



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 07/15/2014**

Board Members:

Present:

Joseph Lasek, MD, Chair
Amanda Kennedy, PharmD
James Marmar, RPh

Kim Ladue, NP
Janet Farina, RPh

Gary Starecheski, RPh
Jaskanwar Batra, MD

Absent:

Mark Pasanen, MD

Jeanne Greenblatt, MD

Staff:

Diane Neal, RPh, Catamaran
Scott Strenio, MD, DVHA
Carrie Germaine, DVHA
Tom Simpatico, MD, DVHA

Michelle Sirois, Catamaran
Mary Beth Bizzari, RPh, DVHA
Stacey Baker, DVHA
Aaron French, MSN, RN, DVHA

Nancy Miner, Catamaran
Nancy Hogue, PharmD, DVHA
Jennifer Egelhof, DVHA
Jason Pope, DVHA

Guests:

Thomas Algozzine, Novartis
Rod Francisco, Sunovion
Peter Persico, Otsuka
Tom Lerman, J&J

Rita Baglini, APS Healthcare
Judy Kando, Sunovion
Keith White, Genentech

Susan Campbell, Boehringer-Ingelheim
James Kokoszyna, Allergan
Scott Williams, J&J

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 June, 2014 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- Review of Pharmacy Benefit Trend for CY 2013 based on plan review done by Catamaran.
- Update on edit to restrict opioid prescriptions to 5 days' supply for patients also receiving buprenorphine for opiate addiction. Discussions are ongoing within DVHA, legal teams, and VDH regarding confidentiality laws.

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

- Provided an update on Hepatitis C Therapy reviews. Approved 33, deferred 17, no appeals, no fair hearings.

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

- None

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

- Incretin Mimetics: Based on the review of claims data and prior authorization requests, it was recommended that there be no changes to the current DVHA approval criteria at this time.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

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

Abbreviated New Drug Reviews:

- Copaxone[®] (glatiramer acetate) Injection 40mg/ml: See Multiple Sclerosis Agents within Therapeutic Drug Class Periodic Review.
- Xartemis[®] XR (oxycodone/acetaminophen) Oral Extended-Release Tablet: It was recommended that Xartemis[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The diagnosis is acute pain AND the member has had a documented side effect, allergy, or treatment failure to at least two short acting opioids not requiring prior approval, one of which is oxycodone w/acetaminophen AND in addition, the prescriber must provide a compelling clinical reason why an extended release product is required for the treatment of acute pain. A quantity limit of 4 tablets per day was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

Full New Drug Reviews

- Anoro Ellipta[®] (umeclidinium and vilanterol) Inhaler: It was recommended that Anoro Ellipta[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of COPD (not FDA approved for asthma). A quantity limit of 1 inhaler (60 blisters) per 30 days was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Aptiom[®] (eslicarbazepine acetate) Oral Tablet: It was recommended that Aptiom[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient has been started and stabilized on the requested medication (Note: Samples are not considered adequate justification for stabilization.) OR the diagnosis is adjunctive therapy of partial-onset seizures and the patient has had a documented side effect, allergy, treatment failure/inadequate response or a contraindication to at least TWO preferred anticonvulsants, one of which is oxcarbazepine. A quantity limit of 1 tablet per day (200mg, 400mg, or 800mg) and 2 tablets per day (600mg) was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Farxiga[®] (dapagliflozin) Oral Tablet: It was recommended that Farxiga[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient is 18 years of age or older AND the patient has a diagnosis of type 2 diabetes mellitus and has had an inadequate response to diet and exercise alone AND the patient has had a documented side effect, allergy, contraindication, or treatment failure with metformin AND the patient has had a documented side effect, allergy, contraindication or treatment failure to Invokana[®]. A quantity limit of 1 tablet per day was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation with the removal of the requirement to step through Invokana[®].

- Luzu[®] (luliconazole 1%) Topical Cream: It was recommended that Luzu[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient has had a documented side effect, allergy, or treatment failure to at least TWO different preferred generic topical antifungal agents OR the patient has a contraindication that supports the need for a specific product or dosage form of a brand topical antifungal.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Velphoro[®] (sucroferric oxyhydroxide) Oral Chewable Tablet: It was recommended that Velphoro[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient must have a documented side effect, allergy, or inadequate response to one preferred phosphate binder.

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)

- Multiple Sclerosis Agents: It was recommended that Copaxone[®] 40mg be added to the DVHA PDL as prior authorization required with the following approval criteria: Patient has a diagnosis of multiple sclerosis AND the patient has a documented side effect, allergy, treatment failure, or contraindication to

at least one preferred drug (not Copaxone 20mg) AND the patient is unable to tolerate or be compliant with Copaxone 20mg daily dosing. A quantity limit of 12 syringes per 28 days was recommended.

Public Comment: Tom Algozzine, Novartis ~ Highlighted some of the attributes of Gilenya®

Board Decision: The Board unanimously approved the above recommendation.

- Second Generation Antipsychotics for Bipolar Depression (includes review of new indication for Latuda® (lurasidone): It was recommended that Latuda® approval criteria be updated within the DVHA PDL with the following: The patient is pregnant and the diagnosis is schizophrenia/schizoaffective disorder or Bipolar I depression OR the patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization) OR the indication for use is schizophrenia/schizoaffective disorder AND the patient has had a documented side effect, allergy, or treatment failure with at least three preferred products (typical or atypical antipsychotics), one of which is ziprasidone. OR the indication for use is schizophrenia/schizoaffective disorder. AND the patient has had a documented side effect, allergy, or treatment failure with ziprasidone and the prescriber feels that neither risperidone nor quetiapine would be appropriate alternatives for the patient because of pre-existing medical conditions such as obesity or diabetes. OR the indication for use is Bipolar I depression AND the patient has had a documented side effect, allergy, or treatment failure with generic quetiapine OR the indication for use is Bipolar I depression AND the prescriber feels that quetiapine would not be an appropriate alternative for the patient because of pre-existing medical conditions such as obesity or diabetes.

Public Comment: Judy Kando, Sunovion ~ Highlighted some of the attributes of Latuda®

Board Decision: The Board unanimously approved the above recommendation.

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

- 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

- None

12. General Announcements:

FDA Safety Alerts

- Olmesartan: FDA review of cardiovascular risks for diabetics taking hypertension drug not conclusive: The FDA has completed its safety review and has found no clear evidence of increased cardiovascular risks associated with use of the blood pressure medication olmesartan in diabetic patients. As a result, the recommendation for use of olmesartan will remain the same, but they will require information about some of the studies to be included in the drug labels.

Public Comment: No public comment.

Board Decision: None needed.

- OTC Acne Products: FDA warns of rare but serious hypersensitivity reactions with certain over-the-counter topical acne products: The FDA is warning that certain over-the-counter topical acne products can cause rare but serious and potentially life-threatening allergic reactions or severe irritation. These hypersensitivity reactions differ from the local skin irritation that may occur at the product application site.

Public Comment: No public comment.

Board Decision: None needed.

- Testosterone Products: FDA adding general warning to testosterone products about potential for venous blood clots: The FDA is requiring manufacturers to include a general warning in the drug labeling of all testosterone products about the risk of blood clots in the veins.

Public Comment: No public comment.

Board Decision: None needed.

13. Adjourn: Meeting adjourned at 7:57 p.m.

Next DUR Board Meeting

Tuesday, September 16, 2014

6:00 – 8:15 p.m.*

HP Building, DVHA Conference Room

312 Hurricane Lane, Williston, VT

(Entrance is in the rear of the building)

* 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.