



**Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 02/09/2010**

Board Members:

Michael Scovner, M.D., Chair
Lynne Vezina, R.Ph.

Norman Ward, M.D.
Andrew Miller, R. Ph

Stuart Graves, M.D.
Kathleen Boland, Pharm.D.

Staff:

Cynthia LaWare, OVHA
Diane Neal, R.Ph., (MHP)
Michael Farber, M.D. OVHA

Nancy Miner, (MHP)
Nancy Hogue, Pharm.D. (MHP)

Jennifer Egelhof, OVHA
Stacey Baker, OVHA

Guests:

Robert Emmons, M.D.
Amy Finn, Merck
Rod Francisco, Forest
Theodore Johnson, M.D.

James Kokoszyna, Allergan
Terry Lee, Gilead Sciences
Craig Lemley, Amylin
Kelley Mackison, Johnson & Johnson

Jeffrey Olson, Gilead Medical Affairs
Vik Patel, Amylin
John Renna, Shire
James Soriano, Shire
Mark Walker, Shire

Michael Scovner, M.D. Chair, called the meeting to order at 7:05 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 January 2010 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: *Cynthia LaWare, Director of Pharmacy Benefit Programs, OVHA*

- Pharmacy Best Practices and Cost Control Report 2010 (SFY 2009): This report has been submitted to the legislature. The full report is available on the OVHA website. Net of rebates there was an increase in spend of 6.63% which appears to have been largely driven by an increase in enrollment of 5.16%. Net spending per beneficiary per month increased by 1.4% for all OVHA beneficiaries.

4. Medical Director Update: *Michael Farber, MD, Medical Director, OVHA*

- DUR Board Meeting Schedule: A proposal was made to spread the DUR Board meetings from a monthly schedule to an every 6 week schedule. There would be a total of 8 meetings per year.
- Clinical Programs Update: There has been a lot of emphasis placed on examining the buprenorphine program for opiate addiction. This will be discussed in more detail later in the meeting and in the months to come.

- Prescriber Comments: No prescriber comments reported by Dr. Farber.

Robert Emmons, M.D. (private practice psychiatrist) – Dr. Emmons (who is not a Medicaid enrolled provider) was invited by a DUR Board member to speak regarding his experience covering for a colleague for a possible Medicaid patient who needed a prior authorization. It was suggested by Dr. Emmons that the Preferred Drug List should be eliminated and replaced with educational efforts and advice. It was also suggested that there should be a method to track and report harm that might occur as a result of drug coverage policies.

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

- No follow-up items

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

(Public comment prior to Board action)

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

Abbreviated New Drug Reviews

- Acuvail® (ketorolac) Ophthalmic Solution: It was recommended that Acuvail® (ketorolac) require prior authorization as a non-preferred product with the criteria for approval being that the patient has had a documented side effect, allergy, or treatment failure to Acular® or Acular LS® or the patient has a documented hypersensitivity to the preservative benzalkonium chloride. In addition, a quantity limit of 30 unit dose packets per fill was recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Asacol HD® (mesalamine) Delayed Release Tablet: It was recommended that Asacol HD® (mesalamine delayed release tablet) require prior authorization as a non-preferred product with the criteria for approval being that the patient has had a documented side effect, allergy, or treatment failure with two (2) preferred products.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Edluar® (zolpidem tartrate) Sublingual Tablet: It was recommended that Edluar® (zolpidem tartrate sublingual) require prior authorization as a non-preferred product with the criteria for approval being that the patient has a medical necessity for a disintegrating tablet formulation (i.e. swallowing disorder). In addition, a quantity limit of one tablet per day was recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

Full Drug Reviews

- Cetraxal[®] (ciprofloxacin) Otic Solution: It was recommended that Cetraxal[®] (ciprofloxacin) otic solution require prior authorization as a non-preferred product with the criteria for approval being that the patient has had a documented side effect, allergy, or treatment failure to one of the following: any generic neomycin/polymixin B/hydrocortisone product, Ciprodex[®] otic suspension or generic ofloxacin otic solution. In addition, a quantity limit of 14 unit dose packages per fill was proposed. The Otic Anti-Infective managed category table was separated into “anti-infective single agent” products and “anti-infective/corticosteroid combination” products.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above including the restructure of the class table. The Board requested that utilization for some of the alternative otic solutions such as the acetic acid products be brought back to a subsequent meeting.

- Embeda[®] (morphine sulfate/naltrexone hydrochloride) Capsule (long acting): It was recommended that Embeda[®] (morphine sulfate/naltrexone hydrochloride) long acting capsule require prior authorization as a non-preferred product with the criteria for approval being that the patient has had a documented side effect, allergy, or treatment failure to generic morphine sulfate SR 12 hour. It was proposed that a history of drug abuse did not warrant approval of Embeda[®] as it was not clear to what extent this formulation will deter misuse, abuse and diversion.

Public Comment: No public comment.

Board Decision: The Board voted to defer a decision on this product until a subsequent meeting after attaining input from experts in pain management and addiction regarding the role of this drug. The Board also requested to know how many different prescribers were prescribing Avinza[®] (morphine sulfate).

- Intuniv[®] (guanfacine) Extended Release Tablet: It was recommended that Intuniv[®] (guanfacine) extended release require prior authorization as a non-preferred product as stimulants are preferred first line therapies. The recommended criteria for approval were the patient has a diagnosis of ADHD and the patient has been started and stabilized on the requested medication (excludes samples) or the patient has a documented treatment failure due to lack of efficacy to two long acting CNS stimulants and the patient has had a documented treatment failure with guanfacine immediate-release or has been unable to be compliant with or tolerate twice three times daily dosing of guanfacine immediate-release or the patient has a documented side effect, allergy, or direct contraindication (eg. comorbid tics, moderate-to-severe anxiety) to any one long-acting CNS stimulant and the patient has had a documented treatment failure with guanfacine immediate-release or has been unable to be compliant with or tolerate twice three times daily dosing of guanfacine immediate-release, In addition, a quantity limit of one tablet per day was recommended.

Public Comment: Theodore Johnson, M.D., Pediatrician – Discussed the desire for non-stimulant choices in ADHD.

John Renna, Shire – Commented on the situations where immediate release guanfacine might be used (autism, disruptive behavior issues) and also on the properties of Intuniv[®].

Board Decision: The Board voted to make Intuniv[®] non-preferred with the criteria as outlined above but did not want to require a trial of immediate release guanfacine prior to approval. The Board also requested that the drug be approved if there is a history of drug abuse with the patient or in the home.

7. Therapeutic Drug Classes-Periodic Review : Diane Neal, R.Ph, (MHP)

(Public comment prior to Board action)

- Scabicides and Pediculicides (includes overview of Ulesfia® (benzyl alcohol 5% lotion)): It was recommended that the class remain unchanged and that Ulesfia® (benzyl alcohol 5% lotion) be added as non-preferred with the criteria for approval being the same as for other non-preferred products (the patient has had a documented side effect or allergy to permethrin or treatment failure with two treatments of permethrin).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above. It was requested that the statement regarding neurotoxic side effects with other products be clarified at the next Board meeting.

8. New Managed Therapeutic Drug Classes

(Public Comment prior to Board action)

- Pulmonary Arterial Hypertension Agents: It was recommended that Adcirca® (tadalafil) be added to the phosphodiesterase-5 (PDE-5) Inhibitor Medications class as non-preferred with criteria for approval being a clinical diagnosis of pulmonary hypertension and no concomitant use of organic nitrate-containing products. In addition, a quantity limit of 2 tablets per day was recommended. A new category entitled “Pulmonary Arterial Hypertension Medications” was also introduced. There are two subcategories of “endothelial receptor antagonists” and “prostanoids”. All drugs would be preferred with the exception of brand name Flolan® where there is a generic equivalent. In addition, it was recommended that a maximum days supply for all drugs in this class be 30 days due to the high cost of these agents.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

9. Review of Newly-Developed/Revised Clinical Coverage Criteria

(Public comment prior to Board action)

- Anti-Diabetics: Peptide Hormones (Byetta®): In light of the new FDA approved indication for monotherapy it was recommended that the criteria for approval be changed to require a failure of only one oral antidiabetic agent processed via automated step therapy. Byetta® would move from PA required to preferred agents after clinical criteria are met.

Public Comment: Vik Patel, Amylin – Commented on the clinical efficacy and role of Byetta® in diabetes.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Gastrointestinals: Inflammatory Bowel Agents (Oral and Rectal Products): No need for further discussion as this was covered in the discussion on Asacol HD® where no other changes to the category were recommended.

- Suboxone[®]/Subutex[®] (buprenorphine): It was recommended that days supply be limited to a maximum of 30 days. Additional reports are going to be pulled and further proposals for additional edits will be brought back to the Board.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

10. RetroDUR: *Diane Neal, R.Ph, (MHP)*

- Cost Savings/Clinical Analysis of Prior Initiatives
 - Specialty Pharmacy – Hepatitis C and Growth Hormone – Overall, the OVHA specialty drug program has resulted in savings of \$796,833 compared to what the reimbursement to pharmacies would have been at the regular retail rate for the period November 2008 through October 2009. Some particular areas to highlight include a savings of \$119,255 just from restricting ribavirin to the generic 200 mg capsule and tablet as opposed to the more costly dosage forms and \$48,151 savings for Synagis[®]. In addition, with the introduction of Specialty pharmacy there has been a shift in patients to preferred products where there is additional savings from increased supplemental rebate collection which is not reflected in the number above.

Public Comment: No public comment.

Board Decision: None needed.

11. Updated New-to-Market Monitoring Log(Consent agenda topic): *Diane Neal, R.Ph, (MHP)*

- The log is posted on the web site. This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

Board Decision: None needed.

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

- Antipsychotics in Children-NY Times article: Discussed the use of antipsychotics in lower income children. It is expected that there will be a report from a multi-state Medicaid group out later this year.

FDA Safety Alerts

- Meridia[®] - (sibutramine Hydrochloride): Early communication about an ongoing safety review: FDA notified healthcare professionals that the review of additional data indicates an increased risk of heart attack and stroke in patients with a history of cardiovascular disease using sibutramine. Based on the serious nature of the review findings, FDA requested and the manufacturer agreed to add a new contraindication to the sibutramine drug label stating that sibutramine is not to be used in patients with a history of cardiovascular disease.

Public Comment: No public comment.

Board Decision: The Board would like to revisit the anti-obesity class of medications and review clinical criteria at some point.

- Norpramin[®] (desipramine) – Sudden Cardiac Death: Sanofi-Aventis and FDA notified healthcare professionals of changes to the Warnings and Overdosage sections of the Prescribing Information for Norpramin[®] (desipramine hydrochloride), indicated for the treatment of depression. The new safety information states that extreme caution should be used when this drug is given to patients who have a family history of sudden death, cardiac dysrhythmias, and cardiac conduction disturbances; and that seizures precede cardiac dysrhythmias and death in some patients.

Public Comment: No public comment.

Board Decision: None needed.

- Valproate: – Neural Tube Birth Defects: The FDA notified health care professionals and patients about the increased risk of neural tube defects and other major birth defects, such as craniofacial defects and cardiovascular malformations, in babies exposed to valproate sodium and related products (valproic acid and divalproex sodium) during pregnancy. Healthcare practitioners should inform women of childbearing potential about these risks, and consider alternative therapies, especially if using valproate to treat migraines or other conditions not usually considered life-threatening.

Public Comment: No public comment.

Board Decision: None needed.

- Voltaren Gel[®] (diclofenac) – Hepatic Effects: Endo, Novartis and FDA notified healthcare professionals of revisions to the Hepatic Effects section of the prescribing information to add new warnings and precautions about the potential for elevation in liver function tests during treatment with all products containing diclofenac sodium.

Public Comment: No public comment.

Board Decision: None needed.

- Zyprexa[®] (olanzapine): Use in Adolescents: Lilly and FDA notified healthcare professionals of changes to the Prescribing Information for Zyprexa[®] related to its indication for use in adolescents (ages 13-17) for treatment of schizophrenia and bipolar I disorder [manic or mixed episodes]. The revised labeling states that when deciding among the alternative treatments available for adolescents, clinicians should consider the increased potential (in adolescents as compared with adults) for weight gain and hyperlipidemia. Clinicians should consider the potential long-term risks when prescribing to adolescents, and in many cases this may lead them to consider prescribing other drugs first in adolescents.

Public Comment: No public comment.

Board Decision: None needed.

13. Adjourn: Meeting adjourned at 9:30 p.m.

Next DUR Board Meeting

Tuesday, April 13, 2010

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.