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**Department of Vermont Health Access  
Pharmacy Benefit Management Program  
DUR Board Meeting Minutes: 12/11/2012**

**Board Members:**

**Present:**

Joseph Lasek, MD, Chair  
Janet Farina, RPh  
Mario Sarafini, DO

Gary Starecheski, RPh  
James Marmar, RPh

Jaskanwar Batra, MD  
Kim Ladue, NP

**Absent:**

Jeanne Greenblatt, MD  
Amanda Kennedy, PharmD

Mark Pasanen, MD

Halle Sobel, MD

**Staff:**

Diane Neal, RPh, Catamaran  
Stacey Baker, DVHA  
Jennifer Egelhof, DVHA

Nancy Miner, Catamaran  
Mary Beth Bizzari, RPh, DVHA  
Leanne Miles, DVHA

Michelle Sirois, Catamaran  
Nancy Hogue, PharmD., DVHA

**Guests:**

Jacqueline Buckley, Vertex  
Rita Baglini, APS/VCCI  
Mike Lucy, EMD Serono

Ed Macmillan, Abbott Diabetes  
Jim Farrell, GSK

Vik Patel, Vertex  
Steve Cieplik, GSK

Joseph Lasek, MD, Chair, called the meeting to order at 6:35 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 November, 2012 meeting minutes were accepted as printed.

*Public Comment:* No public comment.

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

- DVHA is continuing the search for a replacement Medical Director and a Chief Medical Officer. There have been several applicants and interviews.
- DVHA is working with CMS on a weekly basis on the Duals Demonstration Project. A duals integrated formulary may need to be reviewed by the Board in the early part of the new year.
- DVHA has signed a contract with OSHU (Oregon Science and Health University) to help develop benefit plan principals. There will be a presentation on this at the January meeting.

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

- None this meeting.

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

- **Atypical Antipsychotic Medications – Pediatric Use:** The letter sent out to prescribers notifying prescribers of the need for Prior Authorization (PA) for all new atypical antipsychotics was shared. The majority of the surveys (2/3rds) for current users were returned and PA applied. For those surveys not returned, temporary prior authorizations have been applied so medications will not be denied at the pharmacy. There were 129 new starts from 10/1/2012 through 12/9/2012 where a PA was also applied. 179 surveys were returned saying the patient was no longer seeing the prescriber or the patient would not continue on therapy – in these cases, PAs were not applied. Some prescribers requested additional time to complete the surveys which was granted.

*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)

- **Hepatitis C Protease Inhibitors:** A retrospective drug analysis was performed to review utilization and evaluate the appropriateness of the current PA and quantity limit approval criteria. In addition, since adequate adherence to therapy is important for overall therapy success and prevention of resistance, patients' adherence to these medications was assessed. Claims data from 12/1/2011 through 8/31/2012 was reviewed. It was proposed to add criteria for HCV protease inhibitor requests for patients who are co-infected with HCV and HIV infections. It was also suggested that therapy for Incivek® will be limited to 12 weeks duration and 44 weeks for Victrelis®. There was one request for Incivek in a patient who was HCV Genotype Type 2. This was denied as it is not indicated in HCV Genotype Type 2 – this one denial saved the program close to \$ 50,000.00.

*Public Comment:* No public comment.

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

- **Narcotic Analgesics – continued use of short acting with no long acting:** Deferred until next meeting as we have had difficulty getting the data into the correct text file format to run through the analyzer program.
- **New Topics – Board Discussion of Possible Topics:** The Board was asked to provide possible topics for future RetroDUR/DUR. Suggestions included: methadone use in pain and opioid consumption expressed as total morphine equivalents as this has been linked to morbidity and mortality.

*Public Comment:* No public comment.

**Board Decision:** None needed.

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

**Abbreviated New Drug Reviews:**

- Combivent<sup>®</sup> (ipratropium bromide/albuterol) Respimat: It was recommended that Combivent<sup>®</sup> Respimat be added to the PDL as preferred as this is a new propellant-free formulation which replaces the Combivent<sup>®</sup> MDI. There will be a quantity limit of 1 inhaler per 30 days.

*Public Comment:* No public comment.

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

- QNASL<sup>®</sup> (beclomethasone dipropionate HFA) Nasal Spray: It was recommended that QNASL<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 to all three preferred nasal glucocorticoids. There will be a quantity limit of 1 inhaler per 30 days.

*Public Comment:* No public comment.

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

- Subsys<sup>®</sup> (fentanyl) Sublingual Spray: It was recommended that Subsys<sup>®</sup> be added to the PDL as prior authorization required with the following approval criteria: The indication is for cancer breakthrough pain (no approval for acute pain or postoperative pain) AND there is documentation that the patient is opioid tolerant 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 AND the patient has had a documented treatment failure with or intolerance to 2 of the following 3 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.

**Full New Drug Reviews:**

- Arcapta<sup>®</sup> (indacaterol) Neohaler: It was recommended that Arcapta<sup>®</sup> be added to the PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of COPD AND the patient has a documented side effect, allergy, or treatment failure to either Foradil<sup>®</sup> or Serevent<sup>®</sup>.

*Public Comment:* Craig Plavrohinent, Novartis ~ Highlighted some of the attributes of Arcapta<sup>®</sup>.

**Board Decision:** The Board unanimously approved the above recommendation with the addition of a note indicating that the product is not FDA approved for asthma treatment.

- Dymista<sup>®</sup> (azelastine/fluticasone) Nasal Spray: It was recommended that Dymista<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 to loratadine (OTC) OR cetirizine (OTC) AND a preferred nasal corticosteroid used in combination. There will be a quantity limit of 1 inhaler per 30 days.

*Public Comment:* No public comment.

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

- Korlym<sup>®</sup> (mifepristone) Oral Tablet: It was recommended that Korlym<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 patient has a diagnosis of endogenous Cushing's syndrome AND patient is diagnosed with type 2 diabetes mellitus or glucose intolerance AND patient has hyperglycemia secondary to hypercortisolism AND patient has failed or is not a candidate for surgery AND patient does not have any of the following contraindications to Korlym<sup>®</sup>: Pregnancy (pregnancy must be excluded before the initiation of therapy or if treatment is interrupted for  $> 14$  days in females of reproductive potential. Nonhormonal contraceptives should be used during and one month after stopping treatment in all women of reproductive potential) OR patient requires concomitant treatment with systemic corticosteroids for serious medical conditions/illnesses (immunosuppression for organ transplant) OR patient has a history of unexplained vaginal bleeding OR patient has endometrial hyperplasia with atypia or endometrial carcinoma OR patient is concomitantly taking simvastatin, lovastatin, or a CYP3A substrate with a narrow therapeutic index (e.g. cyclosporine, dihydroergotamine, fentanyl, pimozone, quinidine, sirolimus, or tacrolimus). There will be a quantity limit of 4 tablets per day.

*Public Comment:* No public comment.

**Board Decision:** The Board approved the above recommendation with the addition of the following criteria: Patient has a documented side effect, allergy, treatment failure, or contraindication to at least 2 other adrenolytic medications (ie: ketoconazole, metyrapone, mitotane, etomidate, fluconazole) AND the case will be sent to the DVHA Medical Director for final review. There was one opposition to coverage of the medication.

- Zetonna<sup>®</sup> (ciclesonide) Nasal Aerosol: It was recommended that Zetonna<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 to all three preferred nasal glucocorticoids. There will be a quantity limit of 1 inhaler per 30 days.

*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)

- Restless Leg Syndrome: There were no changes recommended to the current approval criteria for Mirapex<sup>®</sup>, Requip<sup>®</sup>, and Horizant<sup>®</sup>; however, Neupro<sup>®</sup> was recently approved for use in Restless Leg Syndrome and it is recommended that it be added to the DVHA 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 moderate to severe restless legs syndrome (RLS) AND the patient has had a documented side effect, allergy, contraindication or treatment failure to generic immediate release ropinirole and pramipexole OR the prescriber provides medical necessity for the transdermal formulation (eg.

swallowing disorder or difficulty taking oral medication). There will be a quantity limit of 1 patch per day.

*Public Comment:* No public comment.

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

- **Parkinson's Medications:** It was recommended that Neupro<sup>®</sup> for the treatment for Parkinson's Disease be added to the DVHA 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 Parkinson's Disease AND the patient has had a documented side effect, allergy, contraindication or treatment failure to generic immediate release ropinirole or pramipexole and ropinirole XL or Mirapex ER<sup>®</sup> OR the prescriber provides medical necessity for the transdermal formulation (eg. swallowing disorder or difficulty taking oral medication). There will be a quantity limit of 1 patch per day.

*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:**

*Diane Neal, RPh, Catamaran*

- **Diabetic Testing Supplies:** It was recommended that there be no changes to this category.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved to the above recommendations.

- **Pancreatic Enzyme Products:** It was recommended that Pancreaze<sup>®</sup> be moved to prior authorization required status on the PDL 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<sup>®</sup> and Zenpep<sup>®</sup>. Current users would be grandfathered.

*Public Comment:* No public comment.

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

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

##### **FDA Safety Alerts**

- **Fungal Meningitis Outbreak Originating from Compounding Pharmacy:** The FDA has provided many updates on this topic.
- **Pradaxa<sup>®</sup>: Update on Safety Review:** The FDA has evaluated new information about the risk of serious bleeding associated with use of the anticoagulants dabigatran (Pradaxa<sup>®</sup>) and warfarin.

Following the approval of Pradaxa<sup>®</sup>, FDA received a large number of post-marketing reports of bleeding among Pradaxa<sup>®</sup> users. As a result, FDA investigated the actual rates of gastrointestinal bleeding and intracranial hemorrhage for new users of Pradaxa<sup>®</sup> compared to new users of warfarin. This assessment was done using insurance claims and administrative data from FDA's Mini-Sentinel pilot of the Sentinel Initiative. The results of this Mini-Sentinel assessment indicate that bleeding rates associated with new use of Pradaxa<sup>®</sup> do not appear to be higher than bleeding rates associated with new use of warfarin, which is consistent with observations from the large clinical trial used to approve Pradaxa<sup>®</sup>. FDA is continuing to evaluate multiple sources of data in the ongoing safety review of this issue.

- **Pramipexole: Possible Risk of Heart Failure:** The FDA notified healthcare professionals about a possible increased risk of heart failure with Mirapex<sup>®</sup> (pramipexole). Results of recent studies suggest a potential risk of heart failure that needs further review of available data. Because of the study limitations, FDA is not able to determine whether Mirapex<sup>®</sup> increases the risk of heart failure. FDA is continuing to work with the manufacturer to clarify further the risk of heart failure with Mirapex<sup>®</sup> and will update the public when more information is available.

**12. Adjourn:** Meeting adjourned at 8:25 p.m.

**Next DUR Board Meeting**

Tuesday, January 15, 2012

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.