



**Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 07/19/11**

Board Members:

Michael Scovner, MD, Chair
Andrew Miller, RPh
Sommer Zarbock, Pharm D

Gary Starecheski, RPh
Kim Ladue, RN

Lynne Vezina, RPh
Amanda Kennedy, Pharm D

Staff:

Diane Neal, RPh, MHP
Michelle Sirois, MHP

Nancy Miner, MHP
Stacey Baker, DVHA

Jennifer Egelhof, DVHA
Michael Farber, MD, DVHA

Guests:

Paul Amato, GSK
Richard Angeli, Merck, Inc.
Susan Campbell, Boehringer-Ingelheim
David Downey, Abbott Labs

Brian Erickson
Nancy Hayes, GSK
Maribeth Kowalski, Purdue Pharma
John Mastrianni, Genentech

Amy Pudvar-Pecor, Purdue Pharma
Helen Pepin, Takeda
Wendy Pollinger, Eli Lilly
Sophia Tashkorski, Takeda

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 May, 2011, meeting minutes were accepted as printed.

Public Comment: No public comment.

3. DVHA Pharmacy Administration Updates: There were no updates for this meeting.

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

- Clinical Programs Update: None to report.
- Prescriber Comments: None to report.

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

- Acetaminophen Dosing: Maximum daily dose continues to be 4000 mg/day. Will revisit combination products at a future meeting to discuss possible limits. There are edits in place to limit the acetaminophen per product to 4000 mg/day.

- OTC Product Coverage Restrictions: Chart of revised OTC coverage distributed.
- Seroquel[®] Low Dose: Letter with patient specific prior authorization forms went out to prescribers for members using 50 mg or less per day of Seroquel[®]. Change was effective 7/11/2011.

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

- Enbrel[®] Dosing in Plaque Psoriasis: Currently, etanercept is one of the preferred products for DVHA after prior authorization criteria are met. In recognition of the potential inappropriate prescribing, the following quantity limits were implemented on June 14, 2011: 8 syringes per 28 days for the first 3 months of therapy, and 4 syringes per 28 days subsequently (for plaque psoriasis); 4 syringes per 28 days (for all other indications). The conducted retrospective quality assurance analysis supports these quantity limits. It was demonstrated that etanercept may be used at doses above 50 mg weekly (i.e. 50 mg twice weekly) for indications where the benefits of this high dose have not been established (e.g. psoriatic arthritis). In addition, a small percentage of members continued on the high etanercept dose beyond the first three months of use. While relatively few members were maintained on etanercept 50 mg twice weekly for longer than three consecutive months, the cost they incurred was twice that of members using the FDA recommended dose. In consideration of the findings of this quality assurance analysis and the recent quantity limits addition to the etanercept approval criteria, no additional changes are recommended at this time.

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:

- Cuvposa[®] (glycopyrrolate) Oral Solution: In consideration of the limited FDA-approved indication, availability of generic alternatives, and less costly treatment options, it is recommended to add Cuvposa[®] to the Department of Vermont Health Access (DVHA) preferred drug list (PDL) as PA required with the criteria for approval being the patient is 3 -16 years old AND the patient has a diagnosis/indication of Sialorrhea or a neurologic condition associated with excessive drooling (e.g. cerebral palsy, mental retardation) AND the dose cannot be obtained from the tablet formulation. The recommended days supply is to limit to 30 days per fill.

Public Comment: No public comment.

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

- Atelvia[®] (risendronate) Delayed Release Tablet: In consideration of the limited FDA-approved indication, availability of generic alternatives and unclear advantage over the immediate-release formulation, it is recommended to add Atelvia[®] to the bone resorption inhibitors managed category as PA required with the criteria for approval being the patient has a diagnosis/indication of postmenopausal osteoporosis AND the patient has had a documented side effect, allergy, or treatment

failure (at least a 1 year trial) to generic alendronate. Treatment failure is defined as documented continued bone loss or fracture after one or more years despite treatment with an oral bisphosphonate.

Public Comment: No public comment.

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

Full New Drug Reviews:

- Butrans[®] (buprenorphine) Transdermal System: Recommended to be added as PA required with the criteria for approval being the patient has a diagnosis of moderate to severe chronic pain, requiring a continuous, around-the-clock opioid analgesic for an extended period of time AND a documented side effect, allergy, or treatment failure to BOTH long-acting morphine sulfate and Duragesic patch OR a documented side effect, allergy, or treatment failure to Duragesic patch and medical necessity for transdermal formulation (i.e., inability to take oral medications). In addition, a quantity limit of four patches per 28 days was recommended. Requests received with an indication of opioid dependence will be denied.

Public Comment: Maribeth Kowalski, Purdue Pharma – highlighted some of the attributes of this medication.

Brian Erickson, M.D. – feels that this medication is safer to use in patients who do not have stable home situations (risk of drug diversion in the household).

Board Decision: The Board voted to modify the proposed approval clinical criteria to diagnosis of moderate to severe chronic pain, requiring a continuous, around-the-clock opioid analgesic for an extended period of time AND a documented side effect, allergy, or treatment failure to BOTH long-acting morphine sulfate and Duragesic patch OR the prescriber provides compelling clinical information to be discussed with the DVHA Medical Director. A reduced quantity limit of two patches per 14 days was recommended.

- Krystexxa[®] (pegloticase) Vial for IV Infusion: Given its FDA-approved indication in chronic gout inadequately controlled with xanthine oxidase inhibitors and the high cost, it is recommended that pegloticase be added to the Preferred Drug List requiring prior authorization with the criteria for approval being the indication is chronic gout AND the patient has had a documented side effect, allergy, treatment failure or a contraindication to BOTH allopurinol and febuxostat. Additionally, a quantity limit of two vials per 28 days is recommended. The recommendation is that this medication should be billed through the Medical Benefit and blocked in the pharmacy benefit.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendation noted above with the addition of a final review by the DVHA Medical Director.

- Nexiclon XR[®] (clonidine) Extended Release Suspension and Tablets: Recommended to be added to the preferred drug list (PDL) as prior authorization required with the criteria for approval for the tablets being the patient has a diagnosis of hypertension AND the patient has had a documented side effect, allergy, or treatment failure to at least TWO agents (either separately or as a combination product) from the following antihypertensive classes: a thiazide diuretic, a beta blocker, an angiotensin converting enzyme inhibitor (ACEI), angiotensin receptor blocker (ARB), or a calcium channel blocker (CCB) AND the patient has been unable to be adherent to or tolerate twice daily

dosing of the generic clonidine immediate-release tablets and for the suspension the patient has a diagnosis of hypertension AND the patient has had a documented side effect, allergy, or treatment failure to at least TWO agents (either separately or as a combination product) from the following antihypertensive classes: a thiazide diuretic, a beta blocker, an angiotensin converting enzyme inhibitor (ACEI), angiotensin receptor blocker (ARB), or a calcium channel blocker (CCB) OR the patient has a medical necessity for a specialty dosage form (i.e. dysphasia, swallowing disorder). Note: Nexiclon XR[®] will not be approved for the treatment of attention hyperactivity deficit disorder as it is a non FDA-approved indication and an FDA-approved formulation of clonidine extended-release (Kapvay[®]) is available. DVHA does not presently manage clonidine-related products. Hence, the development of a new managed category, “Anti-Hypertensives: centrally acting alpha agonists”, is proposed. In consideration of the cost of clonidine transdermal patches, it is recommended to add them to the DVHA PDL as PA required, with the same criteria as Nexiclon XR[®] oral suspension. Methyldopa and guanfacine immediate-release are available generically at a reasonable cost and hence may be added as “preferred”, although their use in hypertension is limited. The recommended length of authorization is 1 year.

Public Comment: No public comment.

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

8. Therapeutic Drug Classes-Periodic Review:
(Public comment prior to Board action)

- Anticoagulants (Injectable): No changes in preferred drugs or clinical criteria recommended.

Public Comment: No public comment.

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

- Erythropoiesis-Stimulating Agents (Anemia Medications): In recognition of the evidence demonstrating the efficacy of the erythropoiesis-stimulating agents in approved indications, the potential for off-label use and the risk of life-threatening adverse events, it is recommended to require prior authorization (PA) for all agents in the class. Currently, Aranesp[®] and Procrit[®] are available without restrictions. Moreover, it is recommended to add additional PA requirements to the current approval criteria for Epogen. The suggested approval criteria for erythropoietic agents are: Aranesp[®], Procrit[®]: The diagnosis or indication for the requested medication is anemia due to one of the following: Chronic kidney disease/renal failure, Post-renal transplant, Use of zidovudine for the treatment of human immunodeficiency virus (HIV) (other causes of anemia, such as iron/folate/vitamin B12 deficiency have been eliminated), Surgery patients at high risk for perioperative blood loss, Cancer chemotherapy, Use of ribavirin or interferon therapy for Hepatitis C, Myelodysplastic syndrome, and Hemoglobin level at initiation of therapy is <10 g/dL OR For patients currently maintained on therapy, hemoglobin level is ≤11 g/dL in dialysis patients with chronic kidney disease, ≤10 g/dL in non-dialysis patients with chronic kidney disease, or ≤12 g/dL in patients treated for other indications. Epogen[®]: The diagnosis or indication for the requested medication is anemia due to one of the following: Chronic kidney disease/renal failure, Post-renal transplant, Use of zidovudine for the treatment of human immunodeficiency virus (HIV) (other causes of anemia, such as iron/folate/vitamin B12 deficiency have been eliminated), Surgery patients at high risk for perioperative blood loss, Cancer chemotherapy, Use of ribavirin or interferon therapy for Hepatitis C, Myelodysplastic syndrome, and Hemoglobin level at initiation of therapy is <10 g/dL OR For patients currently maintained on therapy, hemoglobin level is ≤11 g/dL in dialysis patients

with chronic kidney disease, ≤ 10 g/dL in non-dialysis patients with chronic kidney disease, or ≤ 12 g/dL in patients treated for other indications AND the patient has had a documented side-effect, allergy, or treatment failure to both Aranesp[®] and Procrit[®]. Due to the need for continued monitoring to assess the need for continued therapy and safety, it is further recommended to change the duration of authorization from 1 year to up to 3 months for initial requests and 6 months for subsequent requests.

Public Comment: No public comment.

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

- Hemostatic Agents (includes Lysteda[®]): Amicar[®] and its generic equivalent, aminocaproic acid, are not currently managed by the Department of Vermont Health Access. In recognition of the published literature supporting the effectiveness of aminocaproic acid in treating surgical and non-surgical bleeding conditions secondary to increased fibrinolysis, its low utilization and the unlikelihood of inappropriate use, management of this product is not recommended. Tranexamic acid (Lysteda[®]) was recently added to the DVHA preferred drug list as PA required, with the approval criteria outlined below. No further changes are recommended.

Public Comment: No public comment.

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

- Intermittent Claudication Agents: In recognition of the established role of cilostazol and pentoxifylline extended-release for improving walking distances in patients with intermittent claudication, comparable safety profiles between the agents, the availability of generics, and low utilization within the class, the creation of a new managed category is not recommended. Cilostazol is currently listed as preferred in the “Platelet Aggregation Inhibitors” managed category. Pentoxifylline extended-release is available without restrictions.

Public Comment: No public comment.

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

- Platelet Inhibitors: It is recommended that the generic for Agrylin[®] (anagrelide) be added to the preferred drug list (PDL) as preferred and the brand be added as PA required with the criteria that the patient has had a documented intolerance to the generic formulation of the medication. No other changes to the platelet aggregation inhibitors managed category are recommended.

Public Comment: No public comment.

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

- Pulmonary Arterial Hypertension Agents: It was recommended that no changes be made to the current PDL approval criteria for phosphodiesterase (PDE)-5 inhibitors and endothelin receptor antagonists. However, in consideration of the cost of injectable prostanoids and the availability of a generic, it is recommended to move Flolan[®] to PA required with the criteria for approval being there is a clinical diagnosis of pulmonary hypertension AND the patient has had a documented intolerance to the generic epoprostenol.

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

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

Diane Neal, RPh, MedMetrics Health Partners (MHP)

- Otic Anti-Infectives: The recommendation was to add some of the older anti-infective otic products that have not been listed in the past to the PDL (that is, expand the category). The following miscellaneous otic products are recommended to be added to the DVHA preferred drug list (PDL) as preferred: acetic acid and acetic acid-aluminum. Cortomycin is a generic formulation of neomycin/polymyxin B/hydrocortisone, currently not listed in the otic anti-infectives clinical criteria table. It is recommended to list the product as preferred. The following miscellaneous otic products are recommended to be added to the PDL as PA required: Acetasol HC, Acetic acid HC, Vosol HC[®], Auralgan[®], Otic Edge[®], PR Otic[®], acetic acid/ antipyrine/ benzocaine/ polycosanol[®] solution, TriOxin[®], Zinotic[®]/Zinotic ES[®] with the criteria for approval being the patient has had a documented side effect, allergy, or treatment failure to at least TWO preferred otic anti-infectives.

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

- Benzocaine Topical Products – Risk of Methemoglobinemia: FDA is warning the public that the use of benzocaine, the main ingredient in over-the-counter (OTC) gels and liquids applied to the gums or mouth to reduce pain, is associated with a rare, but serious condition. This condition is called methemoglobinemia. These products are no longer covered due to the changes in OTC coverage recently implemented.

Public Comment: No public comment.

Board Decision: None needed.

- Drugs Added to FDA Watch List: FDA has issued its latest list of drugs to monitor after having identified potential signs of serious risks or new safety information in the agency's Adverse Event Reporting System (AERS). The quarterly watch list consists of 9 medications that treat conditions ranging from arthritis to schizophrenia.

Public Comment: No public comment.

Board Decision: None needed.

- Long-Acting Beta-Agonists-Post Marketing Safety Studies Required : To further evaluate the safety of Long-Acting Beta-Agonists (LABAs) when used in combination with inhaled corticosteroids for

the treatment of asthma, the FDA is requiring the manufacturers of LABAs to conduct five randomized, double-blind, controlled clinical trials comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone.

Public Comment: No public comment.

Board Decision: None needed.

- Opiate Analgesics-REMS Programs: On April 19, 2011 the Office of National Drug Control Policy (ONDCP) released the Obama Administration's *Epidemic: Responding to America's Prescription Drug Abuse Crisis*- a comprehensive action plan to address the national prescription drug abuse epidemic. This plan includes action in four major areas to reduce prescription drug abuse: education, monitoring, proper disposal, and enforcement. In support of the action plan, the FDA announced the elements of a Risk Evaluation and Mitigation Strategy (REMS) that will require all manufacturers of long-acting and extended-release opioids to ensure that training is provided to prescribers of these medications and to develop information that prescribers can use when counseling patients about the risks and benefits of opioid use.

Public Comment: No public comment.

Board Decision: None needed.

- TNF Blockers, DMARDs-Lymphoma: FDA continues to receive reports of a rare cancer of white blood cells (known as Hepatosplenic T-Cell Lymphoma or HSTCL, primarily in adolescents and young adults being treated for Crohn's disease and ulcerative colitis with medicines known as tumor necrosis factors (TNF) blockers, as well as with azathioprine, and/or mercaptopurine. TNF blockers include Remicade (infliximab), Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab pegol) and Simponi (golimumab).

Public Comment: No public comment.

Board Decision: None needed.

- Tysabri®-PML Update: (FDA) continues to evaluate the risk of progressive multifocal leukoencephalopathy (PML), a rare but serious brain infection, associated with use of Tysabri (natalizumab) for the treatment of multiple sclerosis (MS) and Crohn's disease. The FDA has updated the Tysabri label to give new information about the size of this risk, as well as to include new safety information about patients who have taken other drugs that suppress the immune system, who may be at a higher risk for PML.

Public Comment: No public comment.

Board Decision: None needed.

- 5-alpha reductase inhibitors (5-ARIs): Increased Risk of Prostate Cancer: FDA notified healthcare professionals that the Warnings and Precautions section of the labels for the 5-alpha reductase inhibitor (5-ARI) class of drugs has been revised to include new safety information about the increased risk of being diagnosed with a more serious form of prostate cancer (high-grade prostate cancer).

Public Comment: No public comment.

Board Decision: None needed.

- Angiotensin Receptor Blockers (ARBs): Drug Safety Review Completed: FDA's meta-analysis of 31 randomized controlled trials comparing ARBs to other treatment found no evidence of an increased risk of incident (new) cancer, cancer-related death, breast cancer, lung cancer, or prostate cancer in patients receiving ARBs.

Public Comment: No public comment.

Board Decision: None needed.

- Chantix® (varenicline): Risk of Certain Cardiovascular Adverse Events: FDA notified healthcare professionals and patients that the Prescribing Information for this drug product will be strengthened to inform the public that use of varenicline may be associated with a small, increased risk of certain cardiovascular adverse events in patients who have cardiovascular disease. This safety information will be added to the Warnings and Precautions section and the patient Medication Guide.

Public Comment: No public comment.

Board Decision: None needed.

- Erythropoiesis-Stimulating Agents (ESAs) In Chronic Kidney Disease: Modified Dosing Recommendations: FDA notified healthcare professionals that new, modified recommendations for more conservative dosing of Erythropoiesis-Stimulating Agents (ESAs) in patients with chronic kidney disease (CKD) have been approved to improve the safe use of these drugs. FDA has made these recommendations because of data showing increased risks of cardiovascular events with ESAs in this patient population. The new dosing recommendations are based on clinical trials showing that using ESAs to target a hemoglobin level of greater than 11 g/dL in patients with CKD provides no additional benefit than lower target levels, and increases the risk of experiencing serious adverse cardiovascular events, such as heart attack or stroke.

Public Comment: No public comment.

Board Decision: None needed.

- Valproate Products: Risk of Impaired Cognitive Development in Children Exposed in Utero: FDA notified healthcare professionals that children born to mothers who take the anti-seizure medication valproate sodium or related products (valproic acid and divalproex sodium) during pregnancy have an increased risk of lower cognitive test scores than children exposed to other anti-seizure medications during pregnancy. This conclusion is based on the results of epidemiologic studies that show that children born to mothers who took valproate sodium or related products throughout their pregnancy tend to score lower on cognitive tests (IQ and other tests) than children born to mothers who took other anti-seizure medications during pregnancy.

Public Comment: No public comment.

Board Decision: None needed.

- Victoza® Injection: REMS-Risk of Thyroid C-cell Tumors, Acute Pancreatitis: Novo Nordisk reminded healthcare professionals of important safety information about Victoza (liraglutide [rDNA origin]) injection required in a Risk Evaluation and Mitigation Strategy (REMS). The letter is being sent because a recent assessment of healthcare providers showed that some primary care providers are not fully aware of the serious risks associated with the use of Victoza. Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Victoza causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as human relevance could not be ruled out by clinical or nonclinical studies. Additionally, in clinical trials studying Victoza, there were more cases of pancreatitis in patients treated with Victoza than in patients treated with comparators.

Public Comment: No public comment.

Board Decision: None needed.

- Zocor® (simvastatin): New restrictions, contraindications, and dose limitations to reduce the risk of muscle injury: FDA is recommending limiting the use of the highest approved dose of the cholesterol-lowering medication, simvastatin (80 mg) because of increased risk of muscle damage. Simvastatin 80 mg should be used only in patients who have been taking this dose for 12 months or more without evidence of muscle injury (myopathy). Simvastatin 80 mg should not be started in new patients, including patients already taking lower doses of the drug. In addition to these new limitations, FDA is requiring changes to the simvastatin label to add new contraindications (should not be used with certain medications) and dose limitations for using simvastatin with certain medicines. The recommendation was to grandfather patients who have been started on 80 mg/day but to not allow any newer patients to start on this dose. The statin criteria will be modified to reflect these FDA recommendations.

Public Comment: No public comment.

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

- Rosiglitazone: Long-Awaited Risk-Management Strategy Released: The new document limits the drug to patients already successfully treated with it or those for whom it's pretty much a last-ditch effort to control blood glucose medically. Moreover, "healthcare providers and patients must be enrolled in the Avandia-Rosiglitazone Medicines Access Program in order to prescribe and receive rosiglitazone medicines," the FDA statement says. It will require, among other things, that providers who want to prescribe rosiglitazone, as well as pharmacies that distribute the drug, be specially trained and certified for the purpose. Also, patients will no longer be able to get it in person at their neighborhood pharmacy--it will be available to them only by mail.

Public Comment: No public comment.

Board Decision: None needed.

12. Adjourn: Meeting adjourned at 8:45 p.m.

Next DUR Board Meeting

Tuesday, September, 13, 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.