



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 05/15/2012**

Board Members:

Present:

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
Mark Pasanen, MD
Joseph Lasek, MD

Absent:

Andrew Miller, RPh

Kim Ladue, NP

Staff:

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

Nancy Miner, MHP
Nancy Hogue, PharmD, DVHA
Melissa Guiles, DVHA

Michelle Sirois, MHP
Michael Farber, MD, DVHA
Bill McMaines, MD, DMH

Guests:

Matthew Badalucco, Merck
Rod Francisco, Sunovion
Robert McSparren, BMS
Carl Pep, GSK
Scott Williams, OMJ
Marie Roache, Pfizer
Bruce Gaulin, BMS

Susan Campbell, Boehringer-Ingelheim
Judy Kando, Sunovion
Chris Michaels, Elan
Jai Persico, Endo
Katrina Iserman, Sunovion
Brian Denton, Pfizer Oncology

Christine Dube, MedImmune
Terry Lee, Gilead Sciences
Keith Osburn, Sunovion
Julie Rae, Acorda
Gigi Shafai, Salix
Dean Najarian, Janssen

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 April, 2012 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- Co-pay for VHAP plans will change from \$1 and \$2 to \$1, \$2 and \$3.
- The benefit (ZB plan) that now covers medications for 11 chronic conditions will be expanded to cover all drugs now covered by VHAP.

- SPAP rebates (collected for VPharm Medicare Part D drug wrap) will be collected from manufacturers on a pro-rated basis so will be collected only on the percentage of the claim that DVHA pays rather than the entire amount.
- A common electronic PA form will be required by 2014 for all insurers in Vermont for medical and pharmacy, however, DVHA will not be required to conform to this requirement.
- An expansion of VPMS (to allow access by law enforcement and the DVHA Medical Director) was not passed. This bill had also included prescriber educational requirements and a requirement to show ID at the pharmacy to pick up controlled substance prescriptions.

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

- Clinical Programs Update/Prescriber Comments: None this meeting.

5. Follow-up items from Previous Meeting: *Michael Farber, M.D., DVHA*

- Suboxone[®] Film Provider Exemption: Discussion continued around Dr. Farber's proposed criteria which would allow the use of Suboxone[®] tablets (rather than the preferred Suboxone[®] Film) by select buprenorphine providers without the need for patient-specific approval by the Medical Director. Information was provided by the manufacturer, Reckitt Benckiser, regarding potential issues with pharmacy repackaging of Suboxone[®] sublingual tablets in blister packaging.

Public Comment: No public comment.

Board Decision: The Board approved to keep the procedure as it currently is with approval given for Suboxone[®] tablets on a patient-specific basis by the Medical Director when deemed medically appropriate. A vote was called by the chair to affirm that the Medical Director be able to make case-by-case (patient specific) decisions on Suboxone[®] formulation requests with no restriction on the Medical Director's authority. The vote was 7:3 in favor of this. Three members stated that there should be no change in the current procedure. One pharmacist Board member who was unable to attend the meeting sent in email comments to the Board members stating that he was not in support of making exceptions for single prescribers from routinely adhering to PDL requirements. There were no votes in support of a provider level exemption from the preferred product dosage forms.

6. RetroDur/Prior Authorization Quality Assurance Analysis: *Diane Neal, RPh, MedMetrics Health Partners (MHP)*

(Public comment prior to Board action)

- Xifaxan[®] (rifaximin): An evaluation of PA requests for rifaximin was performed. Many requests were received for other than the FDA approved indications. There are no changes proposed to the DVHA approval criteria for rifaximin 550 mg tablet when used for hepatic encephalopathy. It is now proposed to require PA for Xifaxan[®] (rifaximin) 200 mg tablets when requested for a diagnosis of traveler's diarrhea caused by noninvasive strains of *Escherichia coli* and a treatment failure, adverse reaction, or contraindication with a fluoroquinolone would be required. A quantity limit of 9 tablets per prescription was proposed. Additionally, criteria were proposed for the use of Xifaxan[®] in Small Intestinal Bacterial Overgrowth, Irritable Bowel Syndrome, Inflammatory Bowel Disease: Crohn's Disease or Ulcerative Colitis and *Clostridium difficile* Diarrhea. Criteria and step therapy were proposed for each indication.

Public Comment: Gigi Shafai, Salix - Highlighted some of the attributes of Xifaxan[®].

Board Decision: The Board unanimously approved the recommendation for Xifaxan[®] 200 mg tablets. The Board requested further time to review the information on Hepatic Encephalopathy for Xifaxan[®] 550 mg tablets and will discuss at the June 26, 2012 meeting. The criteria for the other proposed indications were unanimously approved.

- Narcotic Analgesics – Long/Short Acting Combination: Deferred to a future meeting due to lack of time.

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

Full New Drug Review:

- Solesta[®] Gel Prefilled Syringe for Submucosal Injection: It was recommended that Solesta[®] be added to the PDL as Prior Authorization required with the following approval criteria: The diagnosis or indication is treatment of fecal incontinence and the patient is 18 years of age or older and the patient has had an inadequate response with conservative therapy, including diet, fiber supplementation, and anti-diarrheal medication. A quantity limit of 4 syringes per fill, maximum of 1 month supply per fill. If approval criteria are met, authorization may be issued for up to 2 months.

Public Comment: Gigi Shafai, Salix – Highlighted some of the attributes of Solesta[®].

Board Decision: The Board unanimously approved the above criteria.

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

- Atypical Antipsychotics: Only adult criteria were proposed for discussion and decision at this month's meeting. The criteria for each non-preferred product were evaluated and changes proposed. For many non-preferred products a trial of 3 preferred products would be required before approval of the non-preferred product but these 3 trials may be first or second generation antipsychotics. Generic ziprasidone and quetiapine will move to preferred and replace the currently preferred branded products. Branded Zyprexa[®] will move to preferred.

Public Comment: Dean Najarian, Janssen – Highlighted some of the attributes of Invega[®].

Judy Kando, Sunovion – Highlighted some of the attributes of Latuda[®].

Bruce Gaulin, Bristol Myers Squibb – Highlighted some of the attributes of Abilify[®].

Board Decision: The Board unanimously approved the MHP recommendation noted above with the addition of a reference to the FDA black box warning regarding use in dementia, to increase the FDA maximum dose of Latuda[®] to 160 mg, and to add schizo affective disorder as an approvable diagnosis for all non-preferred products that currently list schizophrenia.

- Pediatric Antipsychotic Criteria/Survey: A questionnaire has been developed for prescribers who prescribe antipsychotics to children to provide additional information to the claims data. A draft was developed and presented. This information will be gathered for every child on an antipsychotic. Criteria have been developed around target symptoms. It was proposed that all children currently on antipsychotics would be grandfathered but the survey must be completed for continuation. For new

starts, appropriate target symptoms must be chosen. More work needs to be done on the form before it is instituted and will be brought back to a future meeting.

Public Comment: No public comment.

Board Decision: None needed.

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

- Rifamycins (to replace Hepatic Encephalopathy class): See above in the RetroDUR section.

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

Diane Neal, RPh, MHP

- Anti-hyperkinesia and Anti-Narcolepsy: ADHD (quantity limits): Deferred to next meeting due to lack of time.
- Multiple Sclerosis Medications (new information Gilenya[®] and Tysabri[®]; Ampyra[®]): It was recommended that Ampyra[®] be moved to preferred status after clinical criteria are met on the DVHA PDL with the same approval criteria. Other drug discussion deferred to next meeting.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Nutritional Products: Deferred to next meeting due to lack of time.

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

FDA Safety Alerts

- Aliskiren-Market withdrawal of Valturna[®]: Deferred until next meeting due to lack of time.
- Tysabri[®] - Drug Safety Communication – Update of Risk Factors for PML: Deferred until next meeting due to lack of time.

12. Adjourn: Meeting adjourned at 9:29 p.m.

Next DUR Board Meeting

Tuesday, June 26, 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.