



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 02/22/2011**

Board Members:

Michael Scovner, M.D., Chair
Stuart Graves, M.D.
Sommer Zarbock, Pharm. D.

Gary Starecheski, R.Ph.
Jeanne Greenblatt, M.D.

Lynne Vezina, R.Ph.
Kim Ladue, N.P.

Staff:

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

Nancy Miner, (MHP)
Robin Farnsworth, DVHA

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

Guests:

Richard Angeli, Merck
Paul Amato, GSK
Daniel Baran, Merck
Christine Carmody, Purdue
Renee Hagerty, Takeda
James Kokoszyna, Allergan

Craig Laurent, Genentech
Terry Lee, Gilead Sciences
Tom Martin, Boehringer-Ingelheim
John Mastrianni, Genentech
Robert Mcsparren, Bristol-Myers Squibb
Morrie Olson, Alkermes

Keith Osburn, Sunovion
Carl Pepe, GSK
Janice Pertoso, Alkermes
Kelly Prescott, Vertex
Joe Winalski, BiogenIdec

Michael Scovner, M.D. Chair, called the meeting to order at 6:35 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:00 until 6:30 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 2010 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- Introductions of two new Board members, Gary Starecheski, R.Ph. and Kim Ladue, N.P., were made. There is a third new member who was not able to attend the February meeting.

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

- Clinical Programs Update: DVHA has received reports from prescribers of members who have switched therapy to Suboxone[®] Film and have reported a variety of intolerances. Some of these members have changed back to the Suboxone[®] SL tablet and have reported they were able to tolerate this dosage form. DVHA will continue to monitor this situation and report back to the Board.

- Prescriber Comments: No comments to discuss this month.

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

- Suboxone[®]/Suboxone Film[®]/Subutex[®] (buprenorphine): 547 members have paid claims for Suboxone[®] film in January and the number of unique members on Subutex[®] have decreased. The total cost for paid claims of all formulations has decreased due to the switch to generic buprenorphine (from brand Subutex[®]) and efforts to decrease the average daily dose per member.

Public Comment: No public comment.

Board Decision: None needed.

- Seroquel[®] - Low dose for anxiety or hypnotic: It was recommended that Seroquel[®] (for adults) in doses of ≤ 50 mg/day be placed on prior authorization with the criteria for approval being that the patient will be prescribed > 50 mg/day with combinations of tablet strengths or the indication for use is adjunct treatment of major depressive disorder (MDD) and the patient has had a documented inadequate response to at least 2 different antidepressants from the SSRI, SNRI, TCA, MAOI and/or Miscellaneous antidepressant categories (trazodone dosed at < 150 mg/day would not be considered a trial for this indication) or the indication for use is any anxiety disorder (panic, agoraphobia, social phobia, obsessive-compulsive disorder, PTSD, acute stress disorder, generalized anxiety disorder) and the patient has had a documented inadequate response to at least 2 different antidepressants from the SSRI, SNRI, TCA, MAOI and/or Miscellaneous antidepressant categories or at least 1 antidepressant from the SSRI, SNRI, TCA, MAO and/or Miscellaneous antidepressant categories and buspirone (trazodone dosed at < 150 mg/day and bupropion would not be considered trials for this indication) or the indication for use is a mental health indication (other than the two above indications or a sleep disorder).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above. The Board asked to review prior authorization data in one year.

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

- Celebrex[®] (celecoxib): Based upon a review of the utilization and prior authorization requests for Celebrex[®], this quality assurance analysis confirms that all of the selected requests were approved or denied in accordance with the current Celebrex[®] clinical criteria, which remain appropriate for the medication. Approximately 18 % of prior authorization requests are denied. There have been no consensus guideline updates or published literature that would require changes in the current criteria. It is therefore recommended that no changes to the DVHA prior authorization criteria be implemented at this time.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above with the addition of an automated step therapy of approval if a member has had a warfarin claim filled in the last 120 days.

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

Abbreviated Drug Review:

- Actoplus Met XR[®] (pioglitazone/metformin) Extended Release Tablet: It was recommended that Actoplus Met XR[®] be added to the PDL as Prior-Authorization required with the criteria for approval being the patient has been started and stabilized on the requested medication or the patient has had a documented treatment failure with generic metformin XR or the patient has had a documented treatment failure or has been unable to be adherent to a twice daily dosing schedule of Actoplus Met[®] resulting in a significant clinical impact.

Public Comment: No public comment.

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

- Jalyn[®] (dutasteride/tamsulosin) Capsule: It was recommended that Jalyn[®] capsule be added to the PDL as prior authorization required with the criteria for approval being the patient has a diagnosis of BPH (benign prostatic hypertrophy) and the patient has had a documented treatment failure/inadequate response to combination therapy with generic tamsulosin and finasteride. Also, it was recommended to consolidate the BPH: Alpha Blockers and BPH: Androgen Hormone Inhibitors into a single managed category of BPH Agents.

Public Comment: No public comment.

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

- Oleptro[®] (trazodone) Extended Release Tablet: Due to the absence of significant advantages of Oleptro[®] ER tablet over generically available immediate release trazodone, it was recommended that Oleptro[®] ER tablet be added to the PDL as prior authorization required with the criteria for approval being the diagnosis for use is MDD (major depressive disorder) and 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 treatment failure/inadequate response to immediate release trazodone. Additionally, recommended quantity limits are 2 tablets/day for 150 mg and 1 tablet/day for 300 mg.

Public Comment: No public comment.

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

- Oravig[®] (miconazole) Buccal Tablet: Due to the availability of several generic oral antifungals, it was recommended that Oravig[®] buccal tablets be added to the PDL as prior authorization required with the criteria for approval being the indication for use is treatment of oropharyngeal candidiasis and the patient has had a documented side effect, allergy, treatment failure/inadequate response to both nystatin suspension and clotrimazole troche or the patient is unable to be compliant with nystatin suspension and/or clotrimazole troche dosing schedules. Additionally, a quantity limit of 1 tablet/day, 14 tablets per RX is recommended.

Public Comment: No public comment.

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

- Rybix ODT[®] (tramadol) Orally Disintegrating Tablet: Due to the absence of significant advantages of Rybix ODT[®] over the preferred and less costly generic tramadol oral immediate-release tablet, it is recommended that Rybix ODT[®] be added to the PDL as prior-authorization required with the criteria for approval being the patient has a medical necessity for a disintegrating tablet formulation (i.e. swallowing disorder). Additionally, a quantity limit of 8 tablets per day (400 mg per day) was recommended.

Public Comment: No public comment.

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

- Tribenzor[®] (olmesartan/amlodipine/hydrochlorothiazide) Tablet: Due to a variety of ARB combination products available and the absence of significant advantages of Tribenzor[®] tablet over these, it was recommended that Tribenzor[®] be added to the PDL as prior authorization required with the criteria for approval being the patient has had a documented side effect, allergy, or treatment failure to an angiotensin converting enzyme inhibitor (ACEI), an ACEI combination or any other angiotensin receptor blocker (ARB) or ARB combination and the patient is unable to take the individual components (Azor[®] and hydrochlorothiazide) separately.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendation noted above but asked that the criteria be reworded to read “the patient is unable to comply with taking the individual components”.

- Vimpat[®] (lacosamide) Oral Solution: Due to the absence of significant advantages of Vimpat[®] oral solution over Vimpat[®] tablet, it is recommended that Vimpat[®] oral solution be added to the 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 is adjunctive therapy of partial-onset seizures and the patient has had a documented side effect, allergy, treatment failure/inadequate response or a contraindication to at least TWO preferred anticonvulsants and the patient is unable to use Vimpat[®] tablet (e.g., swallowing disorder)

Public Comment: No public comment.

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

Full New Drug Reviews:

- Dulera[®] (mometasone furoate/formoterol fumarate dehydrate) Inhaler: In recognition of the demonstrated safety and efficacy of mometasone/formoterol in the treatment of asthma and comparable cost to treatment alternatives, it was recommended to add Dulera[®] to the PDL as preferred with a quantity limit of 1 inhaler per 30 days.

Public Comment: Dr. Daniel Baran, Merck –Indicated he was available for questions if needed.

Dr. Edward Kent of South Burlington -- emailed stating that he would like this added to the PDL because he likes to have a choice of agents when customizing care for his patients.

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

- Gilenya[®] (fingolimod) Capsule: It was recommended that Gilenya[®] be added to the PDL as prior authorization required with the criteria for approval being the patient has a diagnosis of relapsing multiple sclerosis and the patient has had a documented side effect, allergy, inadequate response, or contraindication to at least one preferred self-injectable drug. Additionally, a quantity limit of one capsule/day was recommended.

Public Comment: No public comment.

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

- Lysteda[®] (tranexamic acid) Tablet:
Deferred until next meeting.

8. Therapeutic Drug Classes-Periodic Review:

(Public comment prior to Board action)

- Antidiabetics: Oral: Dipeptidyl Peptidase (DPP-4) Inhibitors: In recognition of the established efficacy and safety of the dipeptidyl peptidase-4 (DPP-4) inhibitors for the treatment of type 2 diabetes, the American Diabetes Association and European Association for the Study of Diabetes recommendations which consider metformin to be first-line treatment for type 2 diabetes, and the overall lack of head-to-head evidence demonstrating an advantage of one DPP-4 inhibitor over the other, no changes are recommended to the current approval criteria.

Public Comment: No public comment.

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

- Anti-Infectives: Antibiotics: Quinolones: No changes were recommended to the current preferred drugs or approval criteria for non-preferred products.

Public Comment: No public comment.

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

- Gastrointestinals: Proton Pump Inhibitors: No changes were recommended to the current preferred drugs or approval criteria for non-preferred products.

Public Comment: No public comment.

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

- Hepatitis C Medications (pegylated interferons): It was recommended that the approval criteria for pegylated interferons remain unchanged. However, the following quantity limits were recommended for Peg-intron[®] products (quantity limits already established for Pegasys[®] products): Peg-Intron[®] (pegylated interferon alfa 2b) - 4 pens per 28 days, Peg-Intron Redipen[®] - 4 pens per 28 days, Peg-Intron Redipen Pak 4[®] - 1 kit of 4 pens per 28 days.

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)

No new Drug Classes this month.

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

Diane Neal, R.Ph, (MHP)

- Anti-Depressants:SNRI (Cymbalta[®]) for musculoskeletal pain and generalized anxiety disorder:
The following approval criteria are recommended for the management of Cymbalta[®] for musculoskeletal pain and generalized anxiety disorder: *Non-neuropathic musculoskeletal pain (osteoarthritis, chronic low back pain):* The patient has had a documented side effect, allergy, inadequate response or contraindication to acetaminophen (Tylenol[®]) and at least TWO nonsteroidal anti-inflammatory drugs (NSAIDs) (oral and/or topical) and the patient has had a documented side effect, allergy, or treatment failure to at least ONE drug from TWO of the following classes: tricyclic antidepressant (TCA) class, tramadol, cyclobenzaprine, benzodiazepine (BZD), opioid. (this indication not processed via automated step therapy). *Generalized anxiety disorder (GAD):* 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 inadequate response to at least TWO different antidepressants from the SSRI, SNRI and/or TCA categories (may be preferred or non-preferred) or ONE antidepressant from the SSRI, SNRI and/or TCA categories (may be preferred or non-preferred) and buspirone.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendation noted but requested the removal of the need for trials of drugs from the tricyclic antidepressant (TCA) class, tramadol, cyclobenzaprine, benzodiazepine (BZD), or opioids for the indication of non-neuropathic musculoskeletal pain (osteoarthritis, chronic low back pain).

- Anti-Hyperkineses and Anti-Narcolepsy/Cataplexy (short acting options for patients on Focalin[®] XR):
The following criteria change was recommended to the approval criteria for dexmethylphenidate and Focalin[®]: Addition of “or the patient is also on Focalin[®] XR and the prescriber is adding a shorter acting dosage form”. This will be coded for automated step therapy.

Public Comment: No public comment.

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

- Anti-Migraine: Triptans: It was recommended that this category become primarily generic preferred for oral products. The first preferred oral product will be generic sumatriptan followed by generic naratriptan. After a trial of both products the first preferred brand would be Maxalt MLT[®]. Axert[®] would move to PA required.

Public Comment: No public comment.

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

- Botulinum Toxins (migraine indication, requests for use in patients with neurogenic bladder/detrusor overactivity): It was recommended that the following indications be added to the current approval criteria for Botox[®]: (1) Chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer) and the member has failed or has a contraindication to an adequate trial of at least TWO medications for migraine prophylaxis from at least two different classes (tricyclic antidepressants, beta-blockers, calcium channel blockers or anticonvulsants) and (2) Overactive bladder or detrusor overactivity (if member has failed an adequate trial of at least TWO urinary antispasmodics (either short- or long-acting formulations);). The patient must be >18 years of age for these 2 indications.

Public Comment: No public comment.

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

- Chemical Dependency: Vivitrol[®]: New indication for opiate dependency: It was recommended that the indication for opiate dependency be added and approved after PA with the criteria for approval being an inadequate response, adverse reaction, or contraindication to oral naltrexone. Additionally, the prescriber must provide a rationale for why injectable therapy is being requested (compliance, tolerance, etc) and the patient is not a candidate for Suboxone therapy and the patient should be opioid free for > 7 to 10 days prior to initiation of Vivitrol[®]. Additionally a quantity limit of 1 injection (380 mg) per 28 days was recommended.

Public Comment: Morrie Olson, Alkermes – discussed the use of Vivitrol[®] for opiate and alcohol dependency and answered many questions from the Board.

Board Decision: The Board voted to approve a requirement of prior authorization for opiate dependency but without the need for any step therapy. The clinical criteria for use in alcohol dependency were changed so that only one trial of oral therapy will be required.

- Dermatological Agents: Antivirals: Topical: It was recommended that Denavir[®] and Zovirax[®] no longer be approved for the treatment of genital herpes simplex as they are not considered effective by the CDC. This will be listed as a limitation in the clinical criteria manual.

Public Comment: No public comment.

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

- Smoking Cessation Therapy (Nicotrol[®] Inhaler): It was recommended that Nicotrol[®] Inhaler be moved from preferred status to prior authorization required with the requirement for a trial of both Nicoderm CQ[®] patch and Nicorette[®] gum.

Public Comment: No public comment.

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

11. General Announcements Diane Neal, R.Ph, (MHP)

FDA Safety Alerts

- Abbot Glucose Test Strips: Recall-False Low blood Glucose Results – FDA and Abbott Diabetes Care notified healthcare professionals and patients of a recall of 359 different lots of glucose test strips marketed under the following brand names: Precision Xceed Pro, Precision Xtra, Medisense Optium,

Optium, OptiumEZ and ReliOn Ultima. A report was pulled of DVHA patients and any patients with these products were called. Only one patient was found with the affected lot and that patient had already switched to a different test strip.

Public Comment: No public comment.

Board Decision: None needed.

- Acetaminophen Prescription Products Limited to 325 mg per Dosage Unit: Drug Safety Communication - FDA is asking drug manufacturers to limit the strength of acetaminophen in prescription drug products, which are predominantly combinations of acetaminophen and opioids. This action will limit the amount of acetaminophen in these products to 325 mg per tablet, capsule, or other dosage unit, making these products safer for patients.

Public Comment: No public comment.

Board Decision: None needed.

- Anzemet[®] (dolasetron mesylate): Drug Safety Communication-Reports of Abnormal Heart Rhythms - FDA notified healthcare professionals that a contraindication is being added to the prescribing information advising that the injection form of Anzemet[®] (dolasetron mesylate) should no longer be used to prevent nausea and vomiting associated with cancer chemotherapy (CINV) in pediatric and adult patients. New data demonstrate that Anzemet[®] injection can increase the risk of developing torsade de pointes, an abnormal heart rhythm, which in some cases can be fatal. Patients at particular risk are those with underlying heart conditions or those who have existing heart rate or rhythm problems. Anzemet[®] causes a dose-dependant prolongation in the QT, PR, and QRS intervals on an electrocardiogram. It was recommended that the injection be blocked from the POS pharmacy benefit (if not already done).

Public Comment: No public comment.

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

- Avandia[®]: REMS program - FDA notified healthcare professionals and patients that information on the cardiovascular risks (including heart attack) of rosiglitazone has been added to the physician labeling and patient Medication Guide. This information was first announced by FDA on September 23, 2010 as part of new restrictions for prescribing and use of this drug. The DUR Board has already voted to restrict the use of Avandia[®] so no further action is required.

Public Comment: No public comment.

Board Decision: None needed.

- Multaq[®] (dronedaron)-Drug Safety Communication: Risk of Severe Liver Injury - FDA is alerting healthcare professionals and patients about cases of rare, but severe liver injury, including two cases of acute liver failure leading to liver transplant in patients treated with the heart medication dronedaron (Multaq[®]). This is informational only as we do not manage this medication.

Public Comment: No public comment.

Board Decision: None needed.

- Recombinant Human Growth Hormone-Ongoing Safety Review - FDA is informing the public that results from a study found that persons with certain kinds of short stature (idiopathic growth hormone deficiency and idiopathic or gestational short stature) treated with recombinant human growth hormone during childhood and who were followed over a long period of time, were at a small increased risk of death when compared to individuals in the general population. FDA is currently reviewing all available information on this potential risk and will communicate any new recommendations once it has completed its review.

Public Comment: No public comment.

Board Decision: None needed.

12. Adjourn: Meeting adjourned at 9:27 p.m.

Next DUR Board Meeting

Tuesday, April 05, 2011

7:00 - 9:00 p.m.*

EDS 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.