



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 12/10/2013**

Board Members:

Present:

Jaskanwar Batra, MD
Joseph Lasek, MD, Chair
James Marmar, RPh

Gary Starecheski, RPh
Jeanne Greenblatt, MD
Kim Ladue, NP

Mark Pasanen, MD
Janet Farina, RPh

Absent:

Halle Sobel, MD

Mario Sarafini, DO

Amanda Kennedy, PharmD

Staff:

Diane Neal, RPh, Catamaran
Jennifer Egelhoff, DVHA
Carrie Germaine, DVHA
Susan Drollette, ACP Intern

Michelle Sirois, Catamaran
Mary Beth Bizzari, RPh, DVHA
Thomas Simpatico, MD, DVHA

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

Guests:

Rick Angeli, Merck
James Kokoszyna, Allergan
Stephen Griffee, Novartis

Rita Baglini, APS Healthcare
Danielle Moon, Merck
Scott Ebersol, Merck

Kristen Chopas, Gilead
Wolfgang Zeigenhagen, Genentech

Joseph Lasek, MD, Chair, called the meeting to order at 6:37p.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 October, 2013 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- An overview was given of the DVHA Plan Review of the Pharmacy Program for SFY 2013 that was presented by Catamaran to DVHA in November, 2013.
- Introduction was made of Albany College of Pharmacy Intern, Susan Drollette.

4. **Medical Director Update:**

- Introduction was made of the new Medical Director, Dr. Scott Strenio.
- Brief overview given by Dr. Tom Simpatico (CMO) of UVM Leveraged Pilots. These initiatives are being done with the DVHA CURB (Clinical Utilization Review Board) and UVM.

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

- **Buprenorphine and Opiates:** DVHA is following up with the policy group on whether prior authorizations for various medications (either buprenorphine products for opiate addiction or opiates) that are in place can be adjusted based on more current therapy. A letter to prescribers is planned to explain the 5-day edit for patients who are on buprenorphine products for opiate addiction and opiates (only 5 day supply overlap will be allowed).

Public Comment: No public comment.

Board Decision: None required.

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

- **Opiate Analgesics: Review of Clinical Guidelines and Summary of Edits/Approaches from other State Medicaid Programs:** Susan Drollette, Pharmacy Intern, Albany College of Pharmacy, presented a review of guidelines for treatment of chronic pain, an overview of DVHA opiate analgesic criteria, and the criteria used in other States Medicaid programs.

Public Comment: No public comment.

Board Decision: The Board suggested a future RetroDur on oxycodone IR and hydromorphone IR.

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

Abbreviated New Drug Reviews:

- **Desvenlafaxine[®] ER, Khedezla[®] 24hr Oral Tablet:** It was recommended that Desvenlafaxine[®] ER and Khedezla[®] 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 inadequate response to at least 2 different antidepressants from the SSRI, SNRI, and/or Miscellaneous Antidepressant categories, one of which must be venlafaxine ER capsule (may be preferred or non-preferred) AND the patient has had a documented intolerance with Pristiq[®]. There will be a quantity limit of 1 tablet per day.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- **Forfivo[®] XL (bupropion) Extended Release Oral Tablet:** It was recommended that Forfivo[®] XL be added to the PDL as prior authorization required with the following approval criteria: The patient is unable to take the equivalent dose as generic bupropion XL. There will be a quantity limit of 1 tablet per day.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Lyrica[®] (pregabalin) Oral Solution: It was recommended that Lyrica[®] Oral Solution be added to the PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of epilepsy OR the patient has had a documented side effect, allergy, or treatment failure to TWO drugs in the tricyclic antidepressant (TCA) class and/or anticonvulsant class, if the medication is being used for neuropathic pain OR the patient has had a documented side effect, allergy, or treatment failure to TWO drugs from the following: gabapentin, tricyclic antidepressant, SSRI antidepressant, SNRI antidepressant, miscellaneous antidepressant, cyclobenzaprine, or Savella[®], if medication is being used for fibromyalgia. (this indication not processed via automated step therapy) AND the patient is unable to use Lyrica[®] capsule (eg. swallowing disorder).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Prolensa[®] (bromfenac 0.07%) Ophthalmic Solution: It was recommended that Prolensa[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has had a documented side effect, allergy, or treatment failure to Acular[®] or Acular LS[®].

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Simbrinza[®] (brinzolamide 1%/brimonidine 0.2%) Ophthalmic Suspension: It was recommended that Simbrinza[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has had a documented treatment failure with an ophthalmic product of either an alpha adrenergic agent or a carbonic anhydrase inhibitor.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Zenzedi[®] (dextroamphetamine) Oral Tablet: It was recommended that Zenzedi[®] 2.5 mg and 7.5 mg be added to the PDL as prior authorization required with the following approval criteria: The prescriber provides clinical rationale explaining why other generic dextroamphetamine oral tablets products are not suitable alternatives.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Procentra[®], dextroamphetamine Oral Solution: It was recommended that Procentra[®] and dextroamphetamine oral solution be added to the PDL as prior authorization required with the following approval criteria: The patient has a medical necessity for an oral liquid dosage form (eg. swallowing disorder) AND if the request is for Procentra[®], the patient has a documented intolerance to the generic equivalent.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

Full New Drug Reviews:

- Liptruzet[®] (ezetimibe/atorvastatin) Oral Tablet: It was recommended that Liptruzet[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has had an inadequate response to atorvastatin or Crestor[®]. A quantity limit of 1 tablet per day is proposed.

Public Comment: Scott Ebersol ~ Merck – Highlighted some of the attributes of Liptruzet[®].

Board Decision: The Board unanimously approved the above recommendation.

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

(Public comment prior to Board action)

- New Cholesterol Treatment Guidelines Released: These guidelines (2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines) classify statins as high intensity, moderate intensity and low intensity. Depending on risk factors, particular intensity statins are recommended. This will require a change in structure of the statin class.

Public Comment: No public comment.

Board Decision: The Board would like to bring this topic back to the next meeting to discuss further.

9. Therapeutic Drug Classes-Periodic Review: Diane Neal, RPh, Catamaran

(Public comment prior to Board action)

- Acne Medications: Topical: No changes were recommended to preferred drugs or clinical criteria in either the topical anti-infectives or topical retinoids.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Anti-hypertensives: Angiotensin Converting Enzyme (ACE) Inhibitors and Combinations: No changes were recommended to preferred drugs or clinical criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Anti-hypertensives: Angiotensin Receptor Blockers and Combinations: No changes were recommended to preferred drugs or clinical criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Gastrointestinal: H2 Receptor Antagonists: No changes were recommended to preferred drugs or clinical criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Otic: Anti-Infectives: No changes were recommended to preferred drugs or clinical criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Renal: Phosphate Binders: No changes were recommended to preferred drugs or clinical criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

10. New Managed Therapeutic Drug Classes:

- None

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

Diane Neal, RPh, Catamaran

- Anti-Infectives: Antivirals: Influenza Vaccines: 2013-2014 vaccine versions were added to the table including the quadrivalent vaccines. Also, criteria for Flucelvax[®] and Flublok[®] were proposed as these will require PA.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Ilaris[®] (canakinumab) Injection SJIA (new FDA approved diagnosis): This was deferred until next meeting due to new guidelines.

Public Comment: Stephen Griffie ~Novartis – Highlighted some of the attributes of Ilaris[®].

Board Decision: None needed.

- Makena[®] (hydroxyprogesterone) Injection: It was recommended that the approval criteria for Makena[®] be updated to allow approval starting up to 27 weeks gestation based on the Society for Maternal-Fetal Medicine (SMFM) publications for Preterm Birth Prevention.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

12. General Announcements:

FDA Safety Alerts

- Acetaminophen: Drug Safety Communication – Association with Risk of Serious Skin Reactions: The FDA is informing the public that acetaminophen has been associated with a risk of rare but serious skin reactions. These skin reactions, known as Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP), can be fatal.

Public Comment: No public comment.

Board Decision: None needed.

- Olmesartan Medoxomil: Drug Safety Communication – Label Changes To Include Intestinal Problems (Sprue-Like Enteropathy): The FDA is warning that the blood pressure drug olmesartan medoxomil (Benicar[®], Benicar HCT[®], Azor[®], Tribenzor[®], and generics) can cause intestinal problems known as sprue-like enteropathy. FDA has approved changes to the labels of these drugs to include this concern.

Public Comment: No public comment.

Board Decision: None needed.

- Rosiglitazone – FDA lifts prescribing restrictions: The FDA has determined that recent data for rosiglitazone-containing drugs, such as Avandia[®], Avandamet[®], Avandaryl[®], and generics, do not show an increased risk of heart attack compared to the standard type 2 diabetes medications metformin and sulfonylurea. As a result, the FDA is requiring removal of the prescribing and dispensing restrictions for rosiglitazone medications that were put in place in 2010. This decision is based on our review of data from a large, long-term clinical trial and is supported by a comprehensive, outside, expert re-evaluation of the data conducted by the Duke Clinical Research Institute (DCRI).

Public Comment: No public comment.

Board Decision: There will be an update to the clinical criteria to remove the REMS and special dispensing requirements.

- Zyprexa[®] Relprevv (Olanzapine Pamoate): Drug Safety Communication – FDA Investigating Two Deaths Following Injection: The FDA is investigating two unexplained deaths in patients who received an intramuscular injection of the antipsychotic drug Zyprexa Relprevv[®] (olanzapine pamoate). The patients died 3-4 days after receiving an appropriate dose of the drug, well after the 3-hour post-injection monitoring period required under the Zyprexa Relprevv[®] Risk Evaluation and Mitigation Strategy (REMS). Both patients were found to have very high olanzapine blood levels after death. High doses of olanzapine can cause delirium, cardiopulmonary arrest, cardiac arrhythmias, and reduced level of consciousness ranging from sedation to coma.

Public Comment: No public comment.

Board Decision: None needed.

12. Adjourn: Meeting adjourned at 8:28 p.m.

Next DUR Board Meeting

Tuesday, January 28, 2013

6:15 – 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.