



**Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 04/13/2010**

Board Members:

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

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

Stuart Graves, M.D.
Cheryl Gibson, M.D.

Staff:

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

Nancy Miner, (MHP)
Nancy Hogue, Pharm.D. (MHP)
Michael McAdoo, OVHA

Jennifer Egelhof, OVHA
Stacey Baker, OVHA
Robin Farnsworth, OVHA

Guests:

Steve Berardino, Amgen
Paul Fanikos, BIPI
Michael Finn, GSK
Rod Francisco, Forest

Bernie Janeczko, Centocor
Mark Kaplan, Abbott
James Kokoszyna, Allergan
Paul McDermott, Johnson & Johnson

Danielle Moon, Merck
Brooke Still, Reckitt Benckiser
Tony Tommasello, Reckitt Benckiser
Angelo Valeri, Novartis

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: *Michael Scovner, M.D. Board Chair*

- Introductions were made around the table.
- The February 09, 2010 meeting minutes were accepted as printed.
- Guests were reminded that comments are limited to 3 minutes in duration and a timer will be used to be fair to all. Also, the Medical Director is available for discussion and comments concerning individual patient cases and should be contacted outside the DUR Board meeting.

Public Comment: No public comment.

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

- Director of Pharmacy Benefit Programs Retirement: Cindy LaWare will be retiring at the end of April. Nancy Hogue, Pharm.D, now of MedMetrics Health Partners, has accepted the role.
- Pharmaceutical Marketing Disclosures: The FY09 report from the Vermont Attorney General was presented. Approximately 17% of spending on the top 50 promoted drugs was spent on the marketing of drugs for depression.

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

- **Clinical Programs Update:** OVHA is in the process of forming a new Board called the CURB (Clinical Utilization Review Board) which will specifically look at new technology and technology currently being utilized to determine possible utilization controls and can be viewed as a companion Board to the DUR Board.
- **Prescriber Comments:** No prescriber comments were received.

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

- **Embeda[®] (morphine sulfate/naltrexone hydrochloride) Capsule (long acting):** Deferred until next meeting as more input is being gathered. Dr. Farber commented that the Medical Letter has just reviewed this drug.
- **Otic Anti-infectives:** Deferred until a later meeting.
- **Ulesfia[®] (benzyl alcohol 5% lotion):** It was clarified that this is the only benzyl alcohol product in this category. There are other products indicated for the treatment of lice that are also considered non-neurotoxic. Lindane is the only product that is considered neurotoxic.
- **Non Stimulants for ADHD:** It was clarified that a criteria for both Strattera[®] and Intuniv[®] is that they may be prescribed when there is a history of drug abuse with either the patient or family.

6. **RetroDUR/Prior Authorization Quality Assurance Analysis:** *Diane Neal, R.Ph., (MHP)*

- **Suboxone[®]/Subutex[®] (buprenorphine):** *Michael McAdoo, Managed Care Director, OVHA*
Utilization data was presented. Ideas for strengthening clinical criteria were presented.

Public Comment: Tony Tommasello, Reckitt Benckiser – Discussed daily dosing requirements and treatment factors that lead to successful opiate addiction treatment.

Board Decision: No action needed as no definitive criteria were presented. More detailed data and recommendations as well as a revised PA form will be presented at the next meeting.

- **Amitiza[®] (lubiprostone):** Deferred until next meeting.
- **RetroDUR/Educational Activities Currently in Process:**
 - **Antipsychotics:** AHEC (Area Health Education Programs) out of UVM has chosen to target antipsychotic use and prescribing as one of their next projects. OVHA will be providing some utilization data to AHEC to help in the development of academic detailing programs. Dr. Charlie McLean will attend one of the upcoming Board meetings to discuss their program and specifics surrounding this intervention.

Public Comment: No public comment.

Board Decision: None needed.

- **Congestive Heart failure-Are patients on recommended medications?** The OVHA Chronic Care Initiative with APS (who provides telephonic support) will be developing an outreach to prescribers around patients with a diagnosis of CHF for patients who are not receiving a recommended ACEI/ARB and a recommended beta-blocker.

Public Comment: No public comment.

Board Decision: None needed.

- Future Topics?/DUR Board input: A discussion was held with the Board regarding possible RetroDUR topics. One area of interest was overuse of particular drug classes. A draft of the new CMS Annual Report format has been released and will be brought to the DUR Board for discussion.

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)

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

Abbreviated New Drug Reviews:

- Ozurdex[®] (dexamethasone) Intravitreal Implant: This drug implant is not available in pharmacies and so should be billed through the Medical Benefit. The OVHA Clinical Unit will be asked to take a look at his product for coverage decisions.

Public Comment: James Kokoszyna, Allergan – Described the implant technique and availability of the product.

Board Decision: None needed.

Full New Drug Reviews:

- Bepreve[®] (bepotastine besilate): It was recommended that Bepreve[®] (bepotastine besilate) ophthalmic solution require prior authorization as a non-preferred product with the criteria for approval being the patient has had a documented side-effect, allergy, or treatment failure to BOTH Optivar[®] and Pataday[®] or Patanol[®] (after a step through OTC ketotifen). A quantity limit of one bottle per month was recommended.

Public Comment: No public comment.

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

- Dysport[®] (abobotulinumtoxinA) Injection: It was recommended that Dysport[®] (abobotulinumtoxinA) require prior authorization as a non-preferred product with the criteria for approval being the patient has a diagnosis of a cervical dystonia or spasmodic torticollis and the patient is ≥ 18 years of age and the patient has had a documented side effect, allergy, or treatment failure with Botox[®].

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above but asked that the wording of the criteria be changed to treatment failure with Botox[®] (remove reference to side effect and allergy).

- Onsolis[®] (fentanyl) buccal soluble film: It was recommended that Onsolis[®] (fentanyl) require prior authorization as a non-preferred product with the criteria for approval being the same as the other fentanyl breakthrough pain products. The criteria would be the patient has an indication of cancer breakthrough pain (no approval for acute pain or postoperative pain) and documentation that the patient is opioid tolerant and the member is on a long-acting opioid formulation and the member 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 member is unable to use tablet or liquid formulations. It was recommended that the definition of opioid tolerant be modified as in the fentanyl black box warning (oral morphine \geq 60 mg daily, transdermal fentanyl \geq 25 mcg/hour, oral oxycodone \geq 30 mg daily, oral hydromorphone \geq 8 mg daily or an equianalgesic dose of another opioid daily for a week or longer).

Public Comment: No public comment.

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

- Stelara[®] (ustekinumab) Subcutaneous Injection: It was recommended that Stelara[®] (ustekinumab) require prior authorization as a non-preferred product with the criteria for approval being the prescription must be written by a dermatologist AND the patient has a documented diagnosis of moderate to severe plaque psoriasis and has already been stabilized on Stelara[®] OR the prescription must be written by a dermatologist AND the patient has a documented diagnosis of moderate to severe plaque psoriasis affecting > 10% of the body surface area (BSA) and/or has involvement of the palms, soles, head and neck, or genitalia and has had a documented side effect, allergy, inadequate treatment response, or treatment failure to at least 2 different categories of therapy [i.e. at least 2 topical agents and at least 1 oral systemic agent, (unless otherwise contraindicated)] from the following categories: (1) Topical agents: emollients, keratolytics, corticosteroids, calcipotriene, tazarotene, etc.(2) Systemic agents: methotrexate, sulfasalazine, azathioprine, cyclosporine, tacrolimus, mycophenylate mofetil, etc. (3) Phototherapy: ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA, narrow band ultraviolet B (NUVA), etc. AND the prescriber must provide a clinically valid reason why either Enbrel[®] or Humira[®] cannot be used. A quantity limit of one dose per fill was recommended and patients \leq 100 kg would be limited to 45 mg doses.

Public Comment: Paul McDermott, Johnson & Johnson – Discussed the method of action of Stelara[®] and a brief overview of the drug.

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

- Valturna[®] (aliskiren/valsartan) Tablet: It was recommended that Valturna[®] (aliskiren/valsartan) require prior authorization as a non-preferred product with the criteria for approval being the patient has a diagnosis of hypertension AND the patient has had a documented treatment failure with the combination of a preferred Angiotensin Receptor Blocker (ARB) and Tekturna[®]. A quantity limit of one tablet per day was recommended

Public Comment: Angelo Valeri, Novartis – Proposed altering the approval criteria above to be changed to “OR” rather than “AND”.

Board Decision: The Board approved the MHP recommendations noted above with one abstention.

8. Therapeutic Drug Classes – Periodic Review

Deferred until next meeting.

9. New Managed Therapeutic Drug Classes

No new drug classes this month.

10. Review of Newly-Developed/Revised Clinical Coverage Criteria and/or Preferred Products

Diane Neal, R.Ph., (MHP)

- Anti-Diabetics: Insulin Due to the discontinuation of some insulin pen products (Novolin N[®], Novolin R[®] and Novolin 70/30[®]), it was recommended that the corresponding Humulin products be moved to preferred status.

Public Comment: No public comment.

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

- Byetta[®] and Symlin[®] Fact Sheets: When Byetta[®] and Symlin[®] were originally reviewed by the DUR Board in 2006, information fact sheets were developed and are still being sent to prescribers. It was recommended that these sheets are no longer necessary and the practice should be discontinued.

Public Comment: No public comment.

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

- Suboxone[®]/Subutex[®] (buprenorphine):
Will be brought back for discussion next month (see RetroDUR above).

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

(1) **Selected FDA Safety Alerts** Deferred until next meeting.

(2) **Board Member Resignation** *Michael Scovner, M.D. Board Chair*

It was announced that Rich Harvie R.Ph., a 17 year member of the Board has resigned. Rich was recognized for his many years of service.

13. Adjourn: Meeting adjourned at 9:15 p.m.

Next DUR Board Meeting

Tuesday, May 18, 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.