



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 10/28/2014**

Board Members:

Present:

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

Mark Pasanen, MD
Janet Farina, RPh

Gary Starecheski, RPh
Amanda Kennedy, PharmD

Absent:

Kim Ladue, NP

Jaskanwar Batra, MD

Staff:

Diane Neal, RPh, Catamaran
Scott Strenio, MD, DVHA
Carrie Germaine, DVHA
Jason Pope, DVHA

Michelle Sirois, Catamaran
Mary Beth Bizzari, RPh, DVHA
Stacey Baker, DVHA

Nancy Miner, Catamaran
Nancy Hogue, PharmD, DVHA
Sarah Kidd, Pharmacy Intern, ACPHS

Guests:

Rick Angeli, Merck
Timothy Chatas, UCB
Rod Francisco, Sunovion
Scott Williams, J&J
Arlene Price, J&J

Rita Baglini, APS
Kristen Chopas, Gilead
Olivia Lee, Abbvie
Gina Black, Vertex

Kristen Bruno-Doherty, AstraZeneca
Thomas Currier, Purdue
Wendy Pollinger, Eli Lilly
Michelle Mattox, Vertex

Joseph Lasek, MD, Chair, called the meeting to order at 6:25p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:00 until 6:15 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The September, 2014 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- The CMS Annual Report for FFY2013 has been submitted. There were expanded questions in the survey about opiate use and controls, disease management, buprenorphine limits and e-prescribing.
- NAMD sent a letter to congress with regard to Sovaldi and other pipeline drugs of high cost and the States' Medicaid programs inability to afford those high costs.

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

- Gave an update on Hepatitis C therapy approvals. 41 patients have been approved to date for Hepatitis C treatment with Sovaldi®. There have been approximately 20 denials. There has been limited push back from prescribers on the process for approval.

5. **Follow-up items from Previous Meeting:** *Diane Neal, RPh, Catamaran*

- **Benzodiazepines:** The Board was provided a copy of the letter that was mailed to prescribers of benzodiazepines. Alprazolam and alprazolam ER were moved to PA required and quantity limits were established for certain benzodiazepines as approved by the DUR Board at a previous meeting.

Public Comment: No public comment.

Board Decision: None needed.

- **Buprenorphine & Buprenorphine/Naloxone (end of grandfathering):** The Board was notified that the grandfathering of dose and/or product ended on 9/2/2014. The clinical criteria and PA form have been updated to reflect those changes. All PA requests outside of the preferred product (Suboxone Film) and for doses greater than 16 mg/day will need to be reviewed by the Substance Abuse Unit at DVHA once per year. Certain exceptions apply for pregnant women maintained on buprenorphine mono tablets.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation. There were questions about the Vivitrol® clinical criteria but as this was not on the agenda it could be discussed at a later meeting.

- **Oxycodone IR/Hydrocodone IR:** The Board was provided a copy of the letter that was mailed to prescribers of oxycodone IR and hydrocodone IR. There will be daily quantity limits for all claims and days' supply limitations on the first fill.

Public Comment: No public comment.

Board Decision: None needed.

6. **RetroDur/Prior Authorization Quality Assurance Analysis:** *Sarah Kidd, DVHA Pharmacy Intern, ACPHS*

(Public comment prior to Board action)

- **Diazepam Daily Quantities/Prescribing for Alcohol Withdrawal:** A more detailed analysis of diazepam claims was performed. It was decided that quantity limits would not be established for diazepam when the above benzodiazepine edits were rolled out. There was concern that some of the claims that exceeded the daily quantity limit of 4 tablets/day were being prescribed for alcohol withdrawal. Only 12 of greater than 800 unique utilizers (45 day time period) were receiving greater than 4 tablets/day for greater than 10 days (greatest concern is around high dose and long term therapy). The recommendation is to not establish quantity limits for diazepam at this time but a

future RetroDUR should be performed to look closely at high dose and long term chronic use in individual patients.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Sovaldi[®] (sofosbuvir) in Hepatitis C: A further analysis of RVR (rapid virologic response) and SVR (sustained virologic response) levels in Sovaldi[®] treated patients was undertaken to further DVHA's understanding of the possibility of using interim viral loads to determine whether treatment should be continued. This was a continuation of a project started by a previous pharmacy intern. It was recommended that DVHA continue to formulate a policy and discuss PA limits, limits of dispense supply (perhaps not dispense full month supplies and require both a baseline viral load and a subsequent viral load at 4 -5 weeks with at most a 6 week supply dispensed) and work with the new Specialty Pharmacy. This could result in cost savings if non-responders or those who are not adherent to therapy are identified. SVR at 12 weeks should be obtained to establish clinical cure and help determine whether any future requests for previously treated patients are due to re-infection or relapse.

Public Comment: No public comment.

Board Decision: None needed.

7. Clinical Update: Drug Reviews: *Diane Neal, RPh, Catamaran*
(Public comment prior to Board action)

Abbreviated New Drug Reviews:

- Harvoni[®] (ledipasvir-sofosbuvir) Oral Tablet (initial discussion, no PDL decision): This drug was approved by the FDA in mid-October for the treatment of Genotype 1 Hepatitis C. DVHA has already received several requests. DVHA is waiting on the AASLD guidelines to be updated before proposing clinical criteria.

Public Comment: No public comment.

Board Decision: None needed.

- Sitavig[®] (acyclovir) Buccal Tablet: It was recommended that Sitavig[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of recurrent herpes labialis (cold sores) AND the patient is immunocompetent AND the patient has a documented side effect or treatment failure with oral acyclovir AND valacyclovir. A quantity limit of 2 tablets per prescription fill (per 30 days) was proposed. This drug acts more as a topical agent rather than a systemic agent.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

Full New Drug Reviews

- Myalept[®] (metreleptin) Vial for Subcutaneous Injection: It was recommended that Myalept[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of congenital or acquired generalized lipodystrophy AND the patient has one or more of the following metabolic abnormalities AND is refractory to current standards of care for lipid and diabetic management: (a) insulin resistance (defined as requiring >200 units per day), (b) hypertriglyceridemia or (c) diabetes AND the prescription is written by or in consultation with an endocrinologist AND the prescriber is registered in the MYALEPT REMS program. Note: After preliminary review by the Clinical Call Center, the request will be forwarded to the DVHA Medical Director for final approval. A quantity limit of 1 vial/day is proposed. The reauthorization criteria would be that the patient has experienced an objective response to therapy demonstrated by a sustained reduction in hemoglobin A1c (HbA1c) level from baseline OR a sustained reduction in triglyceride (TG) levels from baseline. A quantity limit of 1 vial/day and a maximum 30 day supply per fill is recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation and requested an initial 6 month approval and then 1 year approvals thereafter.

- Zohydro[®] ER (hydrocodone bitartrate) Extended Release Oral Tablet (non-abuse deterrent formulation): Zogenix has submitted a modified formulation of Zohydro[®] ER with potential abuse deterrent properties for FDA review on October 1, 2014. The new capsule formulation contains additional inactive ingredients that are intended to make the product more difficult to abuse by injection and nasal insufflation. Vermont has specific requirements of prescribers if the non-abuse deterrent formulation is prescribed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved to leave Zohydro[®] ER as new-to-market with Medical Director approval required until the new abuse deterrent formulation is available.

- Zontivity[®] (vorapaxar) Oral Tablet: It was recommended that Zontivity[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient is started and stabilized on the medication. (Note: samples are not considered adequate justification for stabilization) OR the patient has a history of myocardial infarction (MI) or peripheral arterial disease (PAD) AND the indication for use is reduction of thrombotic cardiovascular events AND the medication is being prescribed in combination with aspirin and/or clopidogrel. A quantity limit of 1 tablet per day was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

8. Therapeutic Drug Classes – Periodic Review: Diane Neal, RPh, Catamaran
(Public comment prior to Board action)

- Anticoagulants - Oral: The clinical criteria were updated to include additional FDA approved indications and some modification of the criteria to adjust the quantity limits to match with the indications.

Public Comment: Arlene Price, J&J ~ Highlighted some of the attributes of Xarelto[®]. New comparison data compared to warfarin will be available in the future. This is not published yet (only presented in poster format).

Board Decision: The Board unanimously approved the above recommendation.

9. Clinical Update: New/Updated Clinical Guidelines: Diane Neal, RPh, Catamaran

(Public comment prior to Board action)

- None

10. New Managed Therapeutic Drug Classes:

- None

11. Review of Newly Developed/Revised Clinical Coverage Criteria and/or Preferred Products:
Diane Neal, RPh, Catamaran

- Antidepressants – step therapy requirements for non-preferred agents: The clinical criteria were updated to recognize a trial of tricyclic antidepressants (where appropriate) as one antidepressant trial for certain antidepressants and antipsychotics (when prescribed for depression).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Kalydeco[®] (ivacaftor) Oral Tablet (additional approved genetic mutations): The approval criteria for Kalydeco[®] was updated to the following: The patient has a diagnosis of Cystic Fibrosis AND the patient has one of the following mutations on at least one allele in the cystic fibrosis transmembrane conductance regulator gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R (documentation provided) AND the patient is ≥ 6 years old.

Public Comment: Michelle Maddox, Vertex ~ Highlighted some of the attributes of Kalydeco[®].

Board Decision: The Board unanimously approved the above recommendation.

- Testosterone: Topical (Update for 1/1/15): It was suggested that the Androgel 1% packets become the primary preferred testosterone product. Androgel 1.62% packets and Androgel 1 % and 1.62% pumps would move to non-preferred.

Public Comment: No public comment.

Board Decision: The Board approved the recommendation and requested that for approval of Androgel 1.62% packets there be a trial of 1 % packets and for approval of the pump formulation the patient must have limitations that make use of the packet formulation difficult.

12. General Announcements:

FDA Safety Alerts

- Xolair[®] (omalizumab) – slightly higher risk of cardiovascular/cerebrovascular events: FDA review of safety studies suggests a slightly increased risk of problems involving the heart and blood vessels supplying the brain among patients being treated with the asthma drug Xolair[®] (omalizumab) than in those who were not treated with Xolair[®]. Information about those potential risks was added to the drug label.

Public Comment: No public comment.

Board Decision: None needed.

13. Adjourn: Meeting adjourned at 8:20 p.m.