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Department of Vermont Health Access  
Pharmacy Benefit Management Program  
***DUR Board Meeting Minutes: 04/05/2011***

**Board Members:**

Michael Scovner, M.D., Chair  
Andrew Miller, R. Ph.  
Sommer Zarbock, Pharm. D.

Gary Starecheski, RPh  
Jeanne Greenblatt, M.D.

Lynne Vezina, R.Ph.  
Amanda Kennedy, Pharm. D.

**Staff:**

Nancy Hogue, Pharm.D., DVHA  
Diane Neal, R.Ph., (MHP)

Michelle Sirois, (MHP)

Stacey Baker, DVHA

**Guests:**

Amato, Paul, GSK  
Badalucco, Matt, Merck  
Currier, Thomas, Purdue  
Danielson, Kevin, Pfizer  
DiPerrio, Pamela, GSK

Downey, Dave, Abbott Labs  
Fanikos, Paul, BIPI  
Lewis, Glenda, Gilead Sciences  
Kaplan, Mark, Abbott Labs  
Meany, Bob, Takeda

Michael, Todd, Baxter  
Pepe, Carl, GSK  
Persico, Jai, Endo  
Pertoso, Janice, Alkermes  
Sanduja, Om, Merck

Michael Scovner, M.D. Chair, called the meeting to order at 7:00 p.m. at the DUR Board meeting site in Williston.

**1. Executive Session:**

- An executive session was held from 6:30 until 7:00 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 February 2011 meeting minutes were accepted as printed.

*Public Comment: Janice Pertoso, Alkermes* – questioned the minutes that she thought erroneously reflected a Board decision of requiring step therapy for Vivitrol<sup>®</sup> for the treatment of opiate dependency. It was explained that the minutes include the recommendation for coverage and criteria proposed by MedMetrics Health Partners as well as the final DUR Board decision.

**3. DVHA Pharmacy Administration Updates: Nancy Hogue, Pharm.D. - Pharmacy Director, DVHA**

- An article written by Alex Brill from the American Enterprise Institute for Public Policy Research was discussed. The article titled “Overspending on Multi-Source Drugs in Medicaid” was released to the press last week. This report made several assumptions that were flawed and it is felt that the conclusions are incorrect.

**4. Medical Director Update: Medical Director was absent.**

**5. Follow-up items from Previous Meeting:** *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

- Seroquel<sup>®</sup>/Seroquel<sup>®</sup> XR-Low dose for anxiety or hypnotic: It was recommended to modify the Seroquel<sup>®</sup> XR clinical criteria in order to align with the Seroquel<sup>®</sup> immediate release criteria that will be going into effect. The criteria for approval of Seroquel<sup>®</sup> XR will be that the patient has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization) or the indication for use is schizophrenia or bipolar disorder (bipolar mania, bipolar depression, bipolar maintenance) and the patient has not been able to be adherent to a twice daily dosing schedule of Seroquel<sup>®</sup> immediate release resulting in a significant clinical impact or the indication for use is Adjunct treatment of Major Depressive Disorder (MDD) and the patient has had a documented inadequate response to at least 2 different antidepressants from the SSRI, SNRI, TCA, MAOI and/or Miscellaneous Antidepressant categories (Trazodone dosed at < 150 mg/day would not be considered a trial for this indication) and the patient has not been able to be adherent to a twice daily dosing schedule of Seroquel<sup>®</sup> immediate release resulting in a significant clinical impact.

*Public Comment:* No public comment.

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

- Vivitrol<sup>®</sup> for Opiate Addiction: It was recommended to further clarify the clinical criteria for Vivitrol<sup>®</sup> when being used for the prevention of relapse to opioid dependency to include that the patient has failed Suboxone<sup>®</sup> therapy or is not a candidate for Suboxone<sup>®</sup> therapy (eg. Patient is opiate free and prescriber wishes to prevent relapse to opioid dependence without using maintenance therapy) or patient requires injectable therapy (compliance, tolerance, etc).

*Public Comment:* No public comment.

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

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

- Buprenorphine Utilization: Prescriber utilization (de-identified) broken out by daily strength was provided. Progress has been made since November 2010 to decrease the total dose per day. For the period 2/1/2011 – 3/31/2011, 80.8% of members were on doses of 16 mg/day or less as compared to 76.2% for the period 11/1/2010 – 12/31/2010. There were 134 unique members on buprenorphine-mono in March 2011 which is a significant decrease from the 180 members in July 2010. This is due to the strict criteria of limiting the use to those who are pregnant. Total monthly spending is also down to \$669,796.32 in March 2011 for all forms of buprenorphine as compared to \$ 798,861.20 for June 2010. The per member per month spend on this therapy during this time period has decreased from \$ 6.24 to \$ 5.09.

*Public Comment:* No public comment.

**Board Decision:** None needed.

▪ RetroDUR/Educational Activities Currently in Process:

- Asthma: Update from the Medical Director of APS Healthcare working with the Vermont Chronic Care Initiative, which includes data on 2507 members with asthma. Letters will be sent to primary care physicians who have patients with a high number of rescue inhaler prescriptions. In a 12 month period, 168 patients had claims for 13 – 50 rescue inhalers each and 52 ER visits.

*Public Comment:* No public comment.

**Board Decision:** The Board would like a general education mailing be sent to pharmacies on the topic of asthma with details of the number of members receiving rescue inhalers and ER data.

- Congestive Heart Failure: Update from the Medical Director of APS Healthcare working with the Vermont Chronic Care Initiative, which includes 357 members with CHF. Multiple letters have been sent to providers with good response. Data is still being reviewed; however, a significant change in prescribing has not been seen. The most significant issue is that the appropriate beta-blockers are not being prescribed.

*Public Comment:* No public comment.

**Board Decision:** None needed.

**7. Clinical Update: Drug Reviews: Diane Neal, R.Ph, (MHP)**

(Public comment prior to Board action)

**Abbreviated Drug Review:**

- Lumigan<sup>®</sup> (bimatoprost) 0.01% Ophthalmic Solution: Due to the absence of efficacy advantages over Lumigan<sup>®</sup> 0.03% strength, identical cost, and consensus guideline recommendations for ophthalmic prostaglandin analogues, it is recommended that Lumigan<sup>®</sup> 0.01% be added to the PDL as Prior-Authorization required and be reviewed under the current approval criteria for Lumigan<sup>®</sup> 0.03% which are the patient has had a documented side effect, allergy, contraindication or treatment failure with a preferred beta blocker.

*Public Comment:* No public comment.

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

- Mugard<sup>®</sup> (mucoadhesive) Oral Wound Rinse: Current treatment guidelines recommend that all patients undergoing radiation and/or chemotherapy be maintained on an oral care protocol consisting of cleansing the oral mucosa, maintaining lubrication of the lips and oral tissues and relieving pain and inflammation. For patients who develop oral mucositis, mucosal coating agents or topical anesthetics are recommended. It is recommended that MuGard<sup>®</sup> require prior authorization with the criteria for approval being the patient is receiving radiation and/or chemotherapy and the patient has had a documented side effect, allergy or treatment failure with at least one oral mucosal coating agent (e.g. Amphojel<sup>®</sup>, Kaopectate<sup>®</sup>, Zilactin<sup>®</sup>) or a topical anesthetic (e.g. viscous lidocaine, benzocaine sprays/gels or diphenhydramine solutions) or combination. A quantity limit of 4 bottles per month was also recommended.

*Public Comment:* No public comment.

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

- Silenor<sup>®</sup> (doxepin) Tablet: It was recommended that Silenor<sup>®</sup> be added to the PDL as prior authorization required with the criteria for approval being the patient has had a documented side effect, allergy, contraindication or treatment failure with generic zolpidem and the patient has had a documented intolerance with generic doxepin or there is another clinically valid reason why generic doxepin (capsule or oral solution) cannot be used. In addition, a quantity limit of 1 tablet/day is proposed. Also, a change to the Rozerem<sup>®</sup> criteria to include a contraindication to generic zolpidem was recommended.

*Public Comment:* No public comment.

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

- TobraDexST<sup>®</sup> (tobramycin 0.03%/dexamethasone 0.1%) Ophthalmic Suspension: It was recommended that Tobradex ST<sup>®</sup> be added to the PDL as prior authorization required with the following criteria for approval being the patient has had a documented intolerance with generic tobramycin/dexamethasone.

*Public Comment:* No public comment.

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

- Xeomin<sup>®</sup> (incobotulinumtoxinA)Vial for Injection: It was recommended that Xeomin<sup>®</sup> be added to the PDL as prior authorization required with the criteria for approval being the patient has a diagnosis of cervical dystonia or blepharospasm and the patient is  $\geq 18$  years of age and the patient has had a documented intolerance or treatment failure with Botox<sup>®</sup>.

*Public Comment:* No public comment.

**Board Decision:** The Board would like additional information relative to the net cost of Botox<sup>®</sup> so a decision on the PDL position and criteria was deferred to the next meeting.

- Zuplenz<sup>®</sup> (ondansetron) Oral Soluble Film: It was recommended that Zuplenz<sup>®</sup> be added to the PDL as prior authorization required with the criteria for approval being the prescriber provides documentation of medical necessity for the specialty dosage form (i.e. inability to swallow capsules, dysphagia) and a clinical rationale as to why ondansetron ODT is not a suitable option for the patient. In addition, a quantity limit of 12 films/28 days (4 mg) and 6 films/28 days (8 mg) is proposed.

*Public Comment:* No public comment.

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

## Full New Drug Reviews

- Glassia<sup>®</sup> (alpha<sub>1</sub>-proteinase inhibitor) Vial for IV infusion: At this time, the DVHA does not manage any agents in the alpha-1-Proteinase Inhibitor class. In consideration of the cost and the limited FDA-approved indication, it is recommended to create a new alpha<sub>1</sub>-antitrypsin (AAT) deficiency managed category. The recommended criteria for approval for Glassia<sup>®</sup> are the patient has been started and stabilized on the requested medication or the diagnosis or indication is treatment of alpha<sub>1</sub>-antitrypsin

(AAT)/alpha<sub>1</sub>-proteinase inhibitor deficiency and the patient has had a documented side-effect, allergy, inadequate response to at least one preferred agent.

*Public Comment:* No public comment.

**Board Decision:** The Board voted to require the diagnosis or indication of treatment of alpha<sub>1</sub>-antitrypsin (AAT)/alpha<sub>1</sub>-proteinase inhibitor deficiency for any approval of any drugs in this class. The Board will review the entire class at a future meeting with more information provided on the other products.

- Lysteda<sup>®</sup> (tranexamic acid) Tablet: It was recommended that oral tranexamic acid be added to the PDL as prior authorization required with the approval criteria being the diagnosis or indication is clinically significant heavy menstrual bleeding and the patient has been started and stabilized on oral tranexamic acid within the previous 360 days or the patient does not have a contraindication to therapy with oral tranexamic acid (i.e., active thrombotic disease, history of thrombosis/thromboembolism, or an intrinsic risk of thrombosis/ thromboembolism), and if oral tranexamic acid is to be used concomitantly with an estrogen containing hormonal contraceptive product, the risks of combination therapy have been discussed with the patient and the patient has had a documented side effect, allergy, contraindication, or an inadequate response with at least one oral contraceptive or progestin containing product despite an adequate trial of at least 90 days or a rationale for why these products cannot be used (e.g. actively attempting to conceive) and the patient has had a documented side effect, allergy, contraindication, or an inadequate response with at least one regularly scheduled (not PRN) NSAID or a rationale for why these products cannot be used (e.g. actively attempting to conceive). Additionally, a quantity of 30 tablets per 28 days (two 650 mg tablets three times daily for up to 5 days during menstruation) is proposed with approval duration of 12 months.

*Public Comment:* No public comment.

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

#### **8. Therapeutic Drug Classes-Periodic Review:**

(Public comment prior to Board action)

- Cystic Fibrosis (inhaled antibiotics): It was recommended that the current approval criteria remain unchanged. TOBI<sup>®</sup> is the preferred agent, available without a prior authorization and Cayston<sup>®</sup> requires PA with a diagnosis or indication of cystic fibrosis.

*Public Comment:* Glenda Lewis, Gilead Sciences- Provided information regarding a head-to-head study between Cayston<sup>®</sup> and TOBI<sup>®</sup> that has been presented at a conference. The study should be published in June 2011.

**Board Decision:** The Board unanimously approved the MHP recommendation noted above. The Board would like to re-visit this class when the study is available to review.

- Pulmonary
- Anticholinergics, Inhaled (Inhaled Antimuscarinics) (Single and Combination Agents): No changes are recommended to the current approval criteria, preferred medications or quantity limits.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved no changes to this category.

- Beta-Adrenergic Agents: It was recommended that no changes be made to the current DVHA approval criteria, except for the clarification that a controller medication required in the case of a long-acting  $\beta_2$ -agonist MDI inhaler prescribed for asthma should be an inhaled corticosteroid. In light of recent FDA alerts about oral terbutaline in the use of prevention of preterm labor, it is recommended that terbutaline be moved to prior authorization required with criteria that it is not being prescribed for the prevention/treatment of preterm labor.

*Public Comment:* No public comment.

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

- Corticosteroids, Inhaled (Single and Combination Agents): It was recommended that no changes be made to the current approval criteria, preferred products and quantity limits.

*Public Comment:* Om Sandum, Merck—Available for any questions from the Board.

**Board Decision:** The Board unanimously approved no changes to this category.

- Xolair<sup>®</sup> (omalizumab): Due to the limited role of oral second-generation antihistamines in the management of allergic moderate to severe asthma, it was recommended that this criterion (currently in place) be removed. Additionally, the following changes were proposed: patient has tried and failed an inhaled corticosteroid *or* chronic oral corticosteroid therapy (addition of reference to oral) *or* has a contraindication to such therapy and patient has tested positive to at least one perennial aeroallergen by a skin or blood test (addition of choice of blood test).

*Public Comment:* No public comment.

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

- Antihistamines, Intranasal: It was recommended that the current approval criteria remain unchanged. In addition, a quantity limit of 1 bottle/25 days was recommended for all agents in the class.

*Public Comment:* No public comment.

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

- Antihistamines, Second Generation: It was recommended that no changes be made to the current second-generation antihistamines approval criteria and preferred drugs.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved no changes to this category.

- Corticosteroids, Intranasal: No changes were recommended to the current approval criteria and preferred products.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved no changes to this category.

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

(Public comment prior to Board action)

- No new drug classes this meeting.

**10. General Announcements Diane Neal, R.Ph, (MHP)**

**FDA Safety Alerts**

- Antipsychotic drugs: Class Labeling Change - Treatment During Pregnancy and Potential Risk to Newborns: FDA is informing healthcare professionals that it has updated the *Pregnancy* section of drug labels for the entire class of antipsychotic drugs. The new drug labels now contain more and consistent information about the potential risk for abnormal muscle movements (extrapyramidal signs or EPS) and withdrawal symptoms in newborns whose mothers were treated with these drugs during the third trimester of pregnancy. Presented as informational only, no action recommended.

*Public Comment:* No public comment.

**Board Decision:** None needed.

- Embeda<sup>®</sup> – Wholesaler/Retailer Recall due to Stability Issues: King Pharmaceuticals Inc has voluntarily recalled all dosages of a combination morphine sulfate and naltrexone hydrochloride (*Embeda<sup>®</sup> Extended Release Capsules CII*) from wholesalers and retailers in the United States because a prespecified stability requirement was not met during routine testing. Embeda<sup>®</sup> will not be available until the issue is resolved; it is likely that Embeda<sup>®</sup> will not be available for many months. All further claims for Embeda<sup>®</sup> have been blocked in the DVHA POS pharmacy system.

*Public Comment:* No public comment.

**Board Decision:** None needed.

- Proton Pump Inhibitor drugs (PPIs): Drug Safety Communication – Low Magnesium Levels Can Be Associated with Long-Term Use: FDA is informing the public that prescription proton pump inhibitor (PPI) drugs may cause low serum magnesium levels (hypomagnesemia) if taken for prolonged periods of time (in most cases, longer than one year). In approximately one quarter of the cases reviewed, magnesium supplementation alone did not improve low serum magnesium levels and the PPI had to be discontinued. Presented as informational only, no action recommended.

*Public Comment:* No public comment.

**Board Decision:** None needed.

- Terbutaline: Label Change – Warnings Against Use for Treatment of Preterm Labor: Oral terbutaline should not be used for prevention or any treatment of preterm labor because it has not been shown to be effective and has safety concerns (maternal heart problems and death with the injectable product). The FDA is requiring the addition of a *Boxed Warning* and *Contraindication* to the terbutaline tablet label to warn against this use. See discussion above for decision to move this product to PA required to confirm that it is not being prescribed for preterm labor.

*Public Comment:* No public comment.

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

- Topamax<sup>®</sup> (topiramate): Label Change - Risk For Development of Cleft Lip and/or Cleft Palate in Newborns: FDA is informing the public of new data that show that there is an increased risk for the development of cleft lip and/or cleft palate (oral clefts) in infants born to women treated with topiramate (Topamax<sup>®</sup> and generic products) during pregnancy. The benefits and the risks of topiramate should be carefully weighed when prescribing this drug to women of childbearing age, particularly for conditions not usually associated with permanent injury or death. Presented as informational only, no action recommended.

*Public Comment:* No public comment.

**Board Decision:** None needed.

- Unapproved Cough, Cold, Allergy Products: FDA Prompts Removal from Market: FDA announced that it intends to remove certain unapproved prescription cough, cold, and allergy drug products from the U.S. market. Unapproved prescription cough, cold, and allergy drug products have not been evaluated by the FDA for safety, effectiveness, and quality. People may be at greater risk when using these products than when using FDA-approved prescription drugs or drugs that are appropriately marketed over-the-counter (OTC). Many health care providers are unaware of the unapproved status of drugs and have continued to unknowingly prescribe them because the drugs' labels do not disclose that they lack FDA approval. DVHA will wait for further information on the unapproved products and will block them from paying in the benefit.

*Public Comment:* No public comment.

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

**12. Adjourn:** Meeting adjourned at 8:54 p.m.

### **Next DUR Board Meeting**

Tuesday, May 17, 2011

7:00 - 9:00 p.m.\*

EDS Building, OVHA Conference Room

312 Hurricane Lane, Williston, VT

(Entrance is in the rear of the building)

\* The Board meeting will begin at 6:30 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.