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**Department of Vermont Health Access  
Pharmacy Benefit Management Program  
DUR Board Meeting Minutes: 01/28/2014**

**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  
Amanda Kennedy, PharmD

**Absent:**

None

**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, DVHA

Nancy Miner, Catamaran  
Nancy Hogue, PharmD, DVHA  
Scott Strenio, MD, DVHA  
Pamela Casas, ACP Intern

**Guests:**

Rita Baglini, APS Healthcare  
Rod Francisco, Sunovion  
Marie Roache, Pfizer  
Kevin Delisle, Gilead Sciences

Steve Berardino, Amgen  
Danielle Moon, Merck  
Dan Sheehan, Pfizer

Dave Downey, Abbott Labs  
Jai Persico, Otsuka  
Steve Cieplik, Glaxo Smith Kline

Joseph Lasek, MD, Chair, called the meeting to order at 6:20p.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 December, 2013 meeting minutes were accepted as printed.

*Public Comment:* No public comment.

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

- DVHA will not pursue the dual eligible demonstration project with CMS.
- Introduction was made of Albany College of Pharmacy Intern, Pamela Casas.

#### 4. **Medical Director Update:**

- DVHA will be touring the State to meet with high volume Medicaid providers to discuss what issues they may have with Medicaid.

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

- **New Cholesterol Treatment Guidelines:** It was proposed that the Lipotropics: Statins category be separated by intensity with different approval criteria for each in order to support the new adult cholesterol treatment guidelines released jointly by the American College of Cardiology [ACA] and the American Heart Association [AHA] in conjunction with the National Heart, Lung, and Blood Institute [NHLBI]. Prior authorization and step therapy will no longer be required for generic atorvastatin 40 and 80 mg and all strengths of Crestor<sup>®</sup>.

*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)

- **Oxycodone IR/Hydromorphone IR Retrospective Drug Utilization Review:** Pamela Casas, Pharmacy Intern, Albany College of Pharmacy, presented a review of over 21,000 submitted claims for oxycodone IR and hydromorphone IR from January 1, 2013 through December 31, 2013. Also presented were current guidelines and what other State Medicaid programs are doing with these products. Suggested utilization management edits were recommended.

*Public Comment:* No public comment.

**Board Decision:** DVHA staff requested that DUR Board discussion of the recommendations be deferred until the patient and prescriber impact of the recommendations can be discussed more fully with DVHA staff.

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

##### **Abbreviated New Drug Reviews:**

- **Oxytrol for Women<sup>®</sup> (oxybutynin transdermal system) OTC:** It was recommended that Oxytrol<sup>®</sup> continue to be on the DVHA PDL as prior authorization required and coverage to be restricted to the prescription version.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

- **Vecamyl<sup>®</sup> (mecamylamine) Oral Tablet:** It was recommended that Vecamyl<sup>®</sup> be added to the PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of moderately-severe to severe hypertension AND has had a treatment failure, intolerance, or contraindication to at least 3 antihypertensive therapies of different mechanisms of action at the

maximum dosage. This product will belong to a new therapeutic category of Antihypertensives: Ganglionic Blockers.

*Public Comment:* No public comment.

**Board Decision:** The Board requested and approved that the language around maximum dosage of prior therapies be removed.

#### **Full New Drug Reviews:**

- Breo Ellipta<sup>®</sup> (fluticasone furoate and vilanterol inhalation powder) Inhaler: It was recommended that Breo Ellipta<sup>®</sup> be added to the PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of COPD (Note: will not be approved for use in asthma) AND the patient has a documented side effect, allergy, or inadequate response to Advair<sup>®</sup> or Symbicort<sup>®</sup>. A quantity limit of one inhaler (60 blisters) per 30 days is recommended.

*Public Comment:* Steve Cieplik ~ Glaxo Smith Kline – Highlighted some of the attributes of Breo Ellipta<sup>®</sup>.

**Board Decision:** The Board unanimously approved the above recommendation.

- Olysio<sup>®</sup> (simeprevir) Oral Capsule: Full discussion will be deferred until next meeting as new guidelines for treatment of Hepatitis C will be released this week.

*Public Comment:* No public comment.

**Board Decision:** None needed.

- Sovaldi<sup>®</sup> (sofosbuvir) Oral Tablet: Full discussion will be deferred until next meeting as new guidelines for treatment of Hepatitis C will be released this week.

*Public Comment:* Kevin Delisle ~ Gilead Sciences – Highlighted some of the attributes of Sovaldi<sup>®</sup>.

**Board Decision:** None needed.

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

(Public comment prior to Board action)

- JNC 8 Hypertension Guidelines: The Eighth Joint National Committee (JNC 8) has released its new guidelines on the management of adult hypertension. These were reviewed to ascertain whether the PDL supports the new guidelines.

*Public Comment:* No public comment.

**Board Decision:** There are no changes required of the PDL criteria based on these updated guidelines.

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

- 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

- Anti-Hyperkinesia and Anti-Narcolepsy/Cataplexy: Category was renamed to ADHD and Narcolepsy/Cataplexy Medications and some medications moved to appropriate sub-categories – 3 sub-categories are stimulants, non-stimulants and depressants.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

- Ilaris<sup>®</sup> (canakinumab) Injection SJIA (new FDA approved diagnosis): It was recommended that the approval criteria for Ilaris<sup>®</sup> be updated to include the newly approved diagnosis with the following criteria for that indication. The diagnosis is systemic juvenile idiopathic arthritis (sJIA) with active systemic features and varying degrees of synovitis who have continued disease activity after initial therapy with an inadequate response, contraindication or intolerance to 1 month of anakinra (Kineret<sup>®</sup>), 2 weeks of glucocorticoid monotherapy (oral or IV) or one month of NSAIDs AND the patient is  $\geq 2$  years of age. The category will also be renamed Interleukin (IL)-1 Receptor Blockers (rather than CAPS injectables).

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

- Miscellaneous: Soliris<sup>®</sup> (eculizumab): It was recommended that the approval criteria for Soliris<sup>®</sup> be updated to the following: The patient has a diagnosis of paroxysmal hemoglobinuria (PNH) documented by flow cytometry AND the patient has received the meningococcal vaccine at least 2 weeks prior to therapy initiation OR the patient has a diagnosis of atypical hemolytic uremic syndrome (aHUS) AND the patient has received the meningococcal vaccine at least 2 weeks prior to therapy initiation. Authorization for continued use shall be reviewed to confirm that the patient has experienced an objective response to the therapy. A quantity limit of 12 vials per 28 days was proposed to cover all indications.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation.

## 12. General Announcements:

### FDA Safety Alerts

- Acetaminophen Prescription Combination Drug Products with more than 325mg: FDA Statement – Recommendation to Discontinue Prescribing and Dispensing: The FDA is recommending that health care professionals discontinue prescribing and dispensing prescription combination products that contain more than 325mg of acetaminophen per unit. Limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death.

*Public Comment:* No public comment.

**Board Decision:** The Board decided to not take action on this topic due to the fact that many products are DEA Schedule II and could cause issues at the pharmacy for members presenting with hard-copy prescriptions.

- Onfi<sup>®</sup> (clobazam): Drug Safety Communication – Risk of Serious Skin Reactions: The FDA is warning that the anti-seizure drug Onfi<sup>®</sup> (clobazam) can cause rare but serious skin reactions that can result in permanent harm and death. FDA has approved changes to the labels of this drug to include this concern.

*Public Comment:* No public comment.

**Board Decision:** None needed.

13. Adjourn: Meeting adjourned at 8:19 p.m.

### Next DUR Board Meeting

Tuesday, March 11, 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.