



**Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 11/10/09**

Board Members:

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

Kathleen Boland, Pharm.D.
Norman Ward, M.D.
Andrew Miller, R. Ph

Cheryl Gibson, M.D.
Richard Harvie, R. Ph.
Virginia Hood, M.D.

Staff:

Cynthia LaWare, OVHA
Diane Neal, R.Ph., (MHP)
Robin Farnsworth, OVHA

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

Jennifer Mullikin, OVHA
Stacey Baker, OVHA
Judy Jamieson, OVHA

Guests:

Ward Bennett, Centocor-OBI
Christina Carmody, Endo
Melanie Crain, J&J OMJ
Mike Delucia, Forest

Michael Deorsey, Abbott
Rod Francisco, Forest
Craig Lemley, Amylin
Steven McRae, Genentech

Danielle Moon, Merck
Tim Nies, GSK
Gary Prevost, PriCara
Vanessa Sciortino, Pricara

Michael Scovner, M.D. Chair, called the meeting to order at 7:02 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 October 2009 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- Legislative Committee on Administrative Rules: Discussions are ongoing regarding the 90 day supply rule and the AWP discount rule.
- Co-pay Analysis: There will be a presentation to the Health Access Oversight Committee regarding an analysis of an alternative co-pay structure.

4. Medical Director Update: Medical Director absent.

- Clinical Programs Update: No updates were reported.
- Prescriber Comments: No comments were received.

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

- **Simponi[®] (golimumab) Prefilled Injection:** It was recommended that coverage would require PA with the criteria for approval being that the patient has a diagnosis of RA, psoriatic arthritis or ankylosing spondylitis and has already been stabilized on Simponi[®] **OR** patient age \geq 18 years **AND** diagnosis is RA, psoriatic arthritis or ankylosing spondylitis, and the patient has documentation of an inadequate response, adverse reaction or allergic response to methotrexate, or if methotrexate is contraindicated, at least 1 DMARD **AND** the prescriber must provide a clinically valid reason why either Humira[®] or Enbrel[®] cannot be used. In addition, it was recommended that initial approval durations should be authorized for 3 months with a quantity limit of 1 syringe/month.

Public Comment: Ward Bennet, Centocor – OBI: Relayed the information that a study was presented at a recent meeting of the American College of Rheumatology that showed a statistically significant slowing of disease progression upon radiographic review compared to methotrexate.

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

- **Vectical[®] (calcitriol) Topical Ointment**
Deferred until next meeting. Unable to obtain input from a dermatologist to date.

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

- **Exforge HCT[®] (amlodipine/valsartan/hydrochlorothiazide) Tablet:** Recommended for addition to the PDL as preferred after the following clinical criteria are met: The patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization.) **OR** the patient has had a documented side effect, allergy, or treatment failure to an angiotensin converting enzyme inhibitor (ACEI), an ACEI combination or any other angiotensin receptor blocker (ARB) or ARB combination. In addition, a quantity limit of 1 (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

- **Nucynta[®] (tapentadol) Tablet:** Recommended for addition to the PDL as Prior-Authorization required with the criteria for approval being the member has had a documented side effect, allergy, or treatment failure to at least two of the following 3 immediate release generic short acting narcotic analgesics – morphine, hydromorphone or oxycodone. It was also recommended that these same clinical criteria be applied to Opana[®].

Public Comment: Melanie Crain, J&J OMJ – Commented on the clinical trials with Nucynta[®] and mechanism of action.

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

- Nuvigil® (armodafinil) Tablet: Recommended for addition to the PDL as prior authorization required with the criteria for approval for narcolepsy and excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome (adjunct to standard treatment) being the patient is ≥ 17 years old AND the patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization.) OR the patient has had a documented side-effect, allergy or treatment failure to a CNS stimulant or has a contraindication for use of these agents (e.g. substance abuse history). It was recommended that Nuvigil® not be approved for sleepiness associated with shift work sleep disorder, idiopathic hypersomnolence, excessive daytime sleepiness, fatigue associated with use of narcotic analgesics, or for ADHD. In addition, if Nuvigil® is approved, a quantity limit of 60 tablets for 30 days for the 50 mg strength and 30 tablets for 30 days for 150 mg and 250 mg strengths is recommended.

Public Comment: No public comment.

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

- Savella® (milnacipran) Tablet: Recommended for addition to the PDL as prior authorization required with the criteria for approval being the diagnosis or indication is treatment of fibromyalgia AND the patient has had a documented side effect, allergy, or treatment failure to TWO drugs from the following: gabapentin, tricyclic antidepressant, SSRI antidepressant, SNRI antidepressant, miscellaneous antidepressant or cyclobenzaprine. In addition, a quantity limit of 2 tablets/day was recommended. Also, it was recommended that Savella® be added as an option for prior trial that will allow a patient to meet criteria for use of Lyrica® or Cymbalta® for the diagnosis of fibromyalgia.

Public Comment: Mike Delucia, Forest – Commented on the mechanism of action, pharmacokinetics, efficacy and safety of Savella®.

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

7. Review of Newly-Developed/Revised Clinical Coverage Criteria: Diane Neal, R.Ph, (MHP)
(Public comment prior to Board action)

- Growth Hormones:
A previously presented therapeutic class review of growth hormones determined that all products are equally efficacious. It was recommended that the most cost effective class structure would have Nodritropin® and Omnitrope® as the preferred products (after clinical criteria are met) within this class. Nutropin® would move to non-preferred status after clinical criteria are met. ICORE, the specialty pharmacy vendor for OVHA, will be responsible for contacting physicians and patients' families regarding this change and will ensure that teaching regarding the use of the new products occurs with families. This change was proposed for 01/04/2010.

Public Comment: No public comment.

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

- Lipotropics: Miscellaneous/Combinations (Lovaza® and Zetia®):
It was recommended that “started and stabilized” be added as an approval criteria for Lovaza® so that patients needing ongoing prior approvals could meet criteria (previously the criteria only included an elevated triglyceride level which patients who were responding to therapy would no longer have). A

discussion was held surrounding the approval criteria for Zetia[®] and whether the criteria for approval should remain a trial of both generic simvastatin and Crestor[®].

Public Comment: No public comment.

Board Decision: The DUR Board voted to approve the additional clinical criteria for Lovaza[®] as noted above but declined to change the clinical criteria for Zetia[®].

▪ **Migraine Medications (Triptans):**

It was recommended that regular Maxalt[®] tablets move to prior authorization required. Malaxt[®] MLT would remain preferred. This change was recommended due to a significant net cost difference between the two dosage forms. A patient specific prescriber mailing will be sent to prescribers asking them to change patients on regular Maxalt[®] tablets to Maxalt[®] MLT. This change was proposed for 01/04/2010.

Public Comment: No public comment.

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

8. Drug Classes – Annual Review:

(Public comment prior to Board action)

- **Long Acting Narcotics:** A full therapeutic class review was prepared. The only change to this category is that methadone 40 mg dispersible tablets are no longer allowed to be dispensed at retail and will be removed from the listing. Complaints surrounding the criteria for Duragesic[®]-12 patches were discussed but the criteria were recommended to remain unchanged. The criteria were reworded to be clearer.

Public Comment: No public comment.

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

9. RetroDUR: Diane Neal, R.Ph, (MHP)

- No RetroDur this month.
- **Future Topics:** Possible future topics were discussed.

Public Comment: No public comment.

Board Decision: None needed.

10. New Drug Product Plan Exclusions: Diane Neal, R.Ph, (MHP)

- This will now be a quarterly agenda topic so was not discussed this month.

11. Updated New-to-Market Monitoring Log: 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.

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

FDA Safety Alerts

- **Byetta[®] - altered kidney function:** FDA notified healthcare professionals of revisions to the prescribing information for Byetta[®] (exenatide) to include information on post-marketing reports of altered kidney function, including acute renal failure and insufficiency. Byetta[®] currently requires prior authorization. No changes to criteria were recommended.

Public Comment: No public comment.

Board Decision: None needed.

- **Rituxan[®] - PML:** Genentech and FDA notified healthcare professionals about a third case of progressive multifocal leukoencephalopathy [PML], the first case of PML in a patient with rheumatoid arthritis [RA] treated with Rituxan[®] who has not previously received treatment with a TNF antagonist. Information to date suggests that patients with RA who receive Rituxan[®] have an increased risk of PML. Physicians should consider PML in any patient being treated with Rituxan[®] who presents with new onset neurologic manifestations. Consultation with a neurologist, brain MRI, and lumbar puncture should be considered as clinically indicated. Rituxan[®] is not currently actively managed in the OVHA benefit and no changes to this are recommended.

Public Comment: No public comment.

Board Decision: None needed.

13. Adjourn: Meeting adjourned at 8:43 p.m.

Next DUR Board Meeting

Tuesday, December 08, 2009

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.