



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 04/15/2014**

Board Members:

Present:

Joseph Lasek, MD, Chair
James Marmar, RPh

Gary Starecheski, RPh
Janet Farina, RPh

Mark Pasanen, MD
Jaskanwar Batra, MD

Absent:

Kim Ladue, NP

Jeanne Greenblatt, MD

Amanda Kennedy, PharmD

Staff:

Diane Neal, RPh, Catamaran
Jennifer Egelhoff, DVHA
Carrie Germaine, DVHA
Stacey Baker, DVHA

Michelle Sirois, Catamaran
Mary Beth Bizzari, RPh, DVHA
Thomas Simpatico, MD, DVHA
Mi Ri Yim, Intern, ACPHS

Nancy Miner, Catamaran
Nancy Hogue, PharmD, DVHA
Scott Strenio, MD, DVHA

Guests:

Rita Baglini, APS Healthcare
Kristen Chopas, Gilead
Jim Pitt, Lundbeck
Casimir Zygmunt, Bayer
James Parks, Abbvie

Mario Carnovale, Novartis
Thomas Currier, Purdue
Scott Williams, J&J
Mark Mattinelli, Upsher-Smith
Phillip Wiegand, J&J

Timothy Chatas, UCB
Jai Persico, Otsuka
Melissa Maney, Lundbeck
Kenneth Ley, Jazz

Joseph Lasek, MD, Chair, called the meeting to order at 6:17p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:00 until 6:15 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 March, 2014 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- None this meeting.

4. Medical Director Update: Scott Strenio, MD, DVHA

- None this meeting.

5. Follow-up items from Previous Meeting: *Diane Neal, RPh, Catamaran*

- Dexilant[®] (dexlansoprazole): The Board was provided a copy of a Prescriber letter that was sent out explaining the formulary change of Dexilant[®] moving to prior authorization required. Grandfathering of current users is ending 6/2/2014.

Public Comment: No public comment.

Board Decision: None needed.

- Hepatitis C Medications: The Board was provided a copy of an updated Prior Authorization/Order form and a new Patient Clinical Information form that will be required for all Hepatitis C medication requests.

Public Comment: No public comment.

Board Decision: None needed.

- Xyrem[®] (Sodium Oxybate): *Mi Ri Yim, Pharmacy Intern, Albany College of Pharmacy*
An overview of uses for Xyrem[®], current guidelines, and what other Medicaid programs are doing was presented. The following approval criteria was proposed: For diagnosis of narcolepsy with cataplexy – The patient will not be using alcohol or receiving central nervous system (CNS) depressant agents AND the patient has a documented side effect, allergy, treatment failure, or contraindication to at least TWO agents from the following classes; selective serotonin inhibitor (SSRIs), venlafaxine, or tricyclic antidepressant (e.g. protriptyline, clomipramine). For diagnosis of narcolepsy with Excessive Daytime Sleepiness (EDS) – The patient will not be using alcohol or receiving central nervous system (CNS) depressant drugs AND the patient has a documented side effect, allergy, treatment failure, or contraindication to both of ONE preferred sympathomimetic CNS stimulant (e.g. amphetamine, methamphetamine) and Provigil. There was a quantity limit proposed of 540 ml per 30 days and an approval duration of six months instead of one year was recommended.

Public Comment: *Kenneth Ley ~ Jazz Pharmaceuticals*— Highlighted some of the attributes of Xyrem[®].

Board Decision: The Board unanimously approved the above recommendation.

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

- Mental Health Medications in Children, SFY 2009, 2011, and 2013: A table that summarized mental health medication use in children was discussed. Medications were divided into categories of ADHD medications, antidepressants, antipsychotics, anxiolytics and mood stabilizers. The data was shown by age, by sex, and by whether the child was in foster care or not. Percentages of Medicaid children of an age group and sex on a particular medication class were shown.

Public Comment: No public comment.

Board Decision: None needed.

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

Abbreviated New Drug Reviews:

- Aciphex[®] Sprinkles (rabeprazole) DR Capsules: It was recommended that Aciphex[®] Sprinkles be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient has a requirement for a non-solid oral dosage form (e.g. an oral liquid, dissolving tablet or sprinkle). A quantity limit of one capsule per day was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved after discussion to change the criteria to: The patient has a requirement for a non-solid oral dosage form and the patient has had a documented side effect, allergy, or treatment failure to omeprazole capsule opened and sprinkled, omeprazole or lansoprazole suspension or Prevacid[®] solutab.

- Bethkis[®] (tobramycin) Inhalation: It was recommended that Bethkis[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The diagnosis or indication is cystic fibrosis AND the patient has had a documented intolerance to branded TOBI[®]. A quantity limit of 56 vials per 56 days was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Glycate[®] (glycopyrrolate) Oral Tablet: It was recommended that Glycate[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The indication for use is adjunctive therapy in the treatment of peptic ulcer AND the patient has a documented intolerance to generic glycopyrrolate tablets. A quantity limit of 5 tablets per day was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

Full New Drug Reviews

- Adempas[®] (riociguat) Oral Tablet: It was recommended that Adempas[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of pulmonary arterial hypertension (PAH) WHO Group I with New York Heart Association (NYHA) Functional Class II or III. OR the patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH, WHO Group 4) and the patient has persistent or recurrent disease after surgical treatment (e.g. pulmonary endarterectomy) or has CTEPH that is inoperable. AND the patient is 18 years of age or older AND the patient will not use Adempas[®] concomitantly with the following: Nitrates or nitric oxide donors (such as amyl nitrate) in any form; phosphodiesterase (PDE) inhibitors, including specific PDE-5 inhibitors (such as sildenafil, tadalafil, or vardenafil) or non-specific PDE inhibitors (such as dipyridamole or theophylline) AND the patient is not pregnant AND female patients are enrolled in the Adempas[®] REMS program. A quantity limit of 3 tablets per day was proposed.

Public Comment: Casimir Zygmunt ~ Bayer - Highlighted some of the attributes of Adempas®.

Board Decision: The Board unanimously approved the above recommendation.

- Brintellix® (vortioxetine) Oral Tablet: It was recommended that Brintellix® be added to the DVHA PDL as prior authorization required with the following approval criteria: The diagnosis or indication is Major Depressive Disorder (MDD) AND the patient has had a documented side effect, allergy, or inadequate response (defined by at least 4 weeks of therapy) to at least 3 different antidepressants from the SSRI, SNRI and/or Miscellaneous Antidepressant categories (may be preferred or non-preferred). A quantity limit of one tablet/day was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Fetzima® (levomilnacipran) ER Oral Capsule: It was recommended that Fetzima® be added to the DVHA PDL as prior authorization required with the following approval criteria: The patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization) OR the diagnosis or indication is Major Depressive Disorder (MDD). AND the patient has had a documented side effect, allergy, or inadequate response to at least 2 different antidepressants from the SSRI, SNRI, and/or Miscellaneous Antidepressant categories, one of which must be venlafaxine ER capsule (may be preferred or non-preferred).

Public Comment: No public comment.

- **Board Decision:** The Board unanimously approved the above recommendation with the change to: The patient has had a documented side effect, allergy, or inadequate response to at least 3 different antidepressants from the SSRI, SNRI, tricyclic, and/or Miscellaneous Antidepressant categories, one of which must be venlafaxine ER capsule (may be preferred or non-preferred).

8. Therapeutic Drug Classes – Periodic Review: Diane Neal, RPh, Catamaran
(Public comment prior to Board action)

- Analgesics: Topical NSAID: No changes to the clinical criteria are recommended at this time.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Anticoagulants: Oral (see stroke prevention below): No changes to the clinical criteria are recommended at this time.

Public Comment: Phillip Wiegand ~ J&J -- Highlighted some of the attributes of Xarelto®.

Board Decision: The Board unanimously approved the above recommendation. However, due to the lack of consensus concerning appropriate use of medications in this category, the DUR Board will revisit this category in a few months.

- Antihypertensives: Beta Blockers: No changes to the clinical criteria are recommended at this time. Obsolete products were removed from the table.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Antihypertensives: Calcium Channel Blockers: No changes to the clinical criteria are recommended at this time.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Dermatological: Antifungals: No changes to the clinical criteria are recommended at this time.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Immunomodulators (new indications): It was recommended that the criteria for Cimzia[®] be broadened to include the indication for ankylosing spondylitis and the criteria proposed as: The patient has a diagnosis of ankylosing spondylitis (AS) and has already been stabilized on Cimzia[®] OR diagnosis is AS, and conventional NSAID treatment and DMARD therapy (e.g. methotrexate therapy) resulted in an adverse effect, allergic reaction, inadequate response, or treatment failure. If methotrexate is contraindicated, another DMARD should be tried AND the prescriber must provide a clinically valid reason why either Humira[®] or Enbrel[®] cannot be used. Also added was an indication of psoriatic arthritis with the same criteria as rheumatoid arthritis. It was also recommended that the approval criteria for Stelara[®] include an indication of psoriatic arthritis with the criteria: The patient has a diagnosis of psoriatic arthritis and has already been stabilized on Stelara[®] OR the diagnosis is psoriatic arthritis, and patient has documentation of an inadequate response, adverse reaction, or allergic response to methotrexate, or if methotrexate is contraindicated, at least one DMARD (other DMARDS include leflunomide, sulfasalazine, gold, antimalarials, minocycline, D-penicillamine, azathioprine, cyclophosphamide, and cyclosporine) AND the prescriber must provide a clinically valid reason why either Humira[®] or Enbrel[®] cannot be used.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Platelet Aggregation Inhibitors: No changes to the clinical criteria are recommended at this time.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Smoking Cessation Products: It was recommended that quantity limits be removed on the preferred nicotine replacement products (gum, patches, and lozenges) recognizing the health benefits of quitting smoking and also allowing for combination therapy with short acting (gum or lozenge) and long acting (patch) products. All other quantity limits remain on oral and non-preferred products.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

9. Clinical Update: New/Updated Clinical Guidelines: *Diane Neal, RPh, Catamaran*

(Public comment prior to Board action)

- American Academy of Neurology (AAN) Guidelines on Stroke Prevention in Nonvalvular Atrial Fibrillation (NVAF): New guidelines were released. The current clinical criteria for anticoagulants support the guidelines as written.

Public Comment: None

Board Decision: None needed.

10. New Managed Therapeutic Drug Classes:

- None

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

Diane Neal, RPh, Catamaran

- Gastrointestinal: Proton Pump Inhibitors (compound suspension kits): As part of the previous discussion of Aciphex[®] Sprinkles (proton pump inhibitor) it was recommended to add First-Lansoprazole[®] and First-Omeprazole[®] oral suspensions kits to the PDL as PA requiring products for patients > 12 years old with the criteria for approval being the patient has a requirement for a non-solid oral dosage form (e.g. an oral liquid, dissolving tablet or sprinkle).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Smoking Cessation Products: (See therapeutic class review above)

Public Comment: No public comment.

Board Decision: None needed

12. General Announcements:

FDA Safety Alerts

- FDA clarifies Warning about Pediatric Use of Revatio[®] (sildenafil) for Pulmonary Arterial Hypertension: The FDA has clarified its previous recommendation related to prescribing Revatio[®] (sildenafil) for children with pulmonary arterial hypertension (PAH). Revatio[®] is FDA-approved only to treat PAH in adults, not in children; however, health care professionals must consider whether the benefits of treatment with the drug are likely to outweigh its potential risks for each patient. It is recommended that the criteria for approval for Revatio[®] be modified to remove the age restriction.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

12. Adjourn: Meeting adjourned at 8:23 p.m.

Next DUR Board Meeting

Tuesday, June 3, 2014

6:00 – 8:15 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 6:00 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.