



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 04/10/2012**

Board Members:

Michael Scovner, MD, Chair
Halle Sobel, MD
Jeanne Greenblatt, MD
Sommer Zarbock, PharmD

Gary Starecheski, RPh
Lynne Vezina, RPh
Amanda Kennedy, PharmD
Jaskanwar Batra, MD

Kim Ladue, NP
Mark Pasanen, MD
Joe Lasek, MD
Andrew Miller, RPh

Staff:

Diane Neal, RPh, MHP
Stacey Baker, DVHA
Jennifer Egelhof, DVHA

Nancy Miner, MHP
Nancy Hogue, PharmD, DVHA

Michelle Sirois, MHP
Michael Farber, MD, DVHA

Guests:

Richard Angeli, Merck
Carl Pepe, GSK
Gary Prevost, PriCara
Mark Logan, MD

David Downey, Abbott Labs
Jai Persico, Endo
Jim Pitt, Lundbeck
Kevin Lempfest

Danielle Moon, Merck
Wendy Pollinger, Eli Lilly
Sunil Majethia, Abbott

Michael Scovner, MD, 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, 2012 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- There are two budget initiatives for DVHA around waste prevention: The first is to allow two fills of a medication before mandating a 90 day supply on certain maintenance medications to ensure that the patient is stabilized and tolerating the medication. The second is to restrict the first fill of a medication to a 15 day supply for a select list of medications where there is a high discontinuation rate.
- DVHA would like the Board to make suggestions of which products they think would be appropriate to restrict to a 15 day supply on the first fill.

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

- **Prescriber Comments:** Dr. Mark Logan provided information about his experience using Suboxone[®] film in patients who previously were I.V. drug abusers and his ability to track the film. Dr. Farber asked that the Board consider his proposed criteria which would allow the use of Suboxone tablets by select buprenorphine providers without the need for patient-specific approval by the Medical Director. A discussion ensued concerning the reasons the DVHA prefers Suboxone[®] film dosage form over Suboxone[®] tablet dosage form.

Public Comment: No public comment.

Board Decision: No formal board action was taken as this topic was not announced as being on the agenda and the Board had not received information on this proposal prior to the meeting. The criteria will be distributed to the Board for discussion at the next meeting.

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

- **Citalopram > 40 mg/day:** There was an updated FDA Drug Safety Communication released on March 28, 2012, which includes new warnings about the potential for QT interval prolongation and Torsade de Pointes, as well as, new drug dosage and usage recommendations. It is recommended that the DVHA clinical criteria for citalopram >40 mg/day for age ≤60 years old and >20 mg/day for >60 years old or hepatic impairment be changed to: The patient and/or family has been advised of the cardiac risks associated with this dose AND ECG monitoring and/or electrolyte monitoring (potassium, magnesium) will be performed when indicated. New information was provided that these cardiac side effects have not been shown to occur with escitalopram.

Public Comment: No public comment.

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

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

- **Narcotic Analgesics – Short Acting:** DVHA will be using an Opioid MUE software program to evaluate average doses and to evaluate patients who are chronically on short acting narcotic analgesics but never use a long acting narcotic analgesic product. The pharmacy data will be loaded into this software program.

Public Comment: No public comment.

Board Decision: None needed.

- **Psychotropic Medication Use in Children SFY 2009-2011:** The use of psychotropic medications in children was quantified over the past 3 fiscal years. There has been a trend overall for a decrease or leveling off of the use of these medications in children in general (those not in foster care).

Public Comment: No public comment.

Board Decision: None needed.

- Psychotropic Medication Use in Children in Foster Care SFY 2009-2011: There is a GAO report based on 2008 data from 5 states that showed that there is a higher use of psychotropic medication use in children in foster care compared to other children. Our data was analyzed and showed the same trend. Vermont submitted a proposal and was chosen as one state that will be given technical assistance to study and monitor the use of psychotropic medications in children in foster care.

Public Comment: No public comment.

Board Decision: None needed.

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

Abbreviated Drug Review:

- Conzip[®] (tramadol extended release) capsule: It was recommended to add Conzip[®] capsule to the Department of Vermont Health Access (DVHA) preferred drug list (PDL) as prior authorization required with the criteria for approval being that the member has had a documented side effect or treatment failure to a preferred short-acting tramadol product AND the member has had a documented intolerance to generic tramadol ER. The quantity requested does not exceed 1 capsule per day (300mg per day).

Public Comment: No public comment.

Board Decision: The Board requested that the words “side effect or” be removed from the criteria above. The revised criteria were approved.

- Gralise[®] (gabapentin) Tablet: It was recommended to add Gralise[®] to the DVHA PDL as prior authorization required with the recommended criteria for approval being that the patient has a diagnosis of postherpetic neuralgia (PHN) AND the patient has had a documented side effect, allergy, contraindication or treatment failure with at least one drug from the tricyclic antidepressant class AND the patient has had an inadequate response or adverse reaction to the generic gabapentin immediate-release. A quantity limit of 90 tablets/30 days is proposed.

Public Comment: No public comment.

Board Decision: The Board requested that the words “or adverse reaction” to the generic gabapentin immediate release be removed. The Board approved the modified criteria and would also like a follow up report in 6 months of how many requests have been made for this product.

- Juvisync[®] (sitagliptin/simvastatin) Tablet: It was recommended to add Juvisync[®] to the DVHA PDL as prior authorization required with the recommended criteria for approval being that the patient has had a documented side effect, allergy, contraindication or treatment failure with metformin AND the patient has been started and stabilized on Januvia[®] and simvastatin combination therapy as individual agents. A quantity limit of 1 tablet/day is recommended.

Public Comment: No public comment.

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

- Orencia[®] (abatacept) Subcutaneous Injection: It was recommended to add Orencia[®] subcutaneous injection to the DVHA PDL as prior authorization required with the recommended criteria for approval being that the patient has a diagnosis of RA and has already been stabilized on Orencia[®] OR diagnosis is RA and methotrexate therapy resulted in an adverse effect, allergic reaction, inadequate response, or treatment failure. If methotrexate is contraindicated, another DMARD should be tried prior to approving Orencia[®]. Note: Orencia[®] may be used as monotherapy or concomitantly with DMARDs, other than TNF antagonists. Orencia[®] should not be administered concomitantly with TNF antagonists (i.e. Enbrel[®], Humira[®], or Remicade[®]) and it is not recommended for use with Kineret[®] AND the prescriber must provide a clinically valid reason why either Humira[®] or Enbrel[®] cannot be used. There will be a quantity limit of 4 syringes per 28 days. Also, this subcutaneous injection would be preferred before the intravenous Orencia[®] infusion (after other criteria are met).

Public Comment: No public comment.

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

Full New Drug Reviews:

- Onfi[®] (clobazam) Tablet: It was recommended to add Onfi[®] to the DVHA PDL as prior authorization required with the criteria for approval being the patient has been started and stabilized on the requested medication OR the diagnosis or indication is adjunctive treatment of Lennox-Gastaut Syndrome AND the patient has had a documented side effect, allergy, treatment failure/inadequate response or a contraindication to at least TWO preferred anticonvulsants used for the treatment of Lennox-Gastaut Syndrome (topiramate, lamotrigine, valproic acid) OR the diagnosis or indication is adjunctive treatment of refractory epilepsy (may include different types of epilepsy) AND the patient has had a documented side effect, allergy, treatment failure/inadequate response or a contraindication to at least THREE preferred anticonvulsants.

Public Comment: Daniel Jones, Lundbeck – Nothing to add to the presentation/available for questions.

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

- Firazyr[®] (icatibant) Prefilled Syringe for Subcutaneous Injection: It was recommended to add Firazyr[®] to the DVHA PDL as prior authorization required with the criteria for approval being the diagnosis or indication is treatment of an acute Hereditary Angioedema (HAE) attack. A quantity limit of 3 syringes per fill (9ml) was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above. The Board would like to consider changing the quantity limit to 2 syringes per fill at a later date.

- Solesta[®] Gel Prefilled Syringe for Submucosal Injection:
Deferred until next meeting due to lack of time.

8. Therapeutic Drug Classes-Periodic Review: Diane Neal, RPh, MHP (Public comment prior to Board action)

- Anti-Fungals-Oral: No changes to the current DVHA approval criteria or preferred drugs for Anti-fungals: Allylamines and Anti-fungals: Azoles are proposed.

Public Comment: No public comment.

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

- Anti-Diabetics – Oral - Thiazolidinediones: No changes to the current DVHA approval criteria for Thiazolidinedione products are proposed.

Public Comment: No public comment.

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

- Insulins: At this time it is recommended to move Humalog[®] (insulin lispro) to preferred status.

Public Comment: No public comment.

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

- Osteoporosis Treatments: At this time, generic ibandronate will be added to the DVHA PDL as PA required with the same approval criteria as Boniva[®], with the exception that there be a documented intolerance to the branded product. The approval criteria for Forteo[®] and Prolia[®] have also been updated with recent changes to the FDA labeling. Evista[®] has been added as a preferred product to this category.

Public Comment: No public comment.

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

9. New Managed Therapeutic Drug Classes: *Diane Neal, RPh, MHP*

- Antihypertensives: Central Alpha Blockers: Nexiclon XR[®] will be PA required as previously discussed. Generic clonidine, guanfacine and methyldopa would be preferred products with any branded products requiring PA. All clonidine transdermal products (brand and generic) will require PA with a need for topical dosage form.

Public Comment: No public comment.

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

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

Diane Neal, RPh, MHP

- None

11. General Announcements *Diane Neal, RPh, MHP*

FDA Safety Alerts

- Clostridium difficile-associated diarrhea can be associated with stomach acid drugs known as proton pump inhibitors (PPIs): The FDA is informing the public that the use of stomach acid drugs known as proton pump inhibitors (PPIs) may be associated with an increased risk of clostridium difficile-

associated diarrhea (CDAD). A diagnosis of CDAD should be considered for patients taking PPIs who develop diarrhea that does not improve.

Public Comment: No public comment.

Board Decision: None needed.

- Interactions between certain HIV or hepatitis C drugs and cholesterol-lowering statin drugs can increase the risk of muscle injury: The FDA is issuing updated recommendations concerning drug-drug interactions between drugs for human immunodeficiency virus (HIV) or hepatitis C virus (HCV) known as protease inhibitors and certain cholesterol-lowering drugs known as statins. Protease inhibitors and statins taken together may raise the blood levels of statins and increase the risk for muscle injury (myopathy). The most serious form of myopathy, called rhabdomyolysis, can damage the kidneys and lead to kidney failure, which can be fatal.

Public Comment: No public comment.

Board Decision: None needed.

- Important safety label changes to cholesterol-lowering statin drugs: The FDA has approved important safety label changes for the class of cholesterol-lowering drugs known as statins. These changes were made to provide the public with more information for the safe and effective use of statins and are based on FDA's comprehensive review of the statin class of drugs. The changes include monitoring of liver enzymes, adverse event information, and drug interactions. The need for routine periodic monitoring of liver enzymes has been removed.

Public Comment: No public comment.

Board Decision: None needed.

- Important drug interactions between Victrelis (boceprevir) and ritonavir-boosted human immunodeficiency virus (HIV) protease inhibitor drugs: The FDA is notifying healthcare professionals and patients that drug interactions between the hepatitis C virus (HCV) protease inhibitor Victrelis (boceprevir) and certain ritonavir-boosted human immunodeficiency virus (HIV) protease inhibitors (atazanavir, lopinavir, darunavir) can potentially reduce the effectiveness of these medicines when they are used together.

Public Comment: No public comment.

Board Decision: None needed.

- Tysabri® - Drug Safety Communication – Update of Risk Factors for PML:
Deferred until next meeting.

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

Next DUR Board Meeting

Tuesday, May 15, 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.