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**Department of Vermont Health Access  
Pharmacy Benefit Management Program  
DUR Board Meeting Minutes: 02/19/2013**

**Board Members:**

**Present:**

Halle Sobel, MD  
Mark Pasanen, MD  
Mario Sarafini, DO

Gary Starecheski, RPh  
James Marmar, RPh

Kim Ladue, NP  
Janet Farina, RPh

**Absent:**

Joseph Lasek, MD, Chair  
Amanda Kennedy, PharmD

Jeanne Greenblatt, MD

Jaskanwar Batra, MD

**Staff:**

Diane Neal, RPh, Catamaran  
Stacey Baker, DVHA  
Quynh Anh Mui, ACPHS Intern

Nancy Miner, Catamaran  
Mary Beth Bizzari, RPh, DVHA  
Jennifer Egelhof, DVHA

Michelle Sirois, Catamaran  
Nancy Hogue, PharmD, DVHA

**Guests:**

Thomas Algozzine, Novartis  
Jacqueline Buckley, Vertex  
Thomas Currier, Purdue  
Steven McRae, Affymax  
Erica Hintze, Forest  
Kara Sperandeo, Forest

Rita Baglini, APS  
Susan Campbell, Boehringer-Ingelheim  
Amy Finn, Merck  
Robert McSparren, BMS  
Steve Vane, Forest  
Ryan Leslie, Affymax

Steve Berardino, Amgen  
Mario Carnovale, Novartis  
James Kokoszyna, Allergan  
Jai Persico, Otsuka  
Stephen Cieplik, GSK  
Stephen Sopchak

Gary Starecheski, RPh, Acting Chair, called the meeting to order at 6:39 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 January, 2013 meeting minutes were accepted as printed.

*Public Comment:* No public comment.

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

- The search for a Chief Medical Officer is underway and the Medical Director should be in place very soon.
- The presentation on the OSHU (Oregon Science and Health University) project has been postponed until a new Medical Director has arrived.

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

- None this meeting.

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

- **Skeletal Muscle Relaxants:** Quantity limits were proposed for each skeletal muscle relaxant product. The duration of therapy limit will be 90 days. No quantity limits or duration of therapy were proposed for the anti-spasticity agents as they are often used in higher than FDA approved doses but there appears to be no significant side effects or opportunity of abuse with the anti-spasticity agents.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the proposed quantity limits for the musculoskeletal agents.

- **Gastrointestinal: Anti-ulcer: H.Pylori Combination Therapy:** It was recommended that Helidac<sup>®</sup>, Omeclamox-Pak<sup>®</sup>, Prevpac<sup>®</sup>, and Pylera<sup>®</sup> be added to the PDL as prior authorization required with the following approval criteria: The patient has a documented treatment failure with combinations of individual proton pump inhibitors or H2 antagonists given together with two appropriate antibiotics OR the patient has been unable to be compliant with individual agents prescribed separately. Quantity limits and duration of therapy limits based on FDA approved labeling were also proposed for each agent.

*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)

- **Methadone for Chronic Pain:** The clinical guidelines for management of chronic pain that include methadone were discussed. The complexities of methadone pharmacodynamics and safety issues were also discussed. Starting doses were evaluated as well as total daily dose for ongoing therapy.

*Public Comment:* No public comment.

**Board Decision:** While no changes were proposed to be voted on this meeting, the Board also discussed maximum dosing and hyperalgesia. The topic will be brought back to the April meeting for further discussion.

- **Narcotic Analgesics – Continued use of short acting with no long acting:** Deferred until a future meeting.

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

**Abbreviated New Drug Reviews:**

- Gelnique<sup>®</sup> (oxybutynin) 3% gel: It was recommended that Gelnique<sup>®</sup> be added to the PDL as prior authorization required with the following approval criteria: The patient is unable to swallow a solid oral formulation (e.g. patients with dysphagia) OR the patient is unable to be compliant with solid oral dosage forms. There will be a quantity limit of 1 pump bottle (92gm) per 30 days.

*Public Comment:* No public comment.

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

- Rectiv<sup>®</sup> (nitroglycerin) 0.4% ointment: It was recommended that Rectiv<sup>®</sup> not be added to the PDL due to the limited indication and no other drug alternatives. It will remain available without prior authorization.

*Public Comment:* No public comment.

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

- Sorilux<sup>®</sup> (calcipotriene) 0.005% foam: It was recommended that Sorilux<sup>®</sup> be added to the PDL as prior authorization required with the following approval criteria: The patient is  $\geq 18$  years of age AND the patient has a diagnosis of plaque psoriasis AND the patient has demonstrated inadequate response or intolerance to other dosage forms of calcipotriene (brand or generic).

*Public Comment:* No public comment.

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

**Full New Drug Reviews:**

- Myrbetriq<sup>®</sup> (mirabegron) Extended Release Tablet: It was recommended that Myrbetriq<sup>®</sup> be added to the PDL as Prior Authorization required with the following approval criteria: The patient has had a documented side effect, allergy, treatment failure or contraindication with one preferred long-acting urinary antimuscarinic agent. A quantity limit of 1 tablet/day is recommended.

*Public Comment:* No public comment.

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

- Tudorza<sup>®</sup> (aclidinium bromide) Pressair: It was recommended that Tudorza<sup>®</sup> 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 with Spiriva. A quantity limit of 1 inhaler/30 days is recommended.

*Public Comment:* Kara Sperandeo, Forest ~ Highlighted some of the attributes of Tudorza<sup>®</sup>.

**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)

- Antiemetics – 5HT3 Receptor Antagonists & Neurokinin 1 Receptor Antagonist: There were no changes recommended to the current approval criteria or preferred products for this category.

*Public Comment:* No public comment.

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

- Antiemetics – Delta-9 – Tetrahydrocannabinol (THC) Derivatives: This category was previously called “Antiemetics: Other” and will be renamed to clarify the medications contained within. 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.

- Benign Prostatic Hyperplasia Agents: It was recommended to list alfuzosin ER (generic Uroxatral<sup>®</sup>) as prior authorization required with a quantity limit of one per day with the approval criteria to be the following: The patient has had a documented side effect, allergy, or treatment failure with two preferred alpha blockers. In addition, for approval of brand Uroxatral<sup>®</sup>, the patient must have a documented intolerance to generic alfuzosin ER. List Cialis<sup>®</sup> (tadalafil) coverage as non-covered due to its role in BPH primarily in men with erectile dysfunction. Treatment of erectile dysfunction is not covered by Medicaid programs. No other changes are recommended to the preferred products or clinical criteria for this category.

*Public Comment:* No public comment.

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

- Erythropoiesis Stimulating Agents: There were no changes recommended to the current approval criteria or PDL status for this category. Omontys<sup>®</sup> is only available in dialysis units at this time so coverage will not be provided in the pharmacy benefit.

*Public Comment:* Ryan Leslie, Affymax ~ Highlighted some of the attributes of Omontys<sup>®</sup>.

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

- Ophthalmic Alpha-Agonists: There were no changes recommended to the current approval criteria or PDL status for this category. It was recommended to remove the age distinction for PA requirements from the Iopidine<sup>®</sup> and its generic apraclonidine.

*Public Comment:* No public comment.

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

- Ophthalmics: Carbonic Anhydrase Inhibitors: It was recommended to add the product Cosopt PF<sup>®</sup> as prior authorization required with the following approval criteria: The patient has had a documented

intolerance to the preservatives in the generic combination product. There were no other changes recommended to the current approval criteria for this category.

*Public Comment:* No public comment.

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

- Urinary Antispasmodics: It was recommended that there be no changes to the current clinical criteria for this category. See drug reviews above for Gelnique<sup>®</sup> and Myrbetriq<sup>®</sup> for clinical criteria and PDL placement.

*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:

- None this meeting.

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

##### FDA Safety Alerts

- Samsca<sup>®</sup> (tolvaptan): Drug warning – Potential Risk of Liver Injury: Otsuka and FDA notified healthcare professionals of the possible significant liver injury associated with the use of Samsca<sup>®</sup>.

*Public Comment:* No public comment.

**Board Decision:** None required. Informational only.

- Zolpidem Containing Products: Drug Safety Communication- FDA Requires Lower Recommended Doses: The FDA is notifying the public of new information about zolpidem. FDA recommends that the bedtime dose be lowered because new data show that blood levels in some patients may be high enough the morning after use to impair activities that require alertness, including driving. This is particularly problematic in women who eliminate the drug more slowly.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously voted to not impose quantity limits on zolpidem containing products or to limit starting doses. The Board would like to check in 6 months if there has been a trend in prescribing to decreased doses based on this FDA recommendation.

#### 12. Adjourn: Meeting adjourned at 8:42 p.m.

##### Next DUR Board Meeting

Tuesday, April 2, 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.