



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 12/07/2010**

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R.Ph.

Virginia Hood, M.D.
Jeanne Greenblatt, M.D.

Lynne Vezina, R.Ph.

Staff:

Nancy Hogue, Pharm.D., DVHA
Diane Neal, R.Ph., (MHP)
Michelle Sirois, (MHP)

Nancy Miner, (MHP)
Stacey Baker, DVHA

Jennifer Egelhof, DVHA
Michael Farber, M.D. DVHA

Guests:

Benjamin Alderfer, Amgen
Rick Angeli, Merck
Matt Badalucco, Merck
Steve Berardino, Amgen
Christina Carmody, Purdue
Andrew Christianson, Amgen

Tim Cockayne, Merck
Renee Hagerty, Takeda
James Kokoszyna, Allergan
Rob Mann, GSK
Mike Matsamitsu, Amgen
Brenda Pennels, Boehringer Ingelheim

Peter Persico, Endo
Gary Prevost, PriCara
Om Sanduma, Merck
Elizabeth Shorrock, Boehringer Ingelheim
Christine Tynan, Boehringer Ingelheim
Susan Wood, Boehringer Ingelheim

Michael Scovner, M.D. Chair, called the meeting to order at 7:10 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 2010 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. DVHA Pharmacy Administration Updates: Nancy Hogue, Pharm.D. - Pharmacy Director, DVHA

- No updates to report this meeting.

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

- Dr. Farber announced that Virginia Hood, M.D. will be resigning from the DUR Board due to her appointment as President of the American College of Physicians (ACP). Dr. Hood was thanked for her many years on the Board.
- Clinical Programs Update: No updates this month.
- Prescriber Comments: No comments to discuss this month.

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

- **Long Acting Narcotics Clinical Criteria:** It was recommended that in order to implement a step through Duragesic[®] patch in addition to morphine sulfate SR for all non-preferred products, that the Duragesic-12 strength needs to be available with prior authorization.

Public Comment: No public comment.

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

- **Suboxone[®]/Suboxone Film[®]/Subutex[®] (buprenorphine):** The monthly utilization chart was distributed which shows that utilization has leveled out. The new film dosage form was discussed. It was recommended that the film become the preferred Suboxone dosage form for all new users of Suboxone and that the quantity limit of 16 mg/day be required for these new users. Prescribers will be asked to complete a MedWatch form if a request is received to move back to the tablet after a trial of the film. The generic buprenorphine will become preferred over brand Subutex[®].

Public Comment: No public comment.

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

- **Urinary Antispasmodics :** Last month it was voted that Toviaz[®] move to preferred in January 2011. It was recommended that this change not be implemented as the cost advantages were misunderstood.

Public Comment: No public comment.

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

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

- **Azithromycin:** A retrospective drug analysis of azithromycin (Zithromax[®]) was performed to review utilization and evaluate the appropriateness of the current PA approval criteria as well as the current approval duration. Based on a review of utilization and prior authorization requests for azithromycin exceeding 5 days of therapy, no major changes to the current DVHA prior authorization approval criteria are recommended. However, in recognition of the controversy surrounding long-term antibiotic therapy for chronic post-Lyme disease, it is recommended to add a note that such practice is not supported by evidence-based medicine. In addition, it is suggested to distinguish between uncomplicated Lyme disease and Lyme disease with neurologic or rheumatologic complications, as preferred antibiotic regimen and treatment durations vary between these forms of the disease. In addition, as there are indications, warranting the use of azithromycin therapy >5 days, that are not mentioned in the current DVHA criteria, it is recommended to add them to the criteria. In addition, it is proposed to establish a 30 day maximum of 10 days of treatment to prevent multiple 5 day fills.

Public Comment: No public comment.

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

- RetroDUR/Educational Activities Currently in Process
 - Asthma: The Chronic Care Initiative will be sending prescribers letters about patients with asthma who are not a controller medication but are refilling rescue inhalers. It will also look at asthma patients with inpatient or ER admissions or recurrent oral corticosteroid courses. It will also include some educational information on the Medicaid coverage for peak flow meters and spacers and also charts (asthma action plans) to give to patients to recognize when they are in need of medical intervention from their prescriber.

Public Comment: No public comment

Board Decision: None needed

- Seroquel[®] - Low dose for anxiety or hypnotic: An analysis was performed to look at claims of patients on doses of 50 mg/day or less. About half (48 %) of patients continue on low dose and do not proceed to higher doses (after 120 days). About 43 % do not continue on therapy at any dose. Only 9 % continue to doses > 50 mg/day. Approximately 35 new members have a prescription written for Seroquel[®] 50 mg/day or less each month. Further analysis is ongoing and will be presented at the next meeting.

Public Comment: No public comment

Board Decision: None needed

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

Abbreviated Drug Review:

- Colcrys[®] (colchicine) Tablet: All old formulation of colchicine will no longer be available. It was recommended that Colcrys[®] be placed on prior authorization with the criteria for approval being the diagnosis or indication for the requested medication is Familial Mediterranean Fever (FMF) OR the diagnosis or indication for the requested medication is gout AND the patient has had a documented side effect or treatment failure with at least one drug from the NSAID class OR the patient is not a candidate for therapy with at least one drug from the NSAID class due to one of the following: (a)The patient is 60 years of age or older (b) Patient has a history of GI bleed (c)Patient is currently taking an oral corticosteroid or (d) Patient is currently taking methotrexate. In addition, the following quantity limits are recommended: 3 tablets/day (gout); 4 tablets/day (FMF)

Public Comment: No public comment.

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

Full New Drug Reviews:

- Livalo[®] (pitavastatin) Tablet:
It was recommended that Livalo[®] be placed on prior authorization with the criteria for approval being the patient has had a documented side effect, allergy, or treatment failure to BOTH generic simvastatin AND Crestor[®]. In addition, a quantity limit of 1 tablet/day was recommended. It was also recommended that pravastatin 80 mg tablets be move to preferred status as the price has dropped to a level similar to the other strengths.

Public Comment: No public comment.

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

▪ Pradaxa[®] (dabigatran etexilate) Capsule:

It was recommended that Pradaxa[®] be placed on prior authorization with the criteria for approval being 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 2 capsules/day is recommended.

Public Comment: Susan Wood, Boehringer Ingelheim – Discussed the clinical studies and clinical attributes of Pradaxa[®].

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

▪ Prolia[®] (denosumab) Subcutaneous Injection:

It was recommended that Prolia[®] be placed on prior authorization with the criteria for approval being the patient has a diagnosis/indication of postmenopausal osteoporosis AND the patient has had a documented side effect or treatment failure to a preferred bisphosphonate. Treatment failure is defined as documented continued bone loss or fracture after one or more years despite treatment with an oral bisphosphonate. It was recommended that the quantity limit be 1 syringe per 6 months. The same criteria should also be applied for this drug in the medical benefit.

Public Comment: Mike Matsamitsu, Amgen – Discussed the role of this drug and its placement in Medicare.

Steven Berardino, Amgen – Asked for clarification of criteria compared to other injectable products.

Board Decision: The Board unanimously approved the MHP recommendations noted above. The Board asked to see utilization data in a few months.

▪ Xifaxan[®] (rifaximin) 550 mg Tablet:

It was recommended that Xifaxan[®] 550 mg tablet be placed on prior authorization with the criteria for approval being the patient has a diagnosis of hepatic encephalopathy AND the patient has had a documented side effect, allergy, treatment failure or contraindication to lactulose. In addition, a quantity limit of 2 tablets per day was recommended. Also, a quantity limit of 9 tablets per RX for Xifaxan 200 mg tablets should be established for treatment of traveler's diarrhea and to prevent dosing at 400 mg TID for hepatic encephalopathy.

Public Comment: No public comment.

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

▪ Zymaxid[®] (gatifloxacin) Ophthalmic Solution:

It was recommended that Zymaxid[®] be placed on prior authorization with the criteria for approval being the patient has had a documented side effect, allergy or treatment failure with at least one generic ophthalmic antibiotic (ciprofloxacin or ofloxacin).

Public Comment: No public comment.

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

8. Therapeutic Drug Classes-Periodic Review:

(Public comment prior to Board action)

- Leukotriene Modifiers: In an effort to promote the use of less costly alternatives for allergic rhinitis it is recommended that Singulair[®] move to PA required with the following criteria. A step therapy program would be employed to allow automatic approval when drug claims history indicates a diagnosis of asthma. The step therapy was proposed to look for controller medications. It was also recommended that Accolate[®] move to PA required. Children 5 years and under would be exempt from the criteria. At the roll-out of this program, all Singulair[®] users with an asthma diagnosis in medical claims will be granted a one year PA. The criteria for Singulair[®] would be the diagnosis or indication for the requested medication is asthma OR the diagnosis or indication for the requested medication is allergic rhinitis AND the patient has had a documented side effect, allergy, or treatment failure to a second generation non-sedating antihistamine AND a nasal corticosteroid. The diagnosis for Accolate[®] would be the diagnosis or indication for the requested medication is asthma. The diagnosis for Zyflo[®] XR would be the diagnosis or indication for the requested medication is asthma AND the patient has had a documented side effect, allergy, or treatment failure to Accolate[®] or Singulair[®]. A step therapy for allergic rhinitis would look back 6 months for use of a non-sedating antihistamine and a nasal corticosteroid.

Public Comment: OM Sanduma, Merck – Discussed the use of Singulair[®] in allergic rhinitis and asthma and appropriate therapy of both conditions.

Board Decision: The DUR Board agreed with the changes above but recommended that the step therapy for asthma indication also look for rescue inhalers.

9. New Managed Therapeutic Drug Classes:

(Public comment prior to Board action)

- No new Drug Classes

10. Brand to Generic Changes: Diane Neal, R.Ph, (MHP)

The following brand name products will become non-preferred and their generics will be preferred: Subutex[®], Wellbutrin[®] XL, Mirapex[®] and Flomax[®].

Public Comment: No public comment.

Board Decision: The Board agreed with the changes notes above.

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

Diane Neal, R.Ph, (MHP)

- BPH: Alpha Blockers: It is recommended that this become a generic preferred category. In addition to Flomax[®] brand moving to PA required (above), Uroxatral[®] was also recommended to move to PA required.

Public Comment: No public comment.

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

- BPH: Androgen Hormone Inhibitors: It is recommended that this become a generic preferred category. It was recommended that Avodart[®] and brand Proscar[®] move to PA required.

Public Comment: No public comment.

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

- Ossification Enhancers: Treatment failure was standardized throughout the clinical criteria for all agents. It was recommended that Boniva[®] move from a preferred position to PA required. Current users will be grandfathered for a period of time. Fortical[®] was also recommended to move to non-preferred. Further clarification of clinical criteria for other agents was also recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above. The Board would also like to see a review of the efficacy of Miacalcin[®] as an ossification enhancer at a future meeting.

- Pancreatic Enzymes: All pancreatic products had to submit drug applications to the FDA. There are now only 3 approved products and it is recommended that all 3 be preferred products. The 3 products are Creon[®], Pancreaze[®] and Zenpep[®].

Public Comment: No public comment.

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

- Prenatal Vitamins: Recently, the FDA has determined that none of the previously designated generic prenatal vitamins are considered generic products any longer. Therefore, a change in clinical criteria (which preferred generic products) was required. It was recommended that the preferred prenatal vitamins become PrenaPlus[®], Prenatal Plus/Iron[®], Prenatal Plus[®] and Prenate Plus[®].

Public Comment: No public comment.

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

12. General Announcements Diane Neal, R.Ph, (MHP) **FDA Safety Alerts**

- Propoxyphene Withdrawal – Risk of Cardiac Toxicity
Brand Darvon[®] and Darvocet[®] were withdrawn from the market due to cardiac toxicity. The products (and all generics) were blocked in the pharmacy system at the point of sale several days after the FDA made this announcement.

Public Comment: No public comment

Board Decision: None needed

13. Adjourn: Meeting adjourned at 9:20 p.m.

Next DUR Board Meeting

Tuesday, January 11, 2011

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.