



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 10/22/2013**

Board Members:

Present:

Mario Sarafini, DO
Joseph Lasek, MD, Chair
Amanda Kennedy, PharmD

Gary Starecheski, RPh
Jeanne Greenblatt, MD

Mark Pasanen, MD
Janet Farina, RPh

Absent:

Halle Sobel, MD
James Marmar, RPh

Kim Ladue, NP

Jaskanwar Batra, MD

Staff:

Diane Neal, RPh, Catamaran
Daljit Clark, DVHA
Jennifer Herwood, DVHA

Michelle Sirois, Catamaran
Mary Beth Bizzari, RPh, DVHA
Thomas Simpatico, MD, DVHA

Nancy Miner, Catamaran
Nancy Hogue, PharmD, DVHA
Marika Krull, ACP Intern

Guests:

Thomas Algozzine, Novartis
Timothy Chatas, UCB
Julia Hoff, NovoNordisk
Natalie Prairie, Forest
Marie Roache, Pfizer
Erica Hintze, Forest
Ruchir Parikh, Boehringer Ingelheim

Rita Baglini, APS Healthcare
Thomas Currier, Purdue
Peter Persico, Otsuka
Gary Prevost, PriCara
Scott Williams, J&J
Jeff Dumont, Janssen
Scott Brown

Susan Campbell, Boehringer-Ingelheim
Rodney Francisco, Sunovion
Wendy Pollinger, Eli Lilly
Arlene Price, Janssen
Bob Meamy, Takeda
Tim Birner, Otsuka

Joseph Lasek, MD, Chair, called the meeting to order at 6:39 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 September, 2013 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- An update was given with regard to the Common PA Form feasibility and the work being done to create a common formulary document that will be posted on the Department of Financial Regulation website.

- Introduction was made of Albany College of Pharmacy Intern, Marika Krull.

4. Medical Director Update: Tom Simpatico, MD, Chief Medical Officer, DVHA

- The new Medical Director, Scott Strenio, MD., will begin work in early December.
- Presented poster of the Pediatric Antipsychotic Survey project. There will be more projects in the future done in combination with UVM.
- There was a presentation of the Guiding Principles for Benefit Design and Coverage Decisions by the Center for Evidence-based Policy. The final report will be posted on the DVHA website when complete.

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

- Buprenorphine and Opiates: It has been determined that coding can be done at Point-of-Sale to allow only a 5 day supply of opiate or opiate combination when the patient is also on a buprenorphine product for opiate dependency. However, there are issues when the opiate requires PA (and patient is on a buprenorphine product for opiate dependency) or a PA is requested for a buprenorphine product for opiate dependency (and patient is on an opiate). It is unclear in these situations whether the Clinical Call Center can advise prescribers about therapy prescribed by other prescribers and whether previously granted PAs can be end-dated because the previous drug is not clinically appropriate based on the new therapy.

Public Comment: No public comment.

Board Decision: The Board decided to table this discussion so that DVHA may research policy questions about HIPPA and prior authorization notifications. The DUR Board would like to move forward with the edit (not allow more than 5 days opiate or opiate combination therapy in combination with buprenorphine for opiate dependency products) while continuing to research the issue with opiates that require PA. Prescribers would need to be alerted to this change.

- Long Acting Injectable Antipsychotic Medications: Criteria were proposed to standardize the criteria for all long acting injecting antipsychotic medications. Oral tolerability was added to all drugs.

Public Comment: Tim Birner ~ Otsuka – Highlighted some of the attributes of Abilify Maintena[®].

Board Decision: The Board approved the above recommendations but agreed to remove all steps requiring a different long acting injectable since they must have already been established on the oral.

- Pulmonary: Short Acting Beta-Agonist Inhalers: Several meetings ago it was recommended that Xopenex[®] HFA be moved to prior authorization required on the DVHA PDL effective January 1, 2014. It was recommended at this meeting that the criteria be modified to require only one preferred short acting beta-agonist inhaler prior to approval of a non-preferred inhaler (Xopenex[®] HFA or Ventolin[®] HFA).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

6. RetroDur/Prior Authorization Quality Assurance Analysis: *Marika Krull, Pharmacy Intern, Albany College of Pharmacy, DVHA*
(Public comment prior to Board action)

- Buprenorphine and Benzodiazepines: A review of the issue of combined buprenorphine and benzodiazepine therapy was presented. The literature was reviewed to understand the concerns with combination therapy and also, when combination therapy might be cautiously warranted. It was found to be a controversial issue. Claims data of DVHA members who had concurrent claims for buprenorphine and benzodiazepines was reviewed and summarized. Approximately 15% of patients on buprenorphine for opiate dependency were on a benzodiazepine at some point in the 9 month study period. In at least half of the cases, the same prescriber prescribed both the buprenorphine and the benzodiazepine.

Public Comment: No public comment.

Board Decision: The Board suggested that rather than sending an informational mailing to prescribers that a better approach would be to have the Medical Director follow up personally with the select few prescribers who are prescribing both products for their patients in higher numbers. A review of patients on the combined therapy plus an SSRI or SNRI would also be interesting. For patients with different prescribers, it may be the case that the buprenorphine prescriber is unaware of the benzodiazepine therapy.

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

Abbreviated New Drug Reviews:

- Cystaran[®] (cysteamine) Ophthalmic Solution: It was recommended that Cystaran[®] be added to the DVHA PDL as prior authorization required with the following approval criteria: The indication for use is corneal cysteine accumulation in patients with cystinosis and the recommended quantity limit is 4 bottles per 28 days.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Diclegis[®] (doxylamine succinate/pyridoxine) DR Oral Tablet: It was recommended that Diclegis[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of nausea and vomiting of pregnancy AND the patient has tried and had an inadequate response to conservative management (ie: change in dietary habits, ginger, or acupuncture) AND the patient has tried and had an inadequate response to generic doxylamine and generic pyridoxine (vitamin B6) AND the patient has tried and had an inadequate response to generic ondansetron. There will be a quantity limit of 4 tablets per day.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Namenda[®] XR (memantine) Oral Capsule: It was recommended that Namenda[®] XR be added to the PDL as prior authorization required with the following approval criteria: The diagnosis or indication

for the requested medication is Alzheimer's disease AND the patient has been unable to be compliant with or tolerate twice daily dosing of the immediate release product. A quantity limit of one capsule per day is recommended.

Public Comment: Letter submitted by William Pendlebury, MD, Medical Director, The Memory Center, FAHC supporting the addition to the PDL.

Board Decision: The Board unanimously approved the above recommendation requiring PA.

- Prolensa[®] (bromfenac 0.07%) Ophthalmic Solution: This was deferred until next meeting.
- Simbrinza[®] (brinzolamide 1%/brimonidine 0.2%) Ophthalmic Suspension: This was deferred until next meeting.

Full New Drug Reviews:

- Invokana[®] (canagliflozin) Oral Tablet: It was recommended that Invokana[®] be added to the PDL as preferred after clinical criteria are met with the following approval clinical criteria: The member is 18 years of age or older AND the member has a diagnosis of type 2 diabetes mellitus and has had an inadequate response to diet and exercise alone AND the member has tried and had an inadequate response, intolerance or contraindication to metformin. A quantity limit of 1 tablet per day is proposed.

Public Comment: Arlene Price ~ Janssen – Highlighted some of the attributes of Invokana[®].

Board Decision: The Board unanimously approved the above recommendation.

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

- Acne Medications: Topical: This was deferred until next meeting.
- Anti-hypertensives: Angiotensin Converting Enzyme (ACE) Inhibitors and Combinations: This was deferred until next meeting.
- Anti-hypertensives: Angiotensin Receptor Blockers and Combinations: This was deferred until next meeting.
- Gastrointestinal: H2 Receptor Antagonists: This was deferred until next meeting.
- Otic: Anti-Infectives: This was deferred until next meeting.
- Renal: Phosphate Binders: This was deferred until next meeting.
- Vitamins: Prenatal: It was recommended that Prenatal Vitamins Plus be added to the PDL as preferred and all DHA-containing vitamins will be prior authorization required with the following approval criteria: The patient is unable to obtain an adequate amount of DHA via diet.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

9. New Managed Therapeutic Drug Classes:

- None

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

Diane Neal, RPh, Catamaran

- Anti-diabetics: DPP4 Inhibitors (1/1/14): It was recommended that Tradjenta[®] be moved to prior authorization required on the DVHA PDL for 1/1/2014 with the following approval criteria: The patient has had a documented side effect, allergy, contraindication or treatment failure with metformin AND the patient has had a documented side effect, allergy, contraindication or treatment failure with at least one preferred DDP-4 agent. A quantity limit of 1 tablet per day was proposed.

Public Comment: Ruchir Parikh ~ Boehringer Ingelheim – Highlighted some of the attributes of Tradjenta[®].

Board Decision: The Board unanimously approved the above recommendation.

- Anti-Infectives: Antivirals: Influenza Vaccines: This was deferred until next meeting.
- Anti-Infectives: Cephalosporins: 3rd Generation (1/1/14): It was recommended that Suprax[®] Suspension move to a preferred position on the DVHA PDL with modification of clinical criteria for non-preferred products.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Gastrointestinals: Proton Pump Inhibitors (1/1/14): It was recommended that Dexilant[®] be moved to prior authorization required on the DVHA PDL with the following approval criteria: The member has had a documented side effect, allergy, or treatment failure to Omeprazole RX 20 mg or 40 mg generic capsules AND pantoprazole generic tablets. Current users will be grandfathered for 3 months and a letter will be sent to prescribers.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Pulmonary: Corticosteroids: Intranasal (1/1/14): It was recommended that Nasacort AQ[®] be moved to prior authorization required on the DVHA PDL with the following approval criteria: The patient has had a documented side effect, allergy, or treatment failure to BOTH preferred nasal glucocorticoids.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

11. General Announcements:

FDA Safety Alerts

- Acetaminophen: Drug Safety Communication – Association with Risk of Serious Skin Reactions: Deferred until next meeting.
- Gilenya®: Drug Safety Communication – Possible PML Case in Europe: The FDA is alerting the public that a patient in Europe diagnosed with possible multiple sclerosis (MS) has developed a rare and serious brain infection after taking the drug Gilenya® (fingolimod). This is the first case of this disease, called progressive multifocal leukoencephalopathy or PML, reported following the administration of Gilenya® to a patient who had not previously received Tysabri® (natalizumab), an MS drug associated with a higher risk of PML.

Public Comment: Tom Algozzine ~ Novartis – Provided additional information that was not included in FDA alert.

Board Decision: None needed.

- Olmesartan Medoxomil: Drug Safety Communication – Label Changes To Include Intestinal Problems (Sprue-Like Enteropathy): Deferred until next meeting.
- Zyprexa® Relprevv (Olanzapine Pamoate): Drug Safety Communication – FDA Investigating Two Deaths Following Injection: Deferred until next meeting.

12. **Adjourn:** Meeting adjourned at 8:44 p.m.

Next DUR Board Meeting

Tuesday, December 10, 2013

6:30 – 8:30 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.