



---

**Department of Vermont Health Access  
Pharmacy Benefit Management Program  
DUR Board Meeting Minutes: 06/26/2012**

**Board Members:**

**Present:**

Michael Scovner, MD, Chair  
Halle Sobel, MD  
Andy Miller, RPh  
Kim Ladue, NP

Gary Starecheski, RPh  
Lynne Vezina, RPh  
Sommer Zarbock, PharmD

Jaskanwar Batra, MD  
Mark Pasanen, MD  
Joseph Lasek, MD

**Absent:**

Jeanne Greenblatt, MD

Amanda Kennedy, PharmD

**Staff:**

Diane Neal, RPh, MHP  
Stacey Baker, DVHA  
Jennifer Egelhof, DVHA

Nancy Miner, MHP  
Nancy Hogue, PharmD, DVHA  
Melissa Guiles, DVHA

Michelle Sirois, MHP  
Michael Farber, MD, DVHA

**Guests:**

Thomas Currier, Purdue  
James Kokoszyna, Allergan  
Jim Pitt, Lundbeck  
Preeti Kanojia, Janssen  
Kate Whelley McCabe, Assistant  
Attorney General

David Downey, Abbott Labs  
Chris Michaels, Elan  
Heather Thompson, Endo  
John Donovan, Boehringer Ingelheim  
Wendy Morgan, Attorney General's  
Office

Christine Dube, MedImmune  
Jai Persico, Endo  
Larry Rees, Boehringer Ingelheim

Michael Scovner, MD, Chair, called the meeting to order at 6:59 p.m. at the DUR Board meeting site in Williston.

**1. Executive Session:**

- An executive session was held from 6:30 until 7:00 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 May, 2012 meeting minutes were accepted as printed.
- Dr. Joseph Lasek was nominated and unanimously voted as the new Chair of the DUR Board and will begin his term in September 2012.

*Public Comment:* No public comment.

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

- Kate Whelley McCabe, State of Vermont Assistant Attorney General, presented the Prescribed Product Disclosure Report for Fiscal Year 2011 and reviewed the Vermont Gift Ban.

**4. Medical Director Update:** *Michael Farber, M.D., DVHA*

- Clinical Programs Update/Prescriber Comments: Dr. Farber provided information about previous cases for second consideration for the product dronabinol.

**5. Follow-up items from Previous Meeting:** *Diane Neal, RPh, MedMetrics Health Partners (MHP)*

- Xifaxan® in Hepatic Encephalopathy: Discussion continued whether patients should continue to step through lactulose before being granted prior authorization for Xifaxan® for hepatic encephalopathy. Current literature was referenced and the consensus was that it was still appropriate to step through lactulose. It was recommended that there be no changes to the current criteria of step through lactulose prior to authorization of Xifaxan® for the diagnosis of hepatic encephalopathy.

*Public Comment:* No public comment.

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

- Atypical Antipsychotics – Pediatric Use:  
The survey will be sent to prescribers of all current pediatric patients. The survey will need to be completed in order for current patients to be grandfathered on the present antipsychotic. In addition, it was recommended by the Pediatric Antipsychotic Trend Monitoring Group that prior authorization be required once yearly for patients less than 18 years old.

*Public Comment:* No public comment.

**Board Decision:** None required.

- Letter to Prescribers regarding Days' Supply and Early Refill: The Board was provided with a copy of a letter that was sent to Prescribers about limiting days' supply to 30 days for controlled substances and the increase of the refill percentage changing from 75% to 85%. This letter was only sent to prescribers who were currently prescribing controlled substances in greater than 30 day supply.

*Public Comment:* No public comment.

**Board Decision:** None Needed.

- Pharmacy Newsletter: The Board was provided with a copy of the recent DVHA Pharmacy Bulletin which covered many pharmacy related topics including days' supply and early refills.

*Public Comment:* No public comment.

**Board Decision:** None Needed.

**6. RetroDur/Prior Authorization Quality Assurance Analysis:** *Diane Neal, RPh, MHP*  
(Public comment prior to Board action)

- None this meeting

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

**Abbreviated New Drug Review:**

- Duexis<sup>®</sup> (famotidine/ibuprofen) Oral Tablet: It was recommended that Duexis<sup>®</sup> be added to the PDL as Prior Authorization required with the following approval criteria: The patient has had a documented side effect to two or more preferred generic NSAIDs or the patient is not a candidate for therapy with a preferred generic NSAID mono-therapy due to one of the following: the patient is 60 years of age or older, the patient has a history of GI bleed, the patient is currently taking an oral corticosteroid, the patient is currently taking methotrexate and the patient is unable to take ibuprofen and famotidine separately.

*Public Comment:* No public comment.

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

- Opana<sup>®</sup> ER (oxymorphone ER) (Crush Resistant Formulation) Tablet: It was recommended that Opana<sup>®</sup> ER (crush resistant) be added to the PDL as Prior Authorization required with the following approval criteria: The patient has a diagnosis or condition that requires a continuous, around-the-clock analgesic and the patient has had a documented side effect, allergy, or treatment failure to morphine sulfate SR 12 hr and fentanyl patch. A quantity limit of 60 tablets per strength per 30 days was proposed. NOTE: A history of substance abuse does not warrant approval of Opana<sup>®</sup> ER (crush resistant) since a clear advantage of this product over preferred long-acting opioids in this population has not been established.

*Public Comment:* Heather Thompson, Endo Pharmaceuticals - Highlighted some of the attributes of Opana<sup>®</sup> ER (Crush Resistant).

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

**Full New Drug Review:**

- Kalydeco<sup>®</sup> (ivacaftor) Oral Tablet: It was recommended that Kalydeco<sup>®</sup> be added to the PDL as Prior Authorization required with the following approval criteria: The patient has the appropriate diagnosis of Cystic Fibrosis with documented G551D mutation (provided) and the patient age is  $\geq 6$  years. A quantity limit of 60 tablets per 30 days was proposed. Given the cost, recertification is contingent upon documentation of member response.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation with the addition of an initial 3 month approval period with a recertification of 1 year thereafter.

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

- Anticoagulants - Injectable: It was recommended that there be no changes made to the Anticoagulants – Injectable therapeutic class at this time.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved no changes.

- Anticoagulants – Oral: It was recommended to allow Pradaxa<sup>®</sup> for patients with a history of atrial fibrillation, without a trial of warfarin. No other changes to the approval criteria for oral anticoagulants are recommended.

*Public Comment:* Preeti Kanojia, Janssen – Highlighted some of the attributes of Xarelto<sup>®</sup>.

**Board Decision:** The Board approved the above recommendation with one opposition.

- DPP-4 Inhibitors and Combinations (includes review of Janumet XR<sup>®</sup>, Jentadueto<sup>®</sup>): It was recommended that Janumet XR<sup>®</sup> and Jentadueto<sup>®</sup> be added to the PDL as prior authorization required with the following approval criteria: **Janumet XR<sup>®</sup>** - The patient has had an inadequate response with Januvia<sup>®</sup> or metformin/metformin XR monotherapy or the patient has been started and stabilized on Januvia<sup>®</sup> and metformin/metformin XR combination therapy and the patient is unable to take Januvia<sup>®</sup> and metformin/metformin XR as the individual separate agents. There would be a quantity limit of 1 tablet per day. **Jentadueto<sup>®</sup>** - The patient has had an inadequate response with Tradjenta<sup>®</sup> or metformin monotherapy or the patient has been started and stabilized on Tradjenta<sup>®</sup> and metformin combination therapy and the patient is unable to take Tradjenta<sup>®</sup> and metformin as the individual separate agents. There would be a quantity limit of 2 tablets per day.

*Public Comment:* John Donovan/Larry Rees, Boehringer Ingelheim – Available for questions regarding Jentadueto<sup>®</sup>.

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

- Hereditary Angioedema Agents: There were no changes recommended to the current approval criteria for hereditary angioedema agents.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved no changes.

## 9. New Managed Therapeutic Drug Classes:

- None this meeting.

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

*Diane Neal, RPh, MHP*

- Anti-hyperkinesia and Anti-Narcolepsy: ADHD (quantity limits): Many of the medications are available in multiple dosage strengths so quantity limits are proposed to encourage dose consolidation. However, the DUR Board pharmacists pointed out that a number of products have experienced shortages which may have contributed to multiple dosage units per day.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved to limit Strattera to 1 capsule per day and to build clinical criteria for quantity limit overrides for other products in order to review at an upcoming DUR

meeting. Shortages will be explored and quantity limits will not be proposed for those products that are experiencing shortages.

- Multiple Sclerosis Medications (new information Gilenya® and Tysabri®): In light of recent FDA Safety Label changes it is recommended that the approval criteria for Gilenya® be expanded to indicate that the patient has tolerated the first dose under observation for a minimum of 6 hours with hourly pulse and blood pressure measurement and pre and post electrocardiogram. It is also recommended to expand the approval criteria for Tysabri to include an option that the diagnosis is relapsing multiple sclerosis and the patient has a documented side effect, allergy, treatment failure, or contraindication to one preferred drug and has tested negative for anti-JCV antibodies.

*Public Comment:* No public comment.

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

- Nutritional Products: It was proposed that the criteria be expanded to include diagnoses that are associated with malabsorption or maldigestion and those conditions where feeding is difficult. In addition, the definition of pediatric low weight was made less stringent. Criteria for EleCare and EleCare Jr were also proposed. The duration of approval will also be increased to 1 year.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation but added the additional diagnosis of cancer and would like to review at a later time to examine if there is a large increase in utilization. The need for quantity limits will be addressed at a later date.

## **11. General Announcements** *Diane Neal, RPh, MHP*

### **FDA Safety Alerts**

- Aliskiren-Market withdrawal of Valtorna®: The FDA is warning of possible risks when using blood pressure medications containing aliskiren with other drugs called angiotensin converting enzyme inhibitors (ACEIs) and angiotension receptor blockers (ARBs) in patients with diabetes or kidney (renal) impairment. These drug combinations should not be used (are contraindicated) in patients with diabetes. In addition, a new warning is being added to avoid use of these drug combinations in patients with kidney impairment.
- Tysabri® - Drug Safety Communication – Update of Risk Factors for PML: The FDA is informing the public that testing positive for anti-JC virus (JCV) antibodies has been identified as a risk factor for progressive multifocal leukoencephalopathy (PML). PML is a rare but serious brain infection associated with use of Tysabri® (natalizumab) for the treatment of multiple sclerosis (MS) or Crohn's disease.

**12. Adjourn:** Meeting adjourned at 8:50 p.m.

### **Next DUR Board Meeting**

Tuesday, September 11, 2012

6:30 – 8:30 p.m.\*

HP Building, DVHA Conference Room

312 Hurricane Lane, Williston, VT

(Entrance is in the rear of the building)

DVHA DUR Board Minutes 06/26/2012

\* The Board meeting will begin at 6:00 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.