



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 10/25/2011**

Board Members:

Michael Scovner, MD, Chair
Andrew Miller, RPh

Gary Starecheski, RPh
Lynne Vezina, RPh

Sommer Zarbock, Pharm D

Staff:

Diane Neal, RPh, MHP
Stacey Baker, DVHA

Nancy Miner, MHP
Michael Farber, MD, DVHA

Michelle Sirois, MHP
Jennifer Egelhof, DVHA

Guests:

Rick Angeli, Merck
Steve Berardino, Amgen
Judy Kando, Sunovion
Carl Possidente, Pfizer
Lee Bocheriek, Forest
Vik Patel, Vertex

Carl Pepe, GSK
Peter Persico, Endo
Wendy Pollinger, Eli Lilly
Natalie Prairie, Forest
Scott Maselek, Forest
Pauline Patrick, Forest

Kelly Prescott, Vertex
Scott Williams, OMJ
Erica Hintze, Forest
Daniel Baran, Merck
Jay Rush, Ther-Rx

Michael Scovner, MD, 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 September 2011 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. DVHA Pharmacy Administration Updates:

- There will be new Board members at the next meeting to include two adult psychiatrists as well as others.

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

- Clinical Programs Update: There have been 5 approvals for Butrans[®] since the last meeting. These members had an indication for pain and most had a risk of opiate diversion in their homes.
- Prescriber Comments: None to report.

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

- Citalopram – doses > 40 mg/day
DVHA will go ahead with a prescriber letter to identify members receiving > 40 mg per day of citalopram (Celexa[®]). There has not been any concrete guidance from the psychiatry community as to what to do about therapy for these members. There will also be edits within the system to stop members from initiating or continuing a dose > 40 mg per day.

Public Comment: No public comment.

Board Decision: None needed.

- Makena[®] (17-alpha hydroxyprogesterone caproate). The FDA has issued a statement that they do not intend to take enforcement action against pharmacies who continue to compound 17-alpha hydroxyprogesterone caproate and CMS will allow state Medicaid programs to cover the compounded product with state only dollars. It was recommended that DVHA continue to pay for the compounded 17-alpha hydroxyprogesterone caproate and have Makena[®] available after prior authorization with the criteria for approval being the prescriber has a medical necessity for the member to receive Makena[®] rather than the compounded product.

Public Comment: *Jay Rush, Ther-Rx* – Highlighted some of the attributes of Makena[®].

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)

- Lexapro[®]: A retrospective drug analysis of escitalopram was performed to review utilization and evaluate the appropriateness of current prior authorization approval criteria. From January 1, 2011 to June 30, 2011, there was a monthly average of 599 unique utilizers, resulting in 3,983 total paid claims costing \$538,749.41. The average monthly cost per prescription was \$135.23. In addition, each member's most recent paid claim from January 1, 2011 to June 30, 2011 was reviewed. During this time period, there were paid escitalopram claims for a total of 1085 unique members. Claims for 249 unique members (23%) were processed due to the presence of a PA in the system. Claims for 836 unique members (77%) were processed without PA, indicating that the point-of-service coding ("grandparenting") allowed the claim to process due to the presence of a previous paid claim for escitalopram. A total of 313 escitalopram prior authorization requests were identified from January 1, 2011 to June 30, 2011, excluding requests denied based on quantity limits. Of these 86 % were approved. 17 prior authorization requests were reviewed – of these 9 of 17 were approved based on the patient being started and stabilized. Based on the review of claims data and prior authorization requests, it is recommended that for escitalopram approval one of the 2 treatment failures to SSRIs be citalopram.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above with the addition of the Clinical Call Center asking where the member was getting Lexapro[®] if the prescriber indicates that the member has been started and stabilized.

- Early Refill Analysis of Benzodiazepines and Oxycontin[®]: An analysis of members receiving benzodiazepines and Oxycontin[®] was done to determine if there would be a cost savings to increase the refill limit from 75% to 85%. Increasing the refill limit would also reduce the amount of extra medication that members would be accumulating and possibly diverting. For the six month period evaluated, there would be an approximate savings of \$3,700 and a significant reduction of the units that some members had accumulated. The next analysis will be on stimulant medications and maintenance medications filled in 90 day supplies. It is recommended that the refill limit for benzodiazepines and Oxycontin[®] be increased to 85%.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above. The Board would also like to send prescribers a letter suggesting that an effective method of keeping track of controlled drug patients and prescriptions is to prescribe in 28 day supplies.

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

Abbreviated Drug Review:

- Abstral[®] (fentanyl) Sublingual Tablet: In consideration of the limited advantages of the new transmucosal fentanyl product and cost considerations, it is recommended to add Abstral[®] to the preferred drug list (PDL) as PA required with the criteria for approval being the same as other immediate release fentanyl products. That is there is an indication of cancer breakthrough pain (no approval for acute pain or post-operative pain) AND documentation that the patient is opioid tolerant (oral morphine \geq 60mg/day, transdermal fentanyl 25mcg/hr, oral oxycodone \geq 30mg/day, oral hydromorphone \geq 8mg/day or an equianalgesic dose of another opioid for \geq 1 week) 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.

Public Comment: No public comment.

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

- Axiron[®] (testosterone) Solution: In consideration of the limited FDA-approved indication, potential advantages compared to treatment alternatives and cost considerations, it is recommended to add Axiron[®] to the preferred drug list (PDL) as PA required. The following approval criteria are recommended for Axiron[®]: The patient has had a documented side effect, allergy, or treatment failure to AndroGel[®] or AndroGel Pump[®]. In addition, a quantity limit of 2 bottles per 30 days is proposed.

Public Comment: No public comment.

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

- Nuedexta[®] (dextromethorphan hydrobromide/quinidine sulfate) Capsule: In consideration of the limited FDA-approved indication, absence of long-term studies, potential for numerous drug indications and cost considerations, it is recommended to add Nuedexta[®] to the preferred drug list

(PDL) as PA required. The following approval criteria are recommended for Nuedexta[®]: The diagnosis or indication is pseudobulbar affect (PBA) secondary to amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS) AND the patient does not have any contraindications to use which would include concomitant use with quinidine, quinine, or mefloquine; history of quinidine, quinine, or mefloquine-induced thrombocytopenia, hepatitis; MAOI use within 14 days of starting Nuedexta[®]; prolonged QT interval, congenital long QT syndrome, Torsades de Pointes, or heart failure; complete atrioventricular (AV) block or patients at high risk for AV block; concomitant use with drugs that prolong QT interval and are metabolized by CYP2D6 (eg. Thioridazine, pimozide). A quantity limit of 60 units per 30 days was recommended.

Public Comment: No public comment.

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

Full New Drug Reviews:

- Daliresp[®] (roflumilast) Tablet: It is recommended that Daliresp[®] (roflumilast) be added to the preferred drug list (PDL) as prior authorization required with the following approval criteria: The diagnosis or indication for the requested medication is COPD associated with chronic bronchitis AND the patient has had a documented side effect, allergy, treatment failure, or a contraindication to at least one inhaled long-acting anticholinergic AND at least one inhaled long-acting beta-agonist AND at least one inhaled corticosteroid.

Public Comment: Pauline Patrick, Forest - Highlighted some of the attributes of Daliresp[®].

Board Decision: The Board unanimously approved the MHP recommendation noted above but would like the indication criteria to read as treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations which is the FDA wording.

8. Therapeutic Drug Classes-Periodic Review:

(Public comment prior to Board action)

- Hepatitis C Protease Inhibitors: In recognition of the available published clinical trial data, the absence of comparative head-to-head studies, a lack of efficacy and safety data in HIV or HBV co-infected patients, the potential for resistance with viral mutations and non-adherence, and the significant cost implications of the protease inhibitors in treating chronic hepatitis C infection, it is recommended that both Incivek[®] and Victrelis[®] be added to the preferred drug list (PDL) as prior authorization required with the following approval criteria: Victrelis[®] (boceprevir): The diagnosis or indication for the requested medication is hepatitis C (genotype 1) infection and the patient has already been started and stabilized on the requested medication in combination with pegylated interferon and ribavirin. (note: samples are not considered adequate justification for started and stabilized) OR the patient is ≥ 18 years of age AND the patient has a confirmed diagnosis of chronic hepatitis C (genotype 1) infection AND the prescriber is, or has consulted with, a Hepatologist, Gastroenterologist, or Infectious Disease Specialist AND the patient has not previously failed therapy with Incivek[®] or Victrelis[®] AND the patient has or will be pre-treated with ribavirin and peginterferon therapy for at least 4 weeks prior to initiating Victrelis[®] AND the requested medication will be used in combination with pegylated interferon and ribavirin AND if the patient had received prior therapy with combination pegylated interferon and ribavirin, at least a partial response was demonstrated by week 12 of therapy ($\geq 2\log_{10}$ HCV RNA decline by week-12). Incivek[®] (telaprevir):

The diagnosis or indication for the requested medication is hepatitis C (genotype 1) infection and the patient has already been started and stabilized on the requested medication in combination with pegylated interferon and ribavirin. (note: samples are not considered adequate justification for started and stabilized) OR the diagnosis or indication for the requested medication is hepatitis C (genotype 1) infection AND the patient is ≥ 18 years of age AND the patient has a confirmed diagnosis of chronic hepatitis C (genotype 1) infection AND the prescriber is, or has consulted with, a Hepatologist, Gastroenterologist, or Infectious Disease Specialist AND the patient has not previously failed therapy with Incivek[®] or Victrelis[®] AND the requested medication will be used in combination with pegylated interferon and ribavirin. Additionally, a quantity limit of 504 tablets to complete a 12-week course of treatment is recommended.

Public Comment: Daniel Baran, Merck - Highlighted some of the attributes of Victrelis[®] but objected to the exclusion of historical null responders.

Patel Vik, Vertex – Highlighted some of the attributes of Incivek[®].

Board Decision: The Board unanimously approved the MHP recommendation noted above with the removal of the requirement for Victrelis[®] that if the patient had been previously treated with combination pegylated interferon and ribavirin a partial response was demonstrated by week 12 of therapy ($\geq 2 \log_{10}$ HCV RNA decline by week-12) (not a historical null responders). This requirement will be further researched and discussed at a later meeting.

- **Bile Acid Sequestrants:** No changes to the approval criteria/preferred drugs for bile acid sequestrants are proposed.

Public Comment: No public comment.

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

- **Cholesterol Absorption Inhibitors:** No changes to the approval criteria for cholesterol absorption inhibitors (Zetia[®]) are proposed.

Public Comment: No public comment.

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

- **Fibric Acid Derivatives:** No changes to the approval criteria/preferred drugs for the fibric acid derivative drug class are proposed.

Public Comment: No public comment.

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

- **HMG CoA Reductase Inhibitors (Statins):** No changes to the approval criteria/preferred drugs for HMG CoA reductase inhibitors are proposed.

Public Comment: No public comment.

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

- **Niacin Derivatives:** No changes to the niacin derivatives drug class are proposed.

Public Comment: No public comment.

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

- Omega-3-Acid Ethyl Esters: No changes to the approval criteria for omega-3-acid ethyl esters (Lovaza[®]) are proposed.

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

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

- None

12. Literature Review Diane Neal, RPh, MHP

- Role of Pregabalin (Lyrica[®]) in Diabetic Neuropathy: In recognition of the conflicting national and international guideline recommendations, availability of effective treatment alternatives, the absence of head-to-head data and cost considerations, no changes are recommended to the current approval criteria for Lyrica[®].

Public Comment: No public comment.

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

11. General Announcements Diane Neal, RPh, MHP

FDA Safety Alerts

- Diflucan[®] (fluconazole): Drug Safety Communication- Long-term, High-dose Use During Pregnancy May Be Associated with Birth Defects: The FDA is informing the public that chronic, high doses (400-800 mg/day) of the antifungal drug Diflucan[®] (fluconazole) may be associated with a rare and distinct set of birth defects in infants whose mothers were treated with the drug during the first trimester of pregnancy. This risk does not appear to be associated with a single, low dose of fluconazole 150 mg to treat vaginal yeast infection (candidiasis). Provided as information only – no changes recommended.

Public Comment: No public comment.

Board Decision: None needed.

- Multaq[®] (dronedarone): Drug Safety Communication—Increased Risk of Death or Serious Cardiovascular Events: The FDA is reviewing data from a clinical trial that was evaluating the effects of the antiarrhythmic drug, Multaq[®] (dronedarone), in patients with permanent atrial fibrillation. The study was stopped early after the data monitoring committee found a two-fold increase in death, as well as two-fold increases in stroke and hospitalization for heart failure in patients receiving Multaq[®] compared to patients taking a placebo. Currently Multaq[®] is approved

for use in a different, but related patient population. The approval of Multaq[®] was based on another trial (ATHENA) in which use of Multaq[®] was associated with a decreased number of deaths compared to placebo. This category is not currently managed and physicians appear to be well aware of the risks – no changes recommended.

Public Comment: No public comment.

Board Decision: None needed.

- Oral Osteoporosis Drugs (bisphosphonates): Drug Safety Communication—Potential Increased Risk of Esophageal Cancer: The FDA is continuing to review data from published studies to evaluate whether use of oral bisphosphonate drugs is associated with an increased risk of cancer of the esophagus (esophageal cancer). There have been conflicting findings from studies evaluating this risk. No changes recommended at this time until further information released by the FDA.

Public Comment: No public comment.

Board Decision: None needed.

- Reclast[®] (zoledronic acid): Drug Safety Communication—New Contraindication and Updated Warning on Kidney Impairment: The FDA has approved an update to the drug label for Reclast[®] (zoledronic acid) to better inform healthcare professionals and patients of the risk of kidney (renal) failure. Kidney failure is a rare, but serious, condition associated with the use of Reclast[®] in patients with a history of or risk factors for renal impairment. Cases of acute renal failure requiring dialysis or having a fatal outcome following Reclast[®] use have been reported to FDA. Reclast[®] currently requires prior authorization and no changes to current clinical criteria are recommended.

Public Comment: No public comment.

Board Decision: None needed.

- Saphris[®] (asenapine maleate): Drug Safety Communication—Serious Allergic Reactions: The FDA is warning the public that serious allergic reactions have been reported with the use of the antipsychotic medication Saphris[®] (asenapine maleate). The Contraindications, Warnings and Precautions, Adverse Reactions, and Patient Counseling Information sections of the Saphris[®] drug label have been revised to include information about this risk and to inform healthcare professionals that Saphris[®] should not be used in patients with a known hypersensitivity to the drug. Saphris[®] currently requires prior authorization and no changes are recommended.

Public Comment: No public comment.

Board Decision: None needed.

- Zofran[®] (ondansetron): Drug Safety Communication—Risk of Abnormal Heart Rhythms: The FDA is informing the public of an ongoing safety review of the anti-nausea drug Zofran[®] (ondansetron, ondansetron hydrochloride, and their generics). Ondansetron may increase the risk of developing abnormal changes in the electrical activity of the heart, which can result in a potentially fatal abnormal heart rhythm. No changes are recommended at this time to our clinical criteria at this time.

Public Comment: No public comment.

Board Decision: None needed.

- Zyvox® (linezolid): Drug Safety Communication—Serious CNS Reactions Possible When Given to Patients Taking Certain Psychiatric Medications: The FDA has received reports of serious central nervous system (CNS) reactions when the antibacterial drug linezolid (marketed as Zyvox®) is given to patients taking psychiatric medications that work through the serotonin system of the brain (serotonergic psychiatric medications). The FDA has further defined which drugs are of particular concern.

Public Comment: No public comment.

Board Decision: None needed.

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

Next DUR Board Meeting

Tuesday, December 6, 2011

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.