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**Department of Vermont Health Access  
Pharmacy Benefit Management Program  
DUR Board Meeting Minutes: 01/15/2013**

**Board Members:**

**Present:**

Joseph Lasek, MD, Chair  
Mark Pasanen, MD  
Mario Sarafini, DO

Gary Starecheski, RPh  
James Marmar, RPh  
Jeanne Greenblatt, MD

Jaskanwar Batra, MD  
Kim Ladue, NP  
Amanda Kennedy, PharmD

**Absent:**

Janet Farina, RPh

Halle Sobel, MD

**Staff:**

Diane Neal, RPh, Catamaran  
Stacey Baker, DVHA  
Jason Leuck, ACPHS Intern

Nancy Miner, Catamaran  
Mary Beth Bizzari, RPh, DVHA

Michelle Sirois, Catamaran  
Nancy Hogue, Pharm.D, DVHA

**Guests:**

Danielle Moon, Merck  
Rita Baglini, APS/VCCI  
Wolfgang Ziegenhager, Genetech

Jai Persico, Otsuka  
Marie Roache, Pfizer  
Kay Barry, Shire

Wendy Pollinger, Eli Lilly  
Vincent Lawler, Genzyme

Joseph Lasek, MD, Chair, called the meeting to order at 6:30 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 replacement Medical Director and a Chief Medical Officer is a joint effort between DVHA and UVM. The DVHA Commissioner, Mark Larson, has a meeting at UVM soon to review recommendations.
- There will be a presentation on the OSHU (Oregon Science and Health University) project at the February meeting.

#### 4. Medical Director Update:

- None this meeting.

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

- Antipsychotic Medications in Children - Survey: A total of 976 surveys were mailed, 783 have been returned with 188 indicating that the patient is not continuing or is no longer their patient. The survey has encouraged a lot of discussion between prescribers and the state.

*Public Comment:* No public comment.

**Board Decision:** None needed.

- Practice Change Strategies: A brief was distributed that discussed various methods of intervening with prescribers to influence prescribing habits. It is always difficult and many of the methods are not operational by the DUR Board. Academic detailing was strongly supported. Prescribers generally are not in favor of mailed communications.

*Public Comment:* No public comment.

**Board Decision:** None needed.

- Displaying Prior Authorization End Dates to Pharmacies: Catamaran does have the ability to display prior authorization end dates to pharmacies at POS (point-of-sale). We are currently in the process of meeting to discuss the level of effort to roll out this functionality on new prior authorizations at the time of approval and whether existing prior authorizations can be updated.

*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)

- Narcotic Analgesics – Continued use of short acting with no long acting: Deferred until a future meeting. We have finally received an updated NDC file so should be able to present at a later meeting.
- Skeletal Muscle Relaxants: A presentation was done by Jason Leuck, Pharmacy Intern, Albany College of Pharmacy Colchester Campus. The presentation focused on usage of skeletal muscle relaxants in DVHA members. A recommendation was made to add quantity limits to all medications in this category and duration of therapy limits to cyclobenzaprine and carisoprodol.

*Public Comment:* No public comment.

**Board Decision:** The Board would like to also add duration of therapy limits to methocarbamol, orphenadrine, chlorzoxazone, and metaxalone. The medication class is to be brought back at the next meeting for a complete review of quantity limits, duration limits, a letter to prescribers, and prior authorization criteria.

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

**Abbreviated New Drug Reviews:**

- Binosto<sup>®</sup> (alendronate sodium) effervescent tablet: It was recommended that Binosto<sup>®</sup> be added to the PDL as prior authorization required with the following approval criteria: The patient has a diagnosis/indication of postmenopausal osteoporosis or osteoporosis in men AND the prescriber provides documentation of medical necessity for the specialty dosage form (i.e. inability to swallow tablets, dysphagia). There will be a quantity limit of 4 tablets per 28 days.

*Public Comment:* No public comment.

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

- Rayos<sup>®</sup> (prednisone) delayed release tablet: It was recommended that Rayos<sup>®</sup> be added to the PDL as Prior Authorization required with the following approval criteria: The patient has had a trial of generic immediate release prednisone and has documented side effects that are associated with the later onset of activity of immediate release prednisone taken in the morning. 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.

**Full New Drug Reviews:**

- Elelyso<sup>®</sup> (taliglucerase alfa) vial for injection: It was recommended that Elelyso<sup>®</sup> be added to the PDL as Prior Authorization required with the following approval criteria: The diagnosis or indication is Gaucher disease (GD) type I AND the diagnosis has been confirmed by molecular or enzymatic testing. It is recommended that each fill be limited to a 14 day supply.

*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)

- Antidepressants: SNRI and Miscellaneous: There were no changes recommended to the current approval criteria or preferred medications for either the Antidepressants: SNRI or the Antidepressants: Miscellaneous. An update of available products and FDA recommended doses for Cymbalta<sup>®</sup> as well as quantity limits for Cymbalta<sup>®</sup> were proposed.

*Public Comment:* No public comment.

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

- Gastrointestinal: Proton Pump Inhibitors: There were no changes recommended to the current approval criteria or preferred medications for Gastrointestinal: Proton Pump Inhibitors. The combination products have been removed from this category and placed in a new class (see below).

*Public Comment:* No public comment.

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

- Ophthalmic Immunomodulators (Restasis®): It was recommended to update the approval criteria for Restasis® to be the following: The patient has a diagnosis of moderate to severe keratoconjunctivitis sicca (dry eye syndrome) or Sjogren syndrome with suppressed tear production due to ocular inflammation AND the member does not have any of the following contraindications or exclusions to therapy: an active ocular infection, concurrent topical anti-inflammatory drugs, or concurrent punctal plug use AND the patient has had a documented side effect, allergy, or treatment failure to two ocular lubricants (e.g. artificial tears, lubricant gels, etc.).

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation and requested the class name be changed to Ophthalmics: Dry Eye Syndrome to include a list of examples of preferred generic OTC products.

- Pancreatic Enzymes (including new drug reviews of Pertzye®, Ultresa®, and Viokace®): It was recommended to update the approval criteria for Pancrelipase® 5,000 to be the following: The patient has a documented intolerance to brand Zenpep® 5,000. It was also recommended that Pretzye®, Ultresa®, and Viokace® be added to the PDL as Prior Authorization required with the following approval criteria: The patient has been started and stabilized on the requested product OR the patient has had a treatment failure or documented intolerance with both Creon® and Zenpep®.

*Public Comment:* No public comment.

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

## **9. New Managed Therapeutic Drug Classes:**

- Gastrointestinal: Anti-ulcer: H.Pylori Combination Therapy: The dosing schedule and components of each product as well as efficacy of the four available products was discussed.

*Public Comment:* No public comment.

**Board Decision:** None needed this meeting. Class will return next meeting for approval of criteria.

## **10. Review of Newly Developed/Revised Clinical Coverage Criteria and/or Preferred Products:**

*Diane Neal, RPh, Catamaran*

- None this meeting.

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

### FDA Safety Alerts

- Chantix<sup>®</sup> (varenicline): Safety review update of the risk of cardiovascular adverse events: The FDA is informing the public about the results of a large, combined analysis of clinical trials that compared patients who received the smoking cessation drug Chantix<sup>®</sup> (varenicline) to patients who received placebo. FDA required the manufacturer of Chantix<sup>®</sup> to conduct meta-analysis to further evaluate the cardiovascular safety of the drug, and believes it is important to let health care professionals and patients know about the higher occurrence of major adverse cardiovascular events in patients using Chantix<sup>®</sup> compared to placebo. However, cardiovascular events are also higher in patients who continue to smoke.
- Incivek<sup>®</sup> (telaprevir): Serious skin reactions after used in combination treatment with the Hepatitis C drugs peginterferon alfa and ribavirin: The FDA received reports of serious skin reactions, some fatal, in patients taking the hepatitis C drug Incivek<sup>®</sup> (telaprevir) in combination with the drugs peginterferon alfa and ribavirin. Significantly, some patients died when they continued to receive Incivek<sup>®</sup> combination treatment after developing a worsening, or progressive rash and systemic symptoms. As a result, FDA is adding a boxed warning to the Incivek<sup>®</sup> drug label stating that Incivek<sup>®</sup> combination treatment must be immediately stopped in patients experiencing a rash with systemic symptoms or a progressive severe rash.
- Pradaxa<sup>®</sup> (dabigatran etexilate mesylate): Not to be used in patients with mechanical prosthetic heart valves: The FDA notified healthcare professionals and the public that the anticoagulant Pradaxa<sup>®</sup> (dabigatran etexilate mesylate) should not be used to prevent stroke or blood clots in patients with mechanical prosthetic heart valves. A clinical trial in Europe was recently stopped because Pradaxa<sup>®</sup> users were more likely to experience strokes, heart attacks, and blood clots forming on the mechanical heart valves than were users of warfarin. There was also more bleeding after valve surgery in the Pradaxa<sup>®</sup> users than in the warfarin users.

**Board Decision:** The Board unanimously approved adding a criterion for Pradaxa<sup>®</sup> to ensure that the member does not have a mechanical prosthetic heart valve.

- Zyrem<sup>®</sup> (sodium oxybate): Warning against use with alcohol or drugs causing respiratory depression: The FDA is reminding healthcare professionals and patients that the combined use of Zyrem<sup>®</sup> (sodium oxybate) with alcohol or central nervous system depressant drugs can markedly impair consciousness and may lead to severe breathing problems. The use of alcohol with Zyrem<sup>®</sup> is a new contraindication added to the Zyrem<sup>®</sup> label.

**12. Adjourn:** Meeting adjourned at 8:37 p.m.

### **Next DUR Board Meeting**

Tuesday, February 19, 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.