



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 01/10/2012**

Board Members:

Michael Scovner, MD, Chair
Jaskanwar Batra, MD
Jeanne Greenblatt, MD
Mark Pasanen, MD

Gary Starecheski, RPh
Lynne Vezina, RPh
Halle Sobel, MD

Kim Ladue, NP
Joseph Lasek, MD
Amanda Kennedy, PharmD

Staff:

Diane Neal, RPh, MHP
Stacey Baker, DVHA
Nancy Hogue, PharmD., DVHA

Nancy Miner, MHP
Michael Farber, MD, DVHA
Ron Clark, DVHA

Michelle Sirois, MHP
Rebecca Hopko, DVHA
Leanne Miles, DVHA

Guests:

Mario Carnovale, Novartis
Dave Downey, Abbott
Judy Kando, Sunovion
Danielle Moon, Merck
Julie Rae, Acorda
Scott Williams, OMJ
Katrina Iserman

Paul Amato, GSK
Christine Dube, MedImmune
Tom Martin, Boehringer-Ingelheim
Carl Pepe, GSK
Andrew Tenaglia, Bayer
Joe Winalski, BiogenIdec
Catherine Baum, BiogenIdec

Karalyn Connolly, Janssen
Rod Francisco, Sunovion
Chris Michaels, Elan
Gary Prevost, PriCara
Keith White, Genentech
Dean Najarian, Janssen

Michael Scovner, MD, Chair, called the meeting to order at 7:03 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 December, 2011 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. DVHA Pharmacy Administration Updates: Nancy Hogue, RPh, DVHA

- Reviewed the Summary of Draft Recommendations for Single Formulary/Electronic Prior Authorization Report. The final report is due to the legislature by February 13, 2012.
- Notification of change in specialty pharmacy from ICORE to Ascend Specialty Pharmacy effective February 1, 2012.
- DVHA Program Integrity Unit role and contact information discussed.

4. Medical Director Update: *Michael Farber, M D, DVHA*

- **Clinical Programs Update:** In reviewing a member for a prior authorization for Suboxone, found that the member had filled 480 hydromorphone and 330 oxycodone IR tablets in the last few months as well as the Suboxone. Neither prescriber had reviewed the patient profile in the VPMS. Should the DUR Board consider quantity limits on short-acting opiates?
- **Prescriber Comments:** Addiction medication specialists have indicated that pharmacies in the Rutland area are reporting an increase in the sales of TB and insulin syringes which they surmise are being used to inject dissolved Suboxone Film.

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

- **Latuda[®]:** A sub-committee of the DUR Board has reviewed Latuda[®] in further detail in relation to the side effect profile and studies performed. It is recommended that the approval criteria for prior authorization be modified to the following: The patient is pregnant and the diagnosis is schizophrenia OR 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 with at least two preferred products, one of which is Geodon[®] OR the patient has had a documented side effect, allergy, or treatment failure with Geodon[®] and the prescriber feels that neither risperidone nor Seroquel[®] would be appropriate alternatives for the patient because of pre-existing medical conditions, such as obesity or diabetes.

Public Comment: Judy Kando, Sunovion – Provided information on long-term studies done with Latuda[®].

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

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

- **Seroquel[®] Low Dose Initiative:** DVHA claims for all members including all strengths of quetiapine, benzodiazepines, non-benzodiazepine sedative hypnotics, and trazodone between January 1, 2011 and September 30, 2011 were reviewed to determine if there were any shifts in utilization after the low-dose quetiapine restriction was implemented. The examined claims data included the number of unique utilizers, average cost per claim, number of paid claims, and total plan costs. For all DVHA members between January 1, 2011 and September 30, 2011, the average number of unique utilizers per month for quetiapine 25 mg/50 mg decreased 17% between the pre- and post-QL time periods, whereas for benzodiazepines, non-benzodiazepine sedative hypnotics, and trazodone there was no significant change between the two time periods. The average total plan cost per month for the 25 mg/50 mg strengths of quetiapine decreased by an average of \$7,404.20 (9%) between the pre- and post-QL time periods, whereas the average total plan cost/month for all strengths >50 mg was consistent between the pre- and post-QL time periods. This reduction in average total plan cost/month for the 25 mg/50 mg strengths is consistent with the observed decrease in utilization of the two strengths. Average total plan cost per month for benzodiazepines, non-benzodiazepine sedative hypnotics, and trazodone was similar between the pre- and post-QL time periods. Prior authorization requests submitted between July 12, 2011 and October 12, 2011 were reviewed. A total of 224 prior authorization requests were submitted during this time period with an overall approval rate of 83%. The most common reason for denial was a lack of a trial with a preferred medication. Of the 15 reviewed requests that were initially denied, 8 were resubmitted with a different diagnosis or trials

with preferred medications and were subsequently approved. Based on this review of quetiapine, benzodiazepines, and non-benzodiazepine sedative hypnotic utilization and prior authorization requests, as well as lack of negative feedback from prescribers about the initiative, no changes to the current DVHA low-dose quetiapine prior authorization approval criteria are recommended.

Public Comment: No public comment.

Board Decision: DUR Board approved no changes to approval criteria.

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

Abbreviated Drug Review:

- Horizant® (gabapentin enacarbil) ER Tablet: It was recommended to add Horizant® to the Department of Vermont Health Access (DVHA) preferred drug list (PDL) as prior authorization required with the criteria for approval being: The patient has a diagnosis of restless leg syndrome (RLS) AND the patient has had a documented side effect, allergy, contraindication or treatment failure to generic immediate release ropinirole OR pamipexole AND the patient has had an inadequate response or adverse reaction to generic gabapentin immediate-release. Additionally, a quantity limit of one tablet/day is proposed.

Public Comment: Paul Amato, GSK – Provided additional information on the use of immediate-release gabapentin in RLS.

Board Decision: The Board unanimously approved the MHP recommendation noted above but would like the requirement of ropinirole AND pamipexole to be trialed.

- Phoslyra® (calcium acetate) Oral Solution: It was recommended to add Phoslyra® to the DVHA PDL as PA required. The following approval criteria are recommended for Phoslyra®: The patient has a requirement for a liquid dosage form.

Public Comment: No public comment.

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

Full New Drug Reviews:

- Xarelto® (rivaroxaban) Tablet: It was recommended to add rivaroxaban (Xarelto®) as prior authorization required with the following approval criteria: Patient has a diagnosis of the need for thromboprophylaxis following knee and hip replacement surgery OR the diagnosis or indication is atrial fibrillation AND the patient has been started and stabilized on the requested medication OR the patient has had a documented side effect, allergy, or contraindication (i.e. drug interactions) to warfarin therapy OR the patient has not been able to be adherent to coagulation monitoring or has not been able to achieve optimal INR control [INR 2-3] with warfarin therapy, despite dose titration attempts OR the prescriber has provided another clinically valid reason why generic warfarin cannot be used. In addition, a quantity limit of 1 tablet/day is proposed.

Public Comment: Arlene Price, J&J - Highlighted some of the attributes of Xarelto®.

Board Decision: The Board unanimously approved the MHP recommendation noted above but would like to allow the 10 mg tablet x 30 days without the need for a prior authorization so that completion of prophylactic therapy following hip and knee replacement therapy could occur without need for PA.

8. Therapeutic Drug Classes-Periodic Review:

(Public comment prior to Board action)

- Dipeptidyl Peptidase-4 (DPP-4) Inhibitors: No changes to the current DVHA approval criteria for DPP-4 inhibitors are proposed.

Public Comment: No public comment.

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

- Peptide Hormones: Amylinomimetics (Symlin®): No changes to the current DVHA approval criteria for Symlin® are proposed.

Public Comment: No public comment.

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

- Peptide Hormones: Incretin Mimetics: No changes to the current DVHA approval criteria for incretin mimetics are proposed.

Public Comment: No public comment.

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

- Growth Hormone: No changes to the current DVHA approval criteria for growth hormones are proposed.

Public Comment: No public comment.

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

- Multiple Sclerosis Biologic Response Modifiers: No changes to the current DVHA approval criteria for MS biologic response modifiers are proposed.

Public Comment: No public comment.

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

- Potassium Channel Blockers: No changes to the current DVHA Ampyra® approval criteria are proposed.

Public Comment: Adam Rzetelny and Angela Applebee, Acorda – Highlighted some of the attributes of Ampyra®.

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

- Ophthalmic Antibiotics: No changes to the current DVHA approval criteria for ophthalmic antibiotics are proposed.

Public Comment: No public comment.

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

- Ophthalmic Antihistamines: No changes to the current DVHA approval criteria for ophthalmic antihistamines are proposed.

Public Comment: No public comment.

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

- Ophthalmic Nonsteroidal Anti-inflammatory Drugs: No changes to the current DVHA approval criteria for ophthalmic NSAIDs are proposed. Bromday[®] (bromfenac 0.9%) solution added as PA required with criteria for approval being the patient has had a documented side effect, allergy, or treatment failure to Acular[®] or Acular LS[®].

Public Comment: No public comment.

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

- Vaginal Antibiotics: No changes to the current DVHA PDL are recommended at this time.

Public Comment: No public comment.

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

- Vaginal Antifungals: At this time, the Department of Vermont Health Access does not have PDL restrictions on generically available over-the-counter vaginal anti-infectives. The recent OTC coding changes implemented in July, 2011, only allow generically available products with no opportunity for PA requests for branded products. In recognition of the low utilization of the branded products, no changes are recommended. This will not become a managed category.

Public Comment: No public comment.

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

9. New Managed Therapeutic Drug Classes:
(Public comment prior to Board action)

- None at this time.

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

- Atypical Antipsychotics: Long Acting Injectable Products: It is recommended that that the approval criteria be changed to the following: A medical necessity for a specialty dosage form has been provided (swallowing disorder, non-compliance with oral medications, etc) and for approval for Zyprexa Relprevv[®], the prescriber must also provide clinical rationale why Risperdal Consta[®] or

Invega Sustenna[®] is not a suitable option for this patient. Also, it is recommended that the approval criteria for Invega[®] oral tablets be modified to the following: The patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization.) (Prior therapy with injectable Invega Sustenna[®] is not considered to be started and stabilized for oral Invega[®]. Patients transferring to oral therapy from Invega Sustenna[®] should transition to oral risperidone unless patient previously failed such treatment.) OR the patient has had a documented side effect, allergy, or treatment failure with at least two preferred products.

Public Comment: Dean Najarian, Janssen -- Highlighted some of the attributes of Invega Sustenna[®] and Risperdal Consta[®].

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

11. General Announcements Diane Neal, RPh, MHP

FDA Safety Alerts

- Safety review of a reported death after the first dose of Multiple Sclerosis drug Gilenya[®] (fingolimod): The US Food and Drug Administration (FDA) has received a report of a patient with multiple sclerosis (MS) who died within 24 hours of taking the first dose of Gilenya[®] (fingolimod). At this time, FDA cannot conclude whether the drug resulted in the patient's death. FDA is continuing to evaluate the case and will communicate any new information that results from this investigation.

Public Comment: No public comment.

Board Decision: None needed.

- Review update of Multaq[®] (dronedaron) and increased risk of death and serious cardiovascular adverse events: The FDA has completed a safety review of the heart drug Multaq[®] (dronedaron). This review showed that Multaq[®] increased the risk of serious cardiovascular events, including death, when used by patients in permanent atrial fibrillation (AF). The review was based on data from two clinical trials, the PALLAS trial (Permanent Atrial Fibrillation Outcome Study Using Dronedaron on Top of Standard Therapy) and the ATHENA trial (which supported Multaq's approval for treatment of non-permanent AF). FDA is providing new information and recommendations for the use of Multaq[®] to manage the potential serious cardiovascular risks with the drug.

Public Comment: No public comment.

Board Decision: None needed.

- Safety review of post-market reports of serious bleeding events with the anticoagulant Pradaxa[®] (dabigatran etexilate mesylate): The FDA is evaluating post-marketing reports of serious bleeding events in patients taking Pradaxa[®] (dabigatran etexilate mesylate). Pradaxa[®] is a blood thinning (anticoagulant) medication used to reduce the risk of stroke in patients with non-valvular atrial fibrillation (AF), the most common type of heart rhythm abnormality.

Public Comment: No public comment.

Board Decision: None needed.

- Selective serotonin reuptake inhibitor (SSRI) antidepressant use during pregnancy and reports of a rare heart and lung condition in newborn babies: The FDA is updating the public on the use of selective serotonin reuptake inhibitor (SSRI) antidepressants by women during pregnancy and the potential risk of a rare heart and lung condition known as persistent pulmonary hypertension of the newborn (PPHN). The initial Public Health Advisory in July 2006 on this potential risk was based on a single published study. Since then, there have been conflicting findings from new studies evaluating this potential risk, making it unclear whether use of SSRIs during pregnancy can cause PPHN.

Public Comment: No public comment.

Board Decision: None needed.

- Revised dose limitation for Zocor[®] (simvastatin) when taken with amiodarone: The FDA is notifying the public that it has revised the dose limitation for the cholesterol-lowering drug simvastatin from 10 mg to 20 mg when it is co-administered with the cardiac drug amiodarone. In June 2011, FDA previously recommended that the dose limitation for simvastatin be decreased from 20 mg to 10 mg, and has now reconsidered that recommendation.

Public Comment: No public comment.

Board Decision: None needed.

Other

- ALTITUDE Study of Aliskiren Terminated Early by Novartis: Novartis would like to inform healthcare professionals about important new safety information for aliskiren (Tekturna[®]) following interim results from the Aliskiren Trial in Type 2 Diabetes Using Cardio-Renal Endpoints (ALTITUDE). Aliskiren or aliskiren-containing fixed combination products should not be used in combination with ACE inhibitors or ARB in patients with diabetes. It is recommended that the Department of Vermont Health Access (DVHA) change the approval criteria for all aliskiren or aliskiren-containing products to not allow the use in any member who is a diabetic and also receiving an ACEI or ARB.

Public Comment: No public comment.

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

12. Adjourn: Meeting adjourned at 9:12 p.m.

Next DUR Board Meeting

Tuesday, February 21, 2012

7:00 - 9:00 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 6:30 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.