



Department of Vermont Health Access  
Pharmacy Benefit management Program  
DUR Board meeting Minutes: January 20, 2015

**Board Members:**

**Present:**

Joseph Lasek, MD, Chair  
James Marmar, RPh  
Michael Biddle, PharmD

Mark Pasanen, MD  
Janet Farina, RPh  
Jaskanwar Batra, MD

Gary Starecheski, RPh  
Amanda Kennedy, PharmD

**Absent:**

**Staff:**

Michael Ouellette, RPh, GHS/Emdeon  
Scott Strenio, MD, DVHA  
Thomas Simpatico, MD, DVHA

Laureen Biczak, DO, GHS/Emdeon  
Mary Beth Bizzari, RPh, DVHA  
Jason Pope, DVHA

Nancy Hogue, PharmD, DVHA  
Jennifer Egelhof, DVHA

**Guests:**

Brett White, Avanir  
Christine Dube, MedImmune  
Dan Sheehan, Pfizer  
Dave Downey, Abbott  
Geoffrey McIntosh, Abbvie

Jai Persico, Otsuka  
James Kokoszyna, Allergan  
Jeffery Olson, Gilead  
Jenni Boyton, Amgen  
Maureen Cormier, Abbvie

Rick Angeli, Merck  
Rod Francesco, Sunovoin  
Scott Williams, J&J  
Steve Lash, Genentech  
Timothy Chatas, UCB

Joseph Lasek, MD, Chair, called the meeting to order at 7:12 p.m. at the DUR Board meeting site in Williston.

**1. Executive Session:**

- An executive session was held from 6:00 until 7:12 p.m. Approximately 55 minutes were spent on a Board Member orientation to the new PBM and reviewing the new format of DURB drug reviews and reports.

**2. Introductions and Approval of DUR Board Minutes:**

- Introductions were made around the table.
- The October meeting minutes will be brought to the February meeting for acceptance.

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

- Introduced Michael Biddle as a new member to the DUR board.
- Last meeting tonight for Amanda Kennedy and Gary Starecheski
- National Governors Association published an article on the expanding role of pharmacists, copies are available if anyone is interested.

**4. Medical Director Update: Scott Strenio, MD, DVHA**

- No clinical program update
- Received request from a pediatrician for the PA requirement to be removed for Auralgan.
  - GHS and DVHA will review and report at next meeting

## **5. Follow-up Items from Previous Meetings**

- Vivitrol Step- through for Opiate Dependence

**Recommendation:** Add to existing criteria “For Vivitrol, there is documented intolerance to or a failure of a trial of oral naltrexone”

*Public Comment:* No public comment.

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

- **Zohydro ER new formulation**

Zohydro ER (hydrocodone bitartrate extended-release) used for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Zohydro<sup>®</sup> ER use is not recommended in patients who have received MAO Inhibitors within 14 days. The concomitant use of Zohydro<sup>®</sup> ER with mixed agonists/antagonist analgesics (i.e. pentazocine, nalbuphine, butorphanol) or partial agonists (i.e. buprenorphine) should be avoided.

**Recommendation:** Zohydro<sup>®</sup> ER will remain non-preferred and be available with PA for those unable to tolerate any preferred medications.

- Currently all requests go to the DVHA Medical Director for approval. Suggestion was made to leave the current criteria in place. New formulation due out later this quarter.

**Board Decision:** The Board approved to continue to have all requests go to the Medical Director for approval.

## **7. Retro DUR/DUR**

- None at this time

## **8. Clinical Update: Drug Reviews**

### **Abbreviated new Drug Reviews**

- None at this time

### **Full New Drug Reviews**

- **Entyvio (vedolizumab) 300mg single-dose vial.**

*Treatment of adult ulcerative colitis (UC) for adults with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids. Concomitant use with natalizumab and TNF blockers should be avoided. There should be regular screening for progressive multifocal leukoencephalopathy (PML); however, there were no reported cases. Nevertheless, the risk of PML with Entyvio® use cannot be ruled out, as another product with the same mechanism of action has been associated with PML. It is therefore recommended to monitor patients on Entyvio® for any new onset or worsening of neurological signs and symptoms.*

**Recommendation:** To make it Non-Preferred on the PDL with PA required.

- Clinical discussion in regards to recommendation.
- Treatment failure language for this drug should be similar to the other drugs listed on the PDL. Dr. Biczak stated that the level of detail will be increased to include exact criteria on all New Drug Reviews beginning with the next meeting.

*Public Comment:* No public comment.

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

- **Jublia (efinaconazole) 10% topical solution.**

For the topical treatment of onychomycosis of the toenails. There is no evidence at this time to support that Jublia® is more efficacious or safer than the currently available, more cost effective topical medications.

**Recommendation:** Jublia® be placed in non-preferred position and PA required for those who are unable to tolerate or who fail on preferred medications.

- For the criteria, all oral therapies would have either failed or are contraindicated in order to allow topical therapy. Dr. Hogue suggested that for today we can vote on the preferred or non-preferred status, and follow up on more detailed criteria at the next meeting.

*Public Comment:* No public comment.

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

- **Sivextro (tedizolid) 200 mg tablet**

For the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the certain Gram-positive microorganisms. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Sivextro® and other antibacterial agents, Sivextro® should only be used to treat ABSSSI that are proven or strongly suspected to be caused by susceptible bacteria. There is no evidence at this time to support that Sivextro® is more efficacious or safer than the currently preferred, more cost effective medications.

**Recommendation:** Place Sivextro® in non-preferred position and PA required for those who are unable to tolerate or who fail on preferred medications.

*Public Comment:* No public comment.

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

- **Tanzeum (albiglutide) for injection.**

Adjunct to diet and exercise to improve glycemic control in adults with type 2 DM. Tanzeum® is not recommended as first-line therapy for those inadequately controlled on diet and exercise. Use is contraindicated in patients with a personal or family history of MTC or with MEN. There is no data found to suggest that Tanzeum® is safer or more effective than currently preferred diabetic therapies.

**Recommendation:** Place Tanzeum® in non-preferred position, and PA required for those who are unable to tolerate or who fail on preferred medications.

*Public Comment:* No public comment.

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

- **Harvoni (90 mg ledipasvir and 400 mg sofosbuvir) tablet**

For the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults. This is a pregnancy category B medication. The safety and efficacy of use in children has not been established. Dosage forms are a Fixed-dose, film-coated combination tablets: 90mg ledipasvir/400mg sofosbuvir.

**Recommendation:** Place Harvoni in preferred position with prior authorization required to determine specific clinical conditions and to ensure appropriate use.

- A clinical discussion ensued took place around the recommended treatment based on a patient's fibrosis level. Generally the Board felt that DVHA should continue the use of the current criteria that we have in place for Sovaldi. The Board inquired about current utilization. Only two patients on Harvoni were approved in 2014; DVHA received roughly 100 Sovaldi requests and about 70 were approved. In general, DVHA has not been approving a low fibrosis level.

*Public Comment:* No public comment.

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

- **Viekira pak (ombitasvir, paritaprevir, and ritonavir tablet, dasabuvir tablet)**

To be used with or without ribavirin for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis. Viekira® pak is not recommended for use in patients with decompensated liver disease. Determination of the clinically optimal and most cost-effective regimen for Hepatitis C is complex.

**Recommendation:** Viekira pak will be non- preferred.

*Public Comment:* Maureen Cormier, AbbVie, highlighted some points about Viekira pak being more cost effective because in some cases it is less than a 24 week regimen unlike Harvoni. Questions posed to the AbbVie representative included whether patient compliance been an issue with the multiple doses throughout the day. AbbVie responded they clearly looked at compliance in the clinical trials and found very few issues. Another question raised about whether the packaging allows the drug to be dispensed for 14 days at a time to which AbbVie responded affirmatively.

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

#### **9. Therapeutic Drug Classes- Periodic Review:** Laureen Biczak, DO, GHS/Emdeon

- Sublingual Immunotherapy: The clinical criteria were updated to include the FDA approved indications for Grastek and Ragwitek. The place in therapy for this is very unclear and it is very difficult to compare subcutaneous administration versus oral.

**Recommendation:** Place both drugs in non-preferred position until it is clear what the role is for these medications.

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

#### **10. New managed Therapeutic Drug Classes**

- None at this time

#### **11. Review of Newly-Developed/Revised Clinical Coverage Criteria and/or Preferred Products**

- Hepatitis C updates and recommendations- discussed while reviewing the New Drug Reviews.

#### **12. General Announcements**

- Selected FDA Safety Alerts
  - FDA recommends not using lidocaine to treat teething pain and requires new Boxed Warning (6/26/2014) <http://www.fda.gov/drugs/drugsafety/ucm402240.htm>
    - For next meeting GHS will provide written criteria to put age restrictions on lidocaine viscous
  - Methylphenidate HCl ER tablets (generic Concerta) made by Mallinckrodt and Kudco: FDA concerns about therapeutic equivalence with 2 generic versions of Concerta tablets (11/13/2014) <http://www.fda.gov/drugs/drugsafety/ucm422568.htm>
    - No action required
  - FDA reviews long-term antiplatelet therapy as preliminary trial data shows benefits but a higher risk of non-cardiovascular death (11/16/2014) <http://www.fda.gov/Drugs/DrugSafety/ucm423079.htm>

- No action required
- FDA warns about case of rare brain infection PML with MS drug Tecfidera (dimethyl fumarate) (11/25/2014) <http://www.fda.gov/Drugs/DrugSafety/ucm424625.htm>
  - No action required
- FDA issues final rule on changes to pregnancy and lactation labeling information for prescription drug and biological products 12/3/2014) <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm425317.htm>
  - No action required
- FDA reporting mental health drug ziprasidone (Geodon) associated with rare but potentially fatal skin reaction (12/11/2014) <http://www.fda.gov/Drugs/DrugSafety/ucm426391.htm>
  - No action required
- FDA has reviewed possible risks of pain medicine use during pregnancy (1/9/2015) <http://www.fda.gov/Drugs/DrugSafety/ucm429117.htm>
  - No action required

*Public Comment:* No public comment.

**13. Adjourn:** Meeting adjourned at 8:27 p.m.