



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 05/14/2013**

Board Members:

Present:

Jaskanwar Batra, MD
Jeanne Greenblatt, MD
Amanda Kennedy, PharmD

Gary Starecheski, RPh
James Marmar, RPh
Joseph Lasek, MD, Chair

Mark Pasanen, MD
Janet Farina, RPh
Halle Sobel, MD

Absent:

Kim Ladue, NP

Mario Sarafini, DO

Staff:

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

Michelle Sirois, Catamaran
Mary Beth Bizzari, RPh, DVHA
Jennifer Herwood, DVHA

Nancy Miner, Catamaran
Nancy Hogue, PharmD, DVHA

Guests:

Rita Baglini, APS
David Downey, Abbott
Wendy Pollinger, Eli Lilly
Scott Williams, J&J
Timothy Birner, Otsuka

Jennifer Buttle, Merck
Robert McSparren, BMS
Jason Strempek, Forest
Bruce Sill, BMS
Kara Sperandeo, Forest

Mario Carnovale, Novartis
Peter Persico, Otsuka
William Mullen, Reckitt Benckiser
Sophia Tashkovski, Takeda

Joseph Lasek, MD, Chair, called the meeting to order at 6:32 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 April, 2013 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- Mary Beth Bizzari, Pharmacy Unit, DVHA, gave an update on the Psychotherapeutic Monitoring Quality Improvement Collaborative (PMQIC). This is the grant program looking at the use of psychotherapeutic medications for children in foster care in collaboration with DCF and DMH.

- Jennifer Herwood, Clinical Unit, DVHA, discussed the Center for Evidence Based Policy activities. DVHA is working with Oregon Health and Science University to help adopt principles and policies to help guide benefit design.

4. Medical Director Update:

- None this meeting.

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

- **Methadone for Chronic Pain:** It was recommended that methadone move to prior authorization required status with the following approval criteria: The patient has a diagnosis of moderate to severe pain, requiring a continuous, around-the-clock analgesic for an extended period of time and the patient has been started and stabilized on the requested medication or the patient has had a documented side effect, allergy, or treatment failure to morphine sulfate SR 12 hr and generic fentanyl patch and the initial methadone daily dose does not exceed 40 mg. A letter will be sent to prescribers and current users will be grandfathered.

Public Comment: No public comment.

Board Decision: The Board unanimously approved a few changes to the recommendation. They voted to remove the requirement to fail fentanyl patch treatment, as well as, to change the initial methadone dose to 30 mg.

- **Suboxone[®] Tablet to Film Transition:** An update on the process of transitioning tablet users who do not have a previous claim for film in their profile over to film was discussed. Many prescribers do not appear to have addressed this issue with patients until the patient goes to the pharmacy and their tablet prescription now rejects for prior authorization.

Public Comment: No public comment.

Board Decision: None needed.

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

- **Second Reconsiderations by Medical Director:** A draft form was submitted to the Board for comments. This form would be used by prescribers who wish to have a second reconsideration by the Medical Director of a denied prior authorization request. It is designed to provide more clinical information to DVHA for consideration.

Public Comment: No public comment.

Board Decision: None needed. Dr. Lasek suggested that more room was required for several fields and the form would probably be expanded to 2 pages.

- **Xyrem[®] (sodium oxybate):** A review of Xyrem[®] use and PA requests for July – December 2012 was presented. It was recommended that the clinical criteria be updated to the following: The patient has a diagnosis of narcolepsy with cataplexy and the patient will not be undergoing concomitant treatment with sedative hypnotic agents and the patient does not have succinic semialdehyde dehydrogenase

deficiency and the patient has a documented side effect, allergy, treatment failure, or contraindication to at least two agents from the following classes: selective serotonin inhibitor (SSRI), venlafaxine, or tricyclic antidepressant (e.g. protriptyline, clomipramine). In recognition of the maximum recommended daily dose (9 grams), it is proposed to add the following quantity limit for Xyrem[®]: 540 ml/30 days. It is also recommended to shorten the approval duration to six months in order to evaluate for clinical response and drug interactions.

Public Comment: No public comment.

Board Decision: The Board chose not to vote on the above recommendation at this time. They would like to have a neurologist or sleep specialist review the criteria prior to a vote.

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

Abbreviated New Drug Reviews:

- Delzicol[®] (mesalamine delayed release) Oral Capsule: It was recommended that Delzicol[®] be added to the PDL as a preferred product with a quantity limit of 6 capsules per day.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Xyrem[®] (sodium oxybate) Oral Solution: See above in RetroDUR/DUR section.

Full New Drug Reviews:

- Aubagio[®] (teriflunomide) Oral Tablet: It was recommended that Aubagio[®] be added to the PDL as prior authorization required with the following approval criteria: The patient is at least 18 years of age or older and the patient has a diagnosis of relapsing forms of multiple sclerosis (relapsing-remitting multiple sclerosis and progressive-relapsing multiple sclerosis) and the patient does not have any of the following contraindications to teriflunomide: severe hepatic impairment, current treatment with leflunomide (Arava[®]), patients who are pregnant or women of childbearing potential not using reliable contraception. A quantity limit of 1 tablet/day, maximum 28 day supply per fill was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Linzess[®] (linaclotide) Oral Capsule: It was recommended that Linzess[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of chronic idiopathic constipation (CIC) (145mcg capsules) or the patient has a diagnosis of irritable bowel syndrome with constipation (IBS-C) (290mcg capsules) and the patient has had documented treatment failure to lifestyle and dietary modification (increased fiber and fluid intake and increased physical activity) and the patient has had documented side effect, allergy, or treatment failure to a one week trial each of at least two preferred laxatives from the Bulk-Producing Laxative or Osmotic Laxative categories. A quantity limit of 1 capsule per day was proposed.

Public Comment: Kara Sperandeo ~ Forest – Highlighted some of the attributes of Linzess[®].

Board Decision: The Board unanimously approved the above recommendation with the addition of criteria limiting approval to members greater than 17 years old.

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

New Procedure for Categories with No Changes Recommended: At future meetings, if there are no recommended changes, the group of classes will be approved together. However, the DUR Board members and the public will be given the opportunity to comment on any of the classes even if no changes are proposed.

- Anti-Diabetics: Alpha Glucosidase Inhibitors: There were no changes recommended to the current approval criteria or PDL status for this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Anti-Diabetics: Biguanides: There were no changes recommended to the current approval criteria or PDL status for this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Anti-Diabetics: Dipeptidyl peptidase (DPP-4) Inhibitors: There were no changes recommended to the current approval criteria or PDL status for this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Anti-Diabetics: Meglitinides: There were no changes recommended to the current approval criteria or PDL status for this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Anti-Diabetics: Sulfonylureas: There were no changes recommended to the current approval criteria or PDL status for this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Anti-Diabetics: Thiazolidinediones: There were no changes recommended to the current approval criteria or PDL status for this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Anti-Diabetics: Incretin Mimetics & Amylinomimetics: There were no changes recommended to the current approval criteria, quantity limits or PDL status for this category.

Public Comment: Bruce Hill ~ Bristol Myers Squibb – Highlighted some of the attributes of Byetta® and Bydureon®.

Board Decision: The Board unanimously approved the above recommendation.

- Anti-Diabetics: Insulin: There were no changes recommended to the current approval criteria or PDL status for this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Anti-Infectives: Cephalosporins – 1st Generation: There were no changes recommended to the current approval criteria or PDL status for this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Anti-Infectives: Cephalosporins 3rd Generation: There were no changes recommended to the current approval criteria or PDL status for this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Anti-Infectives: Macrolides/Ketolides: There were no changes recommended to the current approval criteria or PDL status for this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Constipation: Chronic, IBS-C, or Opioid Induced: There were no changes recommended to the current approval criteria or PDL status for this category. See discussion of Linzess® above.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Phosphodiesterase-4 Inhibitors: There were no changes recommended to the current approval criteria or PDL status for this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Pulmonary: Beta Agonists and Anticholinergic Combinations: There were no changes recommended to the current approval criteria or PDL status for this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Smoking Cessation Agents: There were no changes recommended to the current approval criteria or PDL status for this category.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

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

- Pediatric Antipsychotic Medications: It was recommended that criteria be modified to address the need to be able to prescribe risperidone and Abilify[®] for the diagnosis of autism with aggression and/or irritability or intellectual disability with aggression and/or irritability. The general target symptom of aggression will be removed. A prior authorization form to support PA requests for pediatric antipsychotic medications is being developed for prescribers.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation with changes to listed target symptoms and diagnoses.

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

FDA Safety Alerts

- Potiga[®] (ezogabine): Drug Safety Communication – Linked to Retinal Abnormalities and Blue Skin Discoloration: FDA is warning the public that Potiga[®] can cause blue skin discoloration and eye abnormalities characterized by pigment changes in the retina.

Public Comment: No public comment.

Board Decision: None needed.

- Samsca[®] (tolvaptan): Drug Safety Communication – FDA Limits Duration and Usage Due to Possible Liver Injury Leading to Organ Transplant or Death: The FDA has determined that the drug

should not be used for longer than 30 days and should not be used in patients with underlying liver disease because it can cause liver injury, potentially requiring liver transplant or death.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the addition of a duration of therapy limit of 30 days to Samsca[®].

- Valproate Anti-Seizure Products: Drug Safety Communication- Contraindicated for Pregnant Women for Prevention of Migraine Headaches: FDA is advising that anti-seizure medication valproate sodium and related products, valproic acid and divalproex sodium are contraindicated and should not be taken by pregnant women for the prevention of migraine headaches.

Public Comment: No public comment.

Board Decision: None needed

12. Adjourn: Meeting adjourned at 8:33 p.m.

Next DUR Board Meeting

Tuesday, July 30, 2013

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.