



Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: April 07, 2015

Board Members:

Present:

Jaskanwar Batra, MD
Janet Farina, RPh

Mark Pasanen, MD
Michael Biddle, PharmD

James Marmar, RPh

Absent: Joseph Lasek, MD, Chair

Staff:

Michael Ouellette, RPh,
GHS/Emdeon

Jeffery Barkin, GHS/Emdeon

Jason Pope, DVHA

Thomas Simpatico, MD, DVHA
Nancy Hogue, PharmD, DVHA

Mary Beth Bizzari, RPh, DVHA

Stacey Baker, DVHA

Guests:

Rita Baglini, APS Health Care
Kristen Chopas, Gilead
Alicia Teitsma, AstraZeneca

Kristen Bruno-Doherty, Astrazeneca
Thomas Currier, Purdue
James Kokoszyna, Allergan
Jai Persico, Otsuka

James Hayes, Abbvie
Kevin Kobylinski, Astellas
William Mullen, Reckitt Benckiser
Scott Williams, J&J

Jaskanwar Batra, MD, called the meeting to order at 6:30 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:00 until 6:30 p.m.

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The February meeting minutes were accepted as printed.

3. DVHA Pharmacy Administration Updates: Nancy Hogue, PharmD, DVHA

- Actively recruiting for new members, currently we have five candidates that are under review that includes two pharmacists, two medical doctors and one nurse practitioner.

4. Medical Director Update: Thomas Simpatico, MD, DVHA

- No clinical program update

- Dr. Simpatico indicated that looking at psychotropic medications five years out from today, it appears that state Medicaid programs will be spending half as much in total cost to the program because half of the medications will not be covered by patent protection.

5. Follow-up Items from Previous Meetings:

- None at this time

6. Retro DUR/DUR: Mike Ouellette, RPh, GHS/Emdeon and Dr. Jeffery Barkin, MD, GHS/Emdeon

- High dose/Long term use in individual patients on diazepam
 - GHS pulled more data in regards to this but is looking for feedback from the board. After reviewing the data, GHS found many of these patients were also on pain medications and psychiatric medications. It was asked why we are only looking at diazepam. This is a follow up from a full review of benzodiazepines. At that time, quantity limits were placed on all benzodiazepines excluding diazepam to look at why a higher dose was given. Further review and data will be gathered by both DVHA and GHS.
- Amiodarone DDI
 - Due to the long half-life of 26-107 days, a further review of the VT Medicaid members on Amiodarone within the last six months will be done. GHS will come back to the board with recommendations.
- 2015 Retro DUR Initiatives
 - GHS will send a list of retroDUR initiatives to the board members to review and decide which items the board would prefer to review over the next year. Once feedback is received, a schedule will be set for retroDUR. If a pressing matter comes up, we will alter the schedule appropriately.

7. Clinical Update: Drug Reviews:

Abbreviated new Drug Reviews

- None at this time

Full New Drug Reviews: Mike Ouellette, RPh, GHS/Emdeon and Jeffrey Barkin, MD, GHS/Emdeon

- Bunavail® (buprenorphine HCL & naloxone HCL dihydrate) and Zubsolv®(buprenorphine & naloxone)
 - Bunavail and Zubsolv are versions of buprenorphine /naloxone with slightly different dosing and taste. No registered trials have been done on these medications. Normally to get FDA approval, there need to be multiple clinical trials done for approval (2 positive double blind randomized trials). Since Bunavail and Zubsolv have the same ingredients as Suboxone and it is accepted that buprenorphine as Suboxone is effective for the treatment of opioid dependence, these drugs were primarily compared to Suboxone in terms of pharmacokinetic parameters such as AUC (area under the curve). Due to differences in bioavailability, slightly different dosages of Zubsolv and Bunavail are recommended to obtain the same drug exposure as with specific dosages

of Suboxone. Bunavail, Suboxone and Zubsolv all have the indication of treatment of opioid dependence.

Recommendation: The recommendation is to add Bunavail to the non-preferred side of the PDL with quantity limits of 1 film per day (2.1/0.3mg, 6.1/1mg) and 2 films per day (4.2/0.7mg). The recommendation is to add Zubsolv to the non-preferred side of the PDL with quantity limits of 1 SL tablet per day of all strengths. Add Bunavail and Zubsolv to the clinical criteria “AND Requests for Buprenorphine/Naloxone SL tablet, Bunavail or Zubsolv after documented intolerance of Suboxone Film. A MedWatch form must be completed and will be submitted by DVHA to the FDA”

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

8. Therapeutic Drug Classes- Periodic Review: Mike Ouellette, RPh, GHS/Emdeon and Jeffery Barkin, MD, GHS/Emdeon

Anti-Migraines: The Anti-Migraine agents (triptans drug class) was reviewed. After reviewing all of the clinical studies there is no one triptan that is superior or safer when given at equivalent doses. When choosing the appropriate agent, consideration should be given to available dosage forms, drug interactions, and dosing adjustments

- **Recommendation:** The recommendation is to remove the current criteria for Maxalt MLT and move Maxalt MLT to non-preferred with the same criteria as Maxalt. Add criteria to naratriptan and rizatriptan ODT: The patient has had a documented side effect, allergy or treatment failure with Sumatriptan.
- Antiviral Topical: The Antivirals Topical drug class was reviewed. Topical Antivirals are mostly used in the treatment of genital herpes, which is a common disorder with an estimated 50 million Americans affected. The Centers for Disease Control and Prevention guidelines suggest that initial and episodic genital herpes be treated with the oral antiviral treatments. The CDC guidelines deter the use of antiviral topical medication stating “minimal clinical benefits”. Of the studies reviewed there was no Antiviral Topical more effective than another and oral treatment is favored.
 - **Recommendation:** The recommendation is to add Xerese cream (acyclovir 5%/hydrocortisone 1%) to the non-preferred side of the PDL. Add to the clinical criteria Denavir “and a failure of both oral antiviral and Abreva OTC.” Remove “In addition, for approval of Zovirax ointment, the patient has a documented intolerance to generic acyclovir ointment’ under Acyclovir/Zovirax”. Remove “Xerese (acyclovir/hydrocortisone) 5%/1% cream combination not covered. Agents may be prescribed separately.”
- GI Ulcer Therapies: The Gastrointestinal Ulcer Therapies drug class was reviewed. The most recent review done in 2013 from the American College of Gastroenterology included

strength recommendations for the management of GERD. The study strongly recommends that an 8 week course of PPI therapy is the treatment of choice. Also there are no major differences in efficacy in the PPI's

- **Recommendation:** The recommendation for the Histamine-2 Receptor Antagonists is to remove Axid caps (nizatidine), Axid oral solution (nizatidine), Zantac effervescent and Zantac syrup from the non-preferred side of the PDL and the clinical criteria due to these products no longer being available. Move Cimetidine tab to non-preferred and grandfather current users. The recommendation for the proton pump inhibitors is to remove Omeprazole/sodium bicarbonate caps OTC and Zegerid OTC caps from the non-preferred side of the PDL due to unavailability of these products, and add as non-preferred, Zegerid Rx caps, oral suspension (omeprazole/sodium bicarbonate). In the criteria section under other non-preferred medications, change to "If the request is for brand Zegerid Rx capsules" remove "OTC". Under "limitations" remove Zegerid (omeprazole/sodium bicarbonate) RX capsules, powder for suspension are not covered as there is no Federal Rebate offered. Replace with Zegerid (omeprazole/sodium bicarbonate) OTC capsules, powder for suspension are not covered as there is no Federal Rebate offered.
- Fibromyalgia Agents: The Fibromyalgia Agents drug class was reviewed. It was recommended by the Board that SSRI and SNRI options should be listed on the PDL under the Fibromyalgia Agents class. No evidence was reported that suggested superiority of either SSRI or SNRI which are generally used after exercise and lifestyle changes are trialed. There are some interesting studies stating that fibromyalgia may be part of a sleep disorder.
 - **Recommendation:** The recommendation is to add Lyrica, duloxetine and Cymbalta to the non-preferred side of the PDL. All other criteria remain the same.
- Leukotriene Modifiers: The Leukotriene Modifiers drug class was reviewed. In a 2014 systematic review and meta-analysis by Zhang from Allergy and Asthma proceedings, 30 randomized controlled trials (24 for chronic asthma and 6 for acute asthma) were performed to assess the efficacy of Montelukast as first-line or add-on therapy for the prevention and treatment of asthma exacerbations in adult patients diagnosed with asthma. Results suggested that adults with chronic asthma taking Montelukast had a significantly reduced number of exacerbations as compared to placebo. However, Montelukast was inferior to inhaled corticosteroids. Given the high rates of asthma in children the recommendations reflect dosing for age and formulation.
 - **Recommendation:** The recommendation is to move Montelukast tabs (see clinical criteria) to the preferred side of the PDL. Add Montelukast chews 4mg for ages 2-5 5mg for ages 6-14 and Montelukast granules ages 6 months-23 months to the preferred side of the PDL. Add Zflo (zileuton) to the non-preferred side of the PDL. Under clinical criteria add Zflo to the Zflo CR criteria. Add "Montelukast chewable and granules approved for appropriate FDA approved age and indications." Remove "Note: Children 5 years old and under are not subject to PA criteria for Singulair. Separate the clinical criteria for Singulair for asthma and allergic rhinitis so that it reads more clearly.
- Gaucher's Disease: The Gaucher's Disease drug class was reviewed. Enzyme replacement therapy (ERT) was the first available treatment for Gaucher's. The early drugs were

intravenous, now oral treatments are available..however most authorities recommend the ERT's as first line therapy.

- **Recommendation:** The recommendation is to add Zavesca to the non-preferred side of the PDL. In the same section add Zavesca additional criteria: For whom enzyme replacement therapy is not a therapeutic option (e.g. due to allergy, hypersensitivity, or poor venous access). Not approved for the pediatric population. The clinical criteria for Cerdelga will be reviewed and brought back to board for approval.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

9. New managed Therapeutic Drug Classes

- None at this time

10. Review of Newly-Developed/Revised Clinical Coverage Criteria and/or Preferred Products

- None at this time

11. General Announcements Mike Ouellette, RPh, GHS/Emdeon

- Selected FDA Safety Alerts
 - FDA Drug Safety Communication: FDA requires label warnings to prohibit sharing of multi-dose diabetes pen devices among patients
http://www.fda.gov/Drugs/DrugSafety/ucm435271.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
 - No action required
 - Testosterone Products: Drug Safety Communication - FDA Cautions About Using Testosterone Products for Low Testosterone Due to Aging; Requires Labeling Change to Inform of Possible Increased Risk of Heart Attack And Stroke
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm436280.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
 - No action required
 - Chantix (varenicline): Drug Safety Communication - FDA Updates Label to Include Potential Alcohol Interaction
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm437415.htm>
 - No action required
 - 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

http://www.fda.gov/Drugs/DrugSafety/ucm439484.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

- No action required
- Zyprexa Relprevv (olanzapine pamoate): Drug Safety Communication- FDA Review of Study Sheds Light on Two Deaths Associated with the Injectable Schizophrenia Drug
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm439472.htm>
 - No action required
- **Nationwide Alert:** DEA Calls Opioid a Serious Public Health Threat
 - No action required

13. Adjourn: Meeting adjourned at 7:27 p.m.