VERMONT

Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 09/11/2012

Board Members:
Present:

Joseph Lasek, MD, Chair	Gary Starecheski, RPh	Jaskanwar Batra, MD
Kim Ladue, NP	Amanda Kennedy, PharmD	Mark Pasanen, MD

Absent:

Jeanne Greenblatt, MD	Halle Sobel, MD

Staff:

Diane Neal, RPh, Catamaran	Nancy Miner, Catamaran	Michelle Sirois, Catamaran
Stacey Baker, DVHA	Mary Beth Bizzari, RPh, DVHA	Michael Farber, MD, DVHA
Jennifer Egelhof, DVHA	Melissa Guiles, DVHA	

Guests:

Matt Badalucco, Merck	Elizabeth Brewer, Sanofi	Jeff, Novo Nordisk
Mario Carnovale, Novartis	Justin Bakhshai, Novo Nordisk	Kurt Buckner, Novartis
Gary Karg, Novartis	Jessica Kritzman, Abbott Diabetes Care	Terry Eagan, Teva Respiratory

Joseph Lasek, MD, Chair, called the meeting to order at 6:35 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. 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, 2012 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. DVHA Pharmacy Administration Updates:

- None this meeting as Pharmacy Director absent.

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 products Lyrica® and Cymbalta® used in the treatment of pain.

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

- <u>Atypical Antipsychotic Medications – Pediatric Use:</u> The survey is expected to be mailed to prescribers of all current pediatric patients around October 1, 2012. Prescribers will be given 2 months to return the survey and all current patients will be grandfathered on the present antipsychotic.

Public Comment: No public comment.

Board Decision: None needed.

- <u>Quantity Limits for Janumet XR®:</u> The Board previously approved a quantity limit of one tablet per day for all strengths of Janumet XR®; however, it was determined that for the 50/1000 strength we would need to allow two tablets per day in order to reach the dosage of 100/2000.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

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

- None this meeting

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

Abbreviated New Drug Review:

- <u>Edarbyclor® (azilsartan/chlorthalidone) Oral Tablet</u>: It was recommended that Edarbyclor® be added to the PDL as Prior Authorization required with the criteria for approval being the patient has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization) OR the patient has had a documented side effect, allergy, or treatment failure with a preferred Angiotensin Receptor Blocker (ARB) or ARB combination AND the patient is unable to take the individual components separately. A quantity limit of one tablet per day was recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- <u>Oxecta® (oxycodone) Tablet</u>: It was recommended that Oxecta® be added to the PDL as Prior Authorization required with the criteria for approval being the prescriber provides a clinically valid rationale why the generic immediate-release oxycodone cannot be used AND the member has had a documented side effect, allergy, or treatment failure to at least two other preferred short acting narcotic analgesics. Note: A history of substance abuse does not warrant approval of Oxecta® (oxycodone IR) since a clear advantage of this product over preferred short acting opioids in this population has not been established.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

Full New Drug Review:

- Picato® (ingenol mebutate) Topical Gel: It was recommended that Picato® be added to the PDL as Prior Authorization required with the criteria for approval bring the diagnosis or indication is actinic keratosis AND the patient has had a documented side effect, allergy, contraindication, or treatment failure with a generic topical fluorouracil product OR the patient has a documented side effect, allergy, contraindication or treatment failure with preferred brand Aldara®. Quantity limits were recommended of 3 tubes/30 days for 0.015% and 2 tubes/30 days 0.05%.

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)

- Anti-hyperkinesis and Anti-Narcolepsy: ADHD: It was recommended that there be a quantity limit on Strattera® 10 mg, 18 mg, 25 mg, and 40 mg capsules of two per day and a limit of one per day for the 60 mg, 80 mg and 100 mg capsules based on the FDA approved labeling.

Public Comment: Kurt Buckner, Novartis – Highlighted some of the attributes of Focalin XR®.

Board Decision: The Board unanimously approved the above recommendation but is interested in requiring once daily dosing for all strengths of Strattera® to be discussed at a later meeting.

- Anticonvulsants-Benzodiazepines: It was recommended to add diazepam (dosage forms in addition to rectal gel), Valium®, chlorazepate, and Tranxene-T® to the class table as they have never been listed in this class but should be. The following approval criteria are proposed for Klonopin®, Tranxene-T®, and Valium®: The patient has been started and stabilized on the requested medication OR the patient has had a documented intolerance to the generic equivalent of the requested medication.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Incretin Mimetics (including new drug review of Bydureon®): It was recommended that Bydureon® be added to the PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of type II diabetes mellitus AND the patient is at least 18 years of age 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 or treatment failure to Byetta® Or the patient has been unable to be adherent to or tolerate twice daily dosing of Byetta®. It is proposed that there be a quantity limit of 4 vials per 30 days.

Public Comment: *Justin Bakhshai, Novo Nordisk* – Highlighed some of the attributes of Victoza® and requests that the approval criteria requiring a trial of Byetta® be removed.

Board Decision: The Board unanimously approved the above recommendations with a change in the quantity limit for Bydureon® to allow 4 vials per 28 days and to remove the approval criteria for Victoza®

that requires a trial of Byetta®. The change in criteria for Victoza® will be in effect for January 1, 2013.

- Intranasal Corticosteroids: There were no changes recommended to the current approval criteria for intranasal corticosteroids.

Public Comment: *Terry Eagan, Teva Respiratory* -- Highlighted some of the attributes of QNASL®.

Board Decision: The Board unanimously approved no changes. There will be a review of QNASL® at a later meeting and it is now coded as "new-to-market".

- Ophthalmic Prostaglandin Analogues (includes new drug review of Zioptan®): It was recommended that Zioptan® be added to the PDL as prior authorization required with the criteria for approval being the patient has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization) OR the patient has had a documented side effect, allergy, or treatment failure with generic latanoprost, Lumigan®, and Travatan Z® OR has a sensitivity to preservatives used in ophthalmic preparations. It is also recommended that a trial of an ophthalmic beta-blocker no longer be required as a step prior to the use of any ophthalmic prostaglandin inhibitors. It is recommended to move generic latanoprost to a preferred position. In addition, it is recommended that Lumigan® be moved to a PA required position effective January 1, 2013.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

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, Catamaran

- Scabicides and Pediculicides (includes new drug review of Sklice®): The table was divided into products that are specifically Scabicides and Pediculocides. It was recommended that Natroba® become the preferred branded product after two preferred treatments for lice. It was also proposed that Eurax® moves to PA required and spinosad (compare to Natroba®) and Sklice® are added as PA required.

Public Comment: No public comment.

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

- Synagis® (palivizumab) 2012 Red Book Guideline Update: It is proposed that there be an update of the current approval criteria regarding the role of prophylaxis in infants born at 32-35 weeks of gestation: The criteria is clarified that the infant attends child care OR one or more older siblings (or other child permanently in house) < 5 years of age (multiple births younger than 1 year of age do not qualify).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

11. General Announcements *Diane Neal, RPh, Catamaran*

FDA Safety Alerts

- Ampyra® (dalfampridine) – Drug Safety Communication – Seizure Risk for Multiple Sclerosis Patients: The FDA is updating health care professionals and the public about the risk of seizures in patients with multiple sclerosis (MS) who are starting Ampyra® (dalfampridine). Using information received from post-market adverse event reports, FDA recently evaluated seizure risk in MS patients taking Ampyra® (dalfampridine). The majority of seizures happened within days to weeks after starting the recommended dose and occurred in patients having no history of seizures.

Public Comment: No public comment.

Board Decision: None needed.

- Codeine Use in Certain Children After Tonsillectomy and/or Adenoidectomy: Drug Safety Communication – Risk of Rare, But Life-Threatening Adverse Events or Death: The FDA is reviewing reports of children who developed serious adverse effects or died after taking codeine for pain relief after tonsillectomy and/or adenoidectomy for obstructive sleep apnea syndrome. Recently, three pediatric deaths and one non-fatal but life-threatening case of respiratory depression were documented in the medical literature. These children (ages two to five) had evidence of an inherited (genetic) ability to convert codeine into life-threatening or fatal amounts of morphine in the body. All children had received doses of codeine that were within the typical dose range.

Public Comment: No public comment.

Board Decision: None needed.

- Revatio® (sildenafil): Drug Safety Communication – Recommendation Against Use in Children: The FDA is recommending that Revatio® (sildenafil) not be prescribed to children (ages 1 through 17) for pulmonary arterial hypertension (PAH: high pressure in the blood vessels leading to the lungs). This recommendation against use is based on a recent long-term clinical pediatric trial showing that: (1) children taking a high dose of Revatio® had a higher risk of death than children taking a low dose and (2) the low doses of Revatio® are not effective in improving exercise ability. Most deaths were caused by pulmonary hypertension and heart failure, which are the most common causes of death in children with PAH.

Public Comment: No public comment.

Board Decision: The Board unanimously approved to add clinical criteria that restricts use to members greater than 17 years old.

12. Adjourn: Meeting adjourned at 8:05 p.m.

Next DUR Board Meeting
Tuesday, October 30, 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)

* 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.