



**Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 05/17/2011**

Board Members:

Lynne Vezina, RPh
Michael Scovner, MD, Chair
Amanda Kennedy, Pharm D

Andrew Miller, RPh
Kim Ladue, NP

Gary Starecheski, RPh
Sommer Zarbock, PharmD

Staff:

Michelle Sirois, MHP
Diane Neal, RPh, MHP
Michael Farber, MD, DVHA

Nancy Miner, MHP
Nancy Hogue, PharmD, DVHA

Jennifer Egelhof, DVHA
Stacey Baker, DVHA

Guests:

Steve Berardino, Amgen
Thomas Currier, Purdue
Larry Forti, Pfizer
James Kokoszyna, Allergan

Terry Lee, Gilead Sciences
Ed Macmillan, Abbott Diabetes
Sunil Majethia, Abbott
Molly Miller, OMJ

Carl Pepe, GSK
Jai Persico, Endo
Keith White, Genentech
Scott Williams, OMJ

Michael Scovner, M.D. 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 2011 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- Susan Besio, Commissioner of DVHA, will be retiring at the end of June, 2011. A replacement has not yet been named.
- DVHA is continuing to recruit members for the DUR Board. There are currently 5 physicians that have expressed interest.
- Health Care Reform Bill H.202: The DUR Board will be one of the bodies that will review recommendations for a possible single State drug formulary. A report of recommendations needs to be submitted to legislature by DVHA by 01/15/2012.

4. Medical Director Update: *Dr. Michael Farber, Medical Director, DVHA*

- Clinical Programs Update: While reviewing appeals for prior authorizations, Dr. Farber had questions about two policies. One of those (Singulair[®]) is being presented tonight with some proposed additional clinical criteria.
- Prescriber Comments: None to report.

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

- Alpha₁-Proteinase Inhibitors: This category was brought back this month to define criteria for the entire class. All agents will require prior authorization with the criteria for approval being the indication for use is treatment of congenital alpha₁-proteinase inhibitor deficiency-associated lung disease when all of the following criteria are met: Patient alpha₁-antitrypsin (AAT) concentration is < 80 milligrams per deciliter (mg/dl) [or < 11 micromolar (μM)] **AND** the patient has obstructive lung disease as defined by a forced expiratory volume in one second (FEV₁ of >120mL/year) **AND** the medication is being administered intravenously (inhalation administration will not be approved) **AND** the patient is a non-smoker **OR** the patient meets the above criteria except lung function has deteriorated beneath above limits while on therapy. The recommended days supply is 14 days per fill due to the high cost of therapy.

Public Comment: No public comment.

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

- Botulinum Toxins: This category was revisited this month to confirm the recommended criteria for Xeomin[®] (incobotulinumtoxinA). It was recommended to require prior authorization with the criteria for approval being the patient has a diagnosis of cervical dystonia or blepharospasm. **AND** the patient is ≥18 years of age **AND** the patient has had a documented intolerance or treatment failure with BOTOX[®].

Public Comment: No public comment.

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

- Mugard[®]: Revisited this month to determine required step therapy. Recommended as prior authorization required with the criteria for approval being the patient is receiving radiation and/or chemotherapy. **AND** the patient has had a documented side effect, allergy or treatment failure with at least one oral mucosal coating agent (e.g. aluminum hydroxide suspension, Mylanta[®]) or a topical anesthetic (e.g. viscous lidocaine or diphenhydramine solutions) or combinations of similar agents.

Public Comment: No public comment.

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)

- Singulair[®]/Leukotriene Modifiers: Singulair requires prior authorization and step therapy when used for allergic rhinitis. It is available for use in asthma. At the time the new criteria were adopted, no criteria were established for use in urticaria. Several second reconsideration requests were received

for use in urticaria. A review of PA requests was presented. Approximately 6 % were for urticaria. Approximately 19 % of PA requests for Singulair® are being denied which includes those for urticaria. The following additional clinical criteria is recommended: The diagnosis or indication for the requested medication is urticaria. AND the patient has had a documented side effect, allergy, or treatment failure to at least TWO preferred 2nd generation antihistamines (i.e. loratadine (OTC), cetirizine (OTC), fexofenadine).

Public Comment: No public comment.

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

- Suboxone®/Subutex®/Buprenorphine: For the month of April, the per member/per month cost has continued to decline to \$4.70 and the use of buprenorphine mono (which is mostly limited to use in pregnancy) has declined as well. Suboxone® film continues to be the preferred product and more than 50% of users are on film. However, there continues to be requests to be changed back to Suboxone® sublingual tablet due to a variety of reasons.

Public Comment: No public comment.

Board Decision: None needed.

- Top Drugs (volume and cost): The Top 50 Drugs for DVHA by volume and price were provided as a tool to promote discussion of possible categories for future retrospective drug utilization reviews.

Public Comment: No public comment.

Board Decision: The Board would like to do an evaluation of Lexapro® users. A possible letter to prescribers with cost information between Lexapro® and citalopram was discussed. There was also considerable interest in limiting acetaminophen/narcotic combination product dosage forms that contain > 325 mg acetaminophen. This will be further discussed at a later meeting. The Board was asked to think about other possible topics for discussion.

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

Abbreviated Drug Review

- Kombiglyze XR® (saxagliptin/metformin) Extended Release Tablet: In recognition of the role of Kombiglyze XR® as adjunctive therapy in diabetic patients who have not achieved target goals using first-line therapies, such as metformin and to offer a second DPP-4/metformin combination, it is recommended that Kombiglyze XR® be added to the PDL as Preferred After Clinical Criteria are met with the following approval criteria: The patient has had an inadequate response with Onglyza® or metformin/metformin XR monotherapy OR the patient has been started and stabilized on the requested medication or Onglyza® and metformin/metformin XR combination therapy. In addition, a quantity limit of 1 tablet/day is proposed.

Public Comment: No public comment.

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

- Nitromist[®] (nitroglycerin) Lingual Aerosol Spray: At this time, Nitrolingual Pumpspray[®], its generic nitroglycerin lingual spray, and Nitrostat[®] are available without a prior authorization. While a clinical advantage over treatment alternatives is unclear, Nitromist[®] is comparably priced to the Nitrolingual Pumpspray[®]. Hence, it is recommended to add Nitromist[®] to the DVHA PDL, without prior authorization, as preferred.

Public Comment: No public comment.

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

Full New Drug Review

- Carbaglu[®] (carglumic acid) Dispersible Tablets: Given the high cost of Carbaglu[®] and that the agent is indicated in a very specific and rare condition, it is recommended that Carbaglu[®] be added to the Preferred Drug List requiring prior authorization with the criteria for approval being the indication is hyperammonemia due to the N-acetylglutamate synthetase (NAGS) deficiency **AND** the prescriber specializes in metabolic disorders (e.g., medical geneticist).

Public Comment: No public comment.

Board Decision: The Board approved the criteria with the modification of the criteria to read that the product has been recommended by a specialist. All requests must also be approved by the Medical Director due to high cost after preliminary approval by the Clinical Call Center.

- XGEVA[®] (denosumab) Injection: At this time, the DVHA does not manage ossification enhancing injectables (e.g. Zometa[®], pamidronate) that are indicated for the treatment of bone metastases. In consideration of the cost and the limited FDA-approved indication, it is recommended to add these agents to the ossification enhancing agents managed category. The following criteria for approval are recommended for XGEVA[®]: The patient has been started and stabilized on the requested medication **OR** the diagnosis or indication is bone metastases from solid tumors (e.g. prostate, breast, thyroid, non-small lung cancer)

Public Comment: No public comment.

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

8. Therapeutic Drug Classes-Periodic Review: Diane Neal, RPh (MHP)

- Analgesics: Narcotics: Long Acting: It was recommended that no changes be made to the current approval criteria and preferred drugs.

Public Comment: No public comment.

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

- Immunomodulators:
Ankylosing Spondylitis-Injectables: It was recommended that quantity limits for Enbrel[®] and Humira[®] be added. The quantity limit for Simponi[®] was clarified.

Public Comment: No public comment.

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

▪ Immunomodulators:

Crohn's Disease-Injectables: It was recommended that Cimzia® be moved to PA required with the criteria for approval being the patient has a diagnosis of Crohn's disease and has already been stabilized on Cimzia® OR the patient age > 18 years AND the diagnosis is moderate to severe Crohn's disease and at least 2 of the following drug classes resulted in an adverse effect, allergic reaction, inadequate response, or treatment failure (i.e. resistant or intolerant to steroids or immunosuppressants): aminosalicylates, antibiotics, corticosteroids, and immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate AND the prescriber must provide a clinically valid reason why Humira® cannot be used. Cimzia® will also go through our specialty pharmacy provider ICORE. Quantity limits were recommended for Humira® and Cimzia®.

Public Comment: No public comment.

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

▪ Immunomodulators:

Ulcerative Colitis-Injectables: The only clarification was a reminder that Remicade® requires prior authorization through the Clinical Call Center whether billed through the medical or pharmacy benefit.

Public Comment: No public comment.

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

▪ Immunomodulators:

Psoriasis-Injectables: Stelara® may be processed though either the medical or pharmacy benefit with prior authorization required in either case. Quantity limits were established for both Humira® and Enbrel®.

Public Comment: No public comment.

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

▪ Immunomodulators:

Rheumatoid, Juvenile Idiopathic & Psoriatic Arthritis-Injectables: The indication of juvenile RA was added to the clinical criteria for Actemra® and Orencia®. Cimzia® may now go through our specialty pharmacy vendor ICORE. Quantity limits were added for Enbrel®, Humira® and Kineret®.

Public Comment: No public comment.

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

▪ Pulmonary: Leukotriene Modifiers: See recommendation and Board decision above in RetroDUR section.

▪ Smoking Cessation Therapies: It was recommended that no changes be made to the current Smoking Cessation Therapies approval criteria and preferred drugs.

Public Comment: No public comment.

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

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

- No new categories for this meeting.

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

Diane Neal, RPh (MHP)/Nancy Hogue, RPh, DVHA

- Miscellaneous: Soliris®: It was recommended that the criteria be modified to more accurately reflect knowledge of this disease. The recommended criteria for approval are that the patient has a diagnosis of paroxysmal nocturnal hemoglobinuria documented by flow cytometry AND the patient has received the meningococcal vaccine prior to therapy. All requests for eculizumab (whether billed through the pharmacy or medical benefit J1300) require Prior Authorization through the MedMetrics Clinical Call Center. In addition, there will be a quantity limit of 20 vials total/12 weeks initially then 6 vials/28 days subsequently.

Public Comment: No public comment.

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

- OTC Product Coverage Restrictions: The Legislature approved a SFY 2012 budget initiative to limit OTC coverage in all Medicaid populations for a savings of \$450,000. The Prilosec® OTC change made will save \$330,000. This leaves \$120,000 in further OTC changes that need to be made. The Legislature has stated that these changes cannot be made to the Insulin/Diabetic Supplies, Nutritional Supplements, or the Smoking Cessation products. Some categories are already managed through the PDL. Categories that will be limited to generics only and categories that will be excluded from coverage were presented. There will not be any allowance for prior authorizations for any of these changes

Public Comment: No public comment.

Board Decision: The Board would like the categories of Antiflatulents and Topical Anesthetics be moved to the excluded from coverage category and the Topical Antiseptics/ Disinfectants moved to the limit to generics only category. The Board would like to review OTC coverage again next year to evaluate for further reductions. This was approved by a majority vote. One member did not approve the recommendations as this member felt the coverage was still too extensive.

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

FDA Safety Alerts

Deferred until next meeting due to time constraints.

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

Next DUR Board Meeting

Tuesday, July 19, 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.