



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 06/03/2014**

Board Members:

Present:

Joseph Lasek, MD, Chair
Amanda Kennedy, PharmD

Kim Ladue, NP
Janet Farina, RPh

Mark Pasanen, MD
Jaskanwar Batra, MD

Absent:

James Marmar, RPh

Jeanne Greenblatt, MD

Gary Starecheski, RPh

Staff:

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

Michelle Sirois, Catamaran
Mary Beth Bizzari, RPh, DVHA
Stacey Baker, DVHA

Nancy Miner, Catamaran
Nancy Hogue, PharmD, DVHA
Jason Fay, Intern, ACPHS

Guests:

Mike Ouellette, GHS
Rita Baglini, APS
Scott Williams, J&J
Dan O'Connell, Gilead

Karen Wheeler, GHS
Timothy Chatas, UCB
Wolfgang Zeigenhagen, Genetech

Thomas Algozzine, Novartis
Wendy Pollinger, Eli Lilly
Brian Stwalley, Forest

Joseph Lasek, MD, Chair, called the meeting to order at 6:14 PM 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 April, 2014 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- An introduction was made to Goold Health Systems, Pharmacy Benefit Manager to take effect on January 1, 2015.

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

- Provided an update on Hepatitis C Therapy reviews. Approved 19, deferred 11.

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

- Hepatitis C Medications – older agents (remove) and viral load at 4 weeks with newer agents: Jason Fay, Pharmacy Intern, Albany College of Pharmacy, presented a look at viral load at 4 weeks with Sovaldi® treatment. Also, as Incivek and Victrelis are no longer the standard of care for hepatitis C, it was proposed that the products be moved to a non-preferred status on the DVHA PDL with the following approval criteria: The diagnosis or indication for the requested medication is hepatitis C (genotype 1) AND The DVHA Medical Director will review the case details to determine eligibility for requested medication.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Methadone – Letter to prescribers: The Board was provided a copy of a letter that was sent to prescribers of methadone. Methadone moves to PA required 7/8/2014 as previously approved by the DUR Board. Initial starting doses will be limited to 30 mg/day. Current users are grandfathered until 1/1/2015 at which time a PA will be required.

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)

- Triptans for Migraine/Quantity Limits and Multiple Agents: A review of triptan prescribing and quantity limits was performed. There had been some concern that rather than obtain a PA to exceed quantity limits, patients were being prescribed multiple triptans. From December 1, 2013 to February 28, 2014, there were a total of 1,182 unique utilizers, resulting in 1,797 total paid claims and a total plan cost of \$165,007.99. The average monthly cost per prescription was \$91.82. Out of the 1,182 unique utilizers over the three month time period, a total of six members (0.5%) were identified with more than one paid claim for triptans for at least two months. Of these six members, three members had recent pharmacy claims for agents that may potentially be used for migraine prophylaxis such as amitriptyline and topiramate. Based on the review of claims data and only six out of 1,182 members being identified with more than one paid claim for triptans for at least two months, no changes to the current quantity limit criteria for triptans are recommended 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:

- Aerospan® (flunisolide) Inhalation Aerosol: It was recommended that Aerospan® be added to the DVHA PDL as preferred. A quantity limit of two inhalers (17.8gm) per 30 days was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Noxafil[®] (posaconazole) Oral Delayed-Release Tablet: It was recommended that Noxafil[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of HIV/immunocompromised status (neutropenia secondary to chemotherapy, hematopoietic stem cell transplant recipients) AND Noxafil[®] is being used for the prevention of invasive Aspergillosis/Candida infections OR the patient is completing a course of therapy with the requested medication that was initiated in the hospital. A quantity limit of 93 tablets per 30 days was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Otrexup[®] (methotrexate) Subcutaneous Single-Dose Auto-Injector: It was recommended that Otrexup[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA) or psoriasis AND the patient has had an inadequate response or intolerance to an oral and non-auto-injector injectable methotrexate. A quantity limit of 4 syringes (1.6ml) per 28 days was proposed.

Public Comment: No public comment.

Board Decision: The Board asked that the criteria be reworded to read: The patient has a diagnosis of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA) or psoriasis AND the patient has been intolerant to oral methotrexate AND the patient has been unable to be compliant with a non-auto-injector form of injectable methotrexate (includes difficulty with manual dexterity).

- Versacloz[®] (clozapine) Oral Suspension: It was recommended that Versacloz[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient has a medical necessity for a non-solid oral dosage form and is unable to use clozapine orally disintegrating tablets. A quantity limit of 18ml (900mg) per day was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Zorvolex[®] (diclofenac) Oral Capsule: It was recommended that Zorvolex[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient has had a documented intolerance to diclofenac tablets AND the patient has had a documented side effect, allergy, or treatment failure to four or more preferred generic NSAIDs. A quantity limit of 3 capsules per day was proposed.

Public Comment: No public comment.

Board Decision: The Board approved the above recommendation with one vote opposed.

Full New Drug Reviews

- Fycompa[®] (perampanel) Film Coated Oral Tablet: It was recommended that Fycompa[®] 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. A quantity limit of 1 tablet per day was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Opsumit[®] (macitentan) Oral Tablet: It was recommended that Opsumit[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of PAH WHO Group 1 with NYHA Functional Class II or III AND the patient is not pregnant AND Female patients have been enrolled in the Opsumit[®] REMS program. A quantity limit of 1 tablet per day was proposed.

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)

- Fentanyl Immediate Release Products (includes review of Lazanda[®] (fentanyl nasal spray)): It was recommended that Lazanda[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: Indication of cancer breakthrough pain (no approval for acute pain or postoperative pain) AND documentation that the patient is opioid tolerant (oral morphine \geq 60mg/day, transdermal fentanyl 25mcg/hr, oral oxycodone $>$ 30mg/day, oral hydromorphone $>$ 8mg/day or an equianalgesic dose of another opioid for \geq 1 week) AND the patient is on a long-acting opioid formulation AND the patient is 18 years of age or older AND the prescriber is registered in the Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access Program (<https://tirfremssaccess.com/tirfui/remss/home.action>) AND the patient has had a documented treatment failure with or intolerance to two of the following three immediate-release breakthrough pain treatment options: morphine, hydromorphone, or oxycodone OR the patient is unable to use tablet or liquid formulations.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation. The Board requested that the Therapeutic Class name within the PDL be changed from Narcotics to Opioids.

- Immunomodulators (new drug formulation – Actemra[®] (tocilizumab) Subcutaneous Prefilled Syringe: It was recommended that Actemra[®] Subcutaneous be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of RA and has already been stabilized on Actemra[®] Subcutaneous OR Patient age is $>$ 18 years AND diagnosis is RA and patient has documentation of an inadequate response, adverse reaction, or allergic response to methotrexate,

sulfasalazine, gold, antimalarials, minocycline, D-penicillamine, azathioprine, cyclophosphamide, and cyclosporine) AND the prescriber must provide a clinically valid reason why either Humira[®] or Enbrel[®] cannot be used. The patient must have had an inadequate response to one or more TNF inhibitors. A quantity limit of 4 syringes (3.6ml) per 28 days was proposed.

Public Comment: No public comment.

Board Decision: The Board asked that the started and stabilized criteria also include the intravenous formulation of Actemra and then otherwise 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

- Analgesics: Long Acting Narcotics (new FDA language for indication): The new FDA indication language for long acting narcotics was proposed to be included in the clinical criteria to read “The patient has a diagnosis of severe pain that requires daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate”.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation. The Board requested that the Therapeutic Class name within the PDL be changed from Narcotics to Opioids.

- Alzheimer’s Agents: Namenda[®] XR – manufacturer to discontinue Namenda[®] IR: Due to a business decision by the manufacturer, immediate release Namenda[®] will no longer be available later this year. It was recommended that Namenda[®] XR be moved to a preferred position from PA required so that members may still be able to access a Namenda[®] product without PA.

Public Comment: *Brian Stwalley ~ Forest* –Highlighted some of the attributes of Namenda[®] XR

Board Decision: The Board unanimously approved the above recommendation.

12. General Announcements:

FDA Safety Alerts

- Epidural Corticosteroid Injection: Drug Safety Communication – Risk of Rare But Serious Neurologic Problems: The FDA is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death.

Public Comment: No public comment.

Board Decision: None needed.

- Eszopiclone Containing Sleep Aids: Drug Safety Communication – Can Cause Next-Day Impairment – Recommended 1mg Starting Dose: The FDA is warning that the insomnia drug Lunesta[®] (eszopiclone) can cause next-day impairment of driving and other activities that require alertness. They have decreased the recommended starting dose of Lunesta[®] to 1mg at bedtime.

Public Comment: No public comment.

Board Decision: None needed. The Board would like a RetroDUR done for zolpidem initial doses pre/post FDA Alert. This will be a possible student project for the fall. The DUR Board would also like to review how many members refill their insomnia drug each month (continuous use).

- FDA Drug Safety Communication: FDA Study of Medicare Patients Finds Risks Lower for Stroke and Death but Higher for Gastrointestinal Bleeding with Pradaxa[®] Compared to Warfarin: The FDA recently completed a review of a study in Medicare patients comparing Pradaxa to the blood thinner warfarin for risk of ischemic or clot-related stroke, bleeding in the brain, major gastrointestinal (GI) bleeding, myocardial infarction (MI), and death.

Public Comment: No public comment.

Board Decision: None needed.

12. Adjourn: Meeting adjourned at 8:00 p.m.

Next DUR Board Meeting

Tuesday, July 15, 2014

6:15 – 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.