misc.

Relistor® is indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. There is no evidence at this time to support that Relistor® tablets are safer or more effective than the currently available, more cost effective medications.

**Recommendation**: Relistor® be non-preferred.

**Qbrelis**® (lisinopril); PDL category- ACE Inhibitors.

Qbrelis® is indicated for the treatment of hypertension in adults and pediatric patients ≥6 years (it may be used alone or with other antihypertensive agents); *AND* to reduce signs and symptoms of systolic heat failure; *AND* for the reduction of mortality in the treatment of hemodynamically stable patients within 24 hours of acute myocardial infarction (patients should receive, as appropriate, the standard recommended treatments such as thrombolytics, aspirin, and beta-blockers). There is no evidence at this time to support that Qbrelis® is safer or more effective than the currently available, more cost effective medications.

**Recommendation**: Qbrelis® be non-preferred.

**Invokamet**® (canagliflozin & metformin extended-release); PDL category- SGLT 2 Inhibitor Combinations.

Invokamet® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both canagliflozin and metformin is appropriate. Use is not recommended in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. There is no evidence at this time to support that Invokamet® XR is safer or more effective than the currently available, more cost effective medications, including the use of each individual ingredient together.

**Recommendation:** Invokamet® be non-preferred.

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

## FDA SAFETY ALERTS

FDA analyses conclude that Xarelto clinical trial results were not affected by faulty monitoring device
http://www.fda.gov/Drugs/DrugSafety/ucm524678.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Testosterone and Other Anabolic Androgenic Steroids (AAS): FDA Statement - Risks Associated With Abuse and Dependence
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm526151.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA launches competition to spur innovative technologies to help reduce opioid overdose deaths
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm520945.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Eye Wash/Eye Irrigating Solutions Distributed by Major Pharmaceuticals and Rugby Laboratories: Recall - Microbial Contamination
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm519570.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Hyoscyamine Sulfate 0.125mg by Virtus Pharmaceuticals: Recall - Superpotent and Subpotent Test Results
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm520868.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Lamotrigine Orally Disintegrating Tablet 200 mg by Impax: Recall - Incorrect Labeling of Blister Cards
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm518486.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Opioid Pain or Cough Medicines Combined With Benzodiazepines: Drug Safety Communication - FDA Requiring Boxed Warning About Serious Risks and Death
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm518710.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Ovarian Cancer Screening Tests: Safety Communication - FDA Recommends Against Use
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm519540htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Direct-Acting Antivirals for Hepatitis C: Drug Safety Communication - Risk of Hepatitis B Reactivating

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm523690.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

**Board Decision:** No formal action required

## ADJOURNMENT: 8:30PM

The next meeting will be held on **March 14, 2016** 5:30pm –8:30pm at the Augusta Armory.