



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 03/11/2014**

Board Members:

Present:

Joseph Lasek, MD, Chair
James Marmar, RPh

Gary Starecheski, RPh
Kim Ladue, NP

Mark Pasanen, MD
Amanda Kennedy, PharmD

Absent:

Jaskanwar Batra, MD

Jeanne Greenblatt, MD

Janet Farina, RPh

Staff:

Diane Neal, RPh, Catamaran
Jennifer Egelhoff, DVHA
Carrie Germaine, DVHA
Stacey Baker, DVHA

Michelle Sirois, Catamaran
Mary Beth Bizzari, RPh, DVHA
Thomas Simpatico, MD, DVHA
Aaron French, MSN, RN, DVHA

Nancy Miner, Catamaran
Nancy Hogue, PharmD, DVHA
Scott Strenio, MD, DVHA

Guests:

Rita Baglini, APS Healthcare
David Downey, Abbott
Geoff McIntosh, Abbvie

Timothy Chatas, UCB
Wendy Pollinger, Eli Lilly

Kristen Chopas, Gilead
Scott Williams, J&J

Joseph Lasek, MD, Chair, called the meeting to order at 6:15p.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 January, 2014 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- DVHA will be entering into a pilot project voted in the last legislature. The purpose is to limit prior authorization requirements for a select group of providers or a select group of drugs (ie: proton pump inhibitors). They will be measuring the outcome of utilization changes and cost.

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

- Dr. Strenio shared information about a dental prescriber with whom DVHA worked to curtail excessive prescribing of opiates.

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

- Oxycodone IR/Hydromorphone IR Retrospective Drug Utilization Review: It was proposed that initial fills of oxycodone IR and hydromorphone IR be limited to a maximum of 14 days' supply and that there be a limit on dosage units per day of 12 units for oxycodone IR and 16 units for hydromorphone IR.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

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

- None this meeting

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

- Hepatitis C Medications: The AASLD guidelines and FDA approved indications for Hepatitis C medication therapy (Olysio[®] and Sovaldi[®]) along with feedback from prescriber groups at FAHC and DHMC was discussed. It was felt that certain patients (depending on clinical status) would be in more urgent need of treatment than others. It was proposed that the Clinical Call Center evaluate certain requests for prior authorization (depending on genotype and previous therapy) and that the remainder would be evaluated by the Medical Director.

Public Comment: No public comment.

Board Decision: The Board was concerned that based on the cost of these therapies that it would be preferable for the DVHA Medical Director evaluate all prior authorization requests. A new form to be completed by the prescriber to collect clinical data specific to each patient will be developed as well as a new Specialty Pharmacy order form.

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

New to Market:

- Zohydro[®] ER (hydrocodone) - Update: A coalition of prescribers, addiction experts, and law enforcement are urging FDA to revoke approval of Zohydro[®] ER. This is an extended release formulation of hydrocodone without abuse deterrent properties.

Public Comment: No public comment.

Board Decision: None needed.

Abbreviated New Drug Reviews:

- Epaned[®] (enalapril) Oral Solution: It was recommended that Epaned[®] be added to the DVHA PDL as preferred for children < 12 years old and as prior authorization required for patients ≥ 12 years old with the following approval criteria: The patient has a requirement for an oral liquid dosage form (ie: swallowing disorder, inability to take oral medications).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Esomeprazole[®] Strontium (esomeprazole strontium) Oral Capsule: It was recommended that Esomeprazole[®] be added to the PDL as prior authorization required with the following approval criteria: The member has had a documented side effect, allergy, or treatment failure to omeprazole RX 20 mg or 40 mg generic capsules AND pantoprazole generic tablets. A quantity limit of one capsule per day was recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Onfi[®] (clobazam) Oral Suspension: It was recommended that Onfi[®] Oral Suspension be added to the 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 or indication is adjunctive treatment of Lennox-Gastaut Syndrome AND the patient has had a documented side effect, allergy, treatment failure/inadequate response or a contraindication to at least TWO preferred anticonvulsants used for the treatment of Lennox-Gastaut syndrome (topiramate, lamotrigine, valproic acid) OR the diagnosis or indication is adjunctive treatment of refractory epilepsy (may include different types of epilepsy) AND the patient has had a documented side effect, allergy, treatment failure/inadequate response or a contraindication to at least THREE preferred anticonvulsants. A quantity limit of 16 ml/day was recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Simponi[®] (golimumab) IV Infusion (Rheumatoid Arthritis): It was recommended that Simponi Aria[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of RA and has already been stabilized on the requested medication OR the patient age is > 18 years AND the diagnosis is RA and the patient has documentation of an inadequate response, adverse reaction or allergic response to methotrexate, or if methotrexate is contraindication, at least 1 DMARD (other DMARDs include leflunomide, sulfasalazine, gold, antimalarials, minocycline, D-penicillamine, azathioprine, cyclophosphamide and cyclosporine) AND the patient has not responded adequately to Simponi[®] subcutaneous AND the prescriber must provide a clinically valid reason why either Humira[®] or Enbrel[®] cannot be used.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Simponi[®] (golimumab) Subcutaneous (100mg dose for Ulcerative Colitis): It was recommended that Simponi[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of ulcerative colitis and has already been stabilized on the requested medication OR the patient age is > 18 years AND the diagnosis is ulcerative colitis and has demonstrated corticosteroid dependence or has had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine AND the prescriber must provide a clinically valid reason why Humira[®] cannot be used. For each immunomodulator disease category where Simponi[®] may be used, the dosage strength appropriate for the indication was specified.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Trokendi XR[®] (topiramate) Extended Release Oral Capsule: It was recommended that Trokendi XR[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has been unable to be compliant with or tolerate twice daily dosing of immediate release topiramate. Quantity limits of 2 capsules/day (200 mg) and one capsule/day (all other strengths) were recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

Full New Drug Reviews:

- Brisdelle[®] (paroxetine) Oral Capsule: It was recommended that Brisdelle[®] be added to the PDL as prior authorization required with the following approval criteria: The indication for use is moderate to severe vasomotor symptoms (VMS) associated with menopause. AND the patient has tried and failed generic paroxetine. A quantity limit of one capsule per day was recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation. The Board recommended that this drug reside in the Antidepressants: SSRI category.

- Mirvaso[®] (brimonidine) Topical Gel: It was recommended that Mirvaso[®] be listed as “not covered” under limitations. Skin redness associated with rosacea is considered a cosmetic indication. Medications used for cosmetic purposes are excluded from coverage.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Olysio[®] (simeprevir) Oral Capsule: See Hepatitis C therapeutic class review above.

Public Comment: No public comment.

Board Decision: None needed.

- Sovaldi® (sofosbuvir) Oral Tablet: See Hepatitis C therapeutic class review above.

Public Comment: No public comment.

Board Decision: None needed.

9. Clinical Update: New/Updated Clinical Guidelines: Diane Neal, RPh, Catamaran
(Public comment prior to Board action)

- American Academy of Neurology (AAN) Guidelines on Stroke Prevention in Nonvalvular Atrial Fibrillation (NVAf):

Deferred until next meeting.

10. New Managed Therapeutic Drug Classes:

- None

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

- None

12. General Announcements:

FDA Safety Alerts

- FDA to review heart failure risk with diabetes drug saxagliptin (marketed as Onglyza® and Kombiglyze® XR): The FDA has requested clinical trial data from the manufacturer of saxagliptin to investigate a possible association between use of these type 2 diabetes drugs and heart failure.

Public Comment: No public comment.

Board Decision: None needed.

- FDA evaluating risk of stroke, heart attack, and death with FDA-approved testosterone products: The FDA is investigating the risk of stroke, heart attack, and death in men taking FDA-approved testosterone products. At this time, FDA has not concluded that FDA-approved testosterone treatment increases the risk of stroke, heart attack, or death. Health care professionals should consider whether the benefits of FDA-approved testosterone treatment is likely to exceed the potential risks of treatment.

Public Comment: No public comment.

Board Decision: None needed.

13. Adjourn: Meeting adjourned at 8:07 p.m.

Next DUR Board Meeting

Tuesday, April 15, 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.