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**Department of Vermont Health Access  
Pharmacy Benefit Management Program  
DUR Board Meeting Minutes: 12/06/2011**

**Board Members:**

Michael Scovner, MD, Chair  
Andrew Miller, RPh  
Jeanne Greenblatt, MD  
Mark Pasanen, MD

Gary Starecheski, RPh  
Lynne Vezina, RPh  
Halle Sobel, MD  
Jaskanwar Batra, MD

Kim Ladue, NP  
Joseph Lasek, MD  
Amanda Kennedy, PharmD

**Staff:**

Diane Neal, RPh, MHP  
Stacey Baker, DVHA  
Nancy Hogue, PharmD, DVHA

Nancy Miner, MHP  
Michael Farber, MD, DVHA

Michelle Sirois, MHP  
Rebecca Hopko, DVHA

**Guests:**

Paul Amato, GSK  
James Kokoszyna, Allergan  
Julie Rae, Acorda  
Karalyn Connolly, Janssen

Amy Finn, Merck  
Carl Pepe, GSK  
Jai Persico, Endo  
Marcus Chappell, Janssen

Jason Kennedy, Merck  
Carl Possidente, Pfizer  
Judith Kando, Sunovion

Michael Scovner, MD, Chair, called the meeting to order at 7:02 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 October 2011 meeting minutes were accepted as printed.

*Public Comment:* No public comment.

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

- The four new physician members of the DUR Board were welcomed.
- There will be a Stakeholder Meeting on 12/14/2011 from 1-3pm to discuss Single Formulary and Electronic Prior Authorization. There is a report of recommendations due to the Legislature on 1/15/2012.
- Amanda Kennedy provided updates from the Academic Detailing Advisory Board.
- Proposed dates for next year's DUR Board meetings were presented.

**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)*

- Latuda<sup>®</sup>: Discussion was deferred to the January 2012 meeting in order to allow for more time to review the adverse drug event profile of Latuda<sup>®</sup> in comparison to other atypical antipsychotics.

*Public Comment:* No public comment.

**Board Decision:** None needed.

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

- Provigil<sup>®</sup>: Utilization by dosage was provided for six months of claims to determine if the quantity limits in place have decreased the daily dosing for members. This will be looked at in further detail at a later meeting.

*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:**

- None this month.

**Full New Drug Reviews:**

- Benlysta<sup>®</sup> (belimumab) Vial for IV Infusion: Recommended to be added to the Department of Vermont Health Access (DVHA) Preferred Drug List (PDL) as prior authorization required with the criteria for approval being the diagnosis or indication is active systemic lupus erythematosus (SLE) AND the patient is positive for autoantibodies (anti-nuclear antibody (ANA) and/or anti-double-stranded DNA (anti-dsDNA) AND the patient has had a documented inadequate response or intolerance to at least TWO of the following agents: NSAIDs, hydroxychloroquine, prednisone, azathioprine, methotrexate, mycophenolate. If the above approval criteria are met, authorization was proposed to be issued for 1 month initially and for 1 year subsequently.

*Public Comment:* *Paul Stack, Human Genome Sciences* - Highlighted some of the attributes of Benlysta<sup>®</sup>.

**Board Decision:** The Board unanimously approved the MHP recommendation noted above but would like the initial approval period to be 2 months with 1 year subsequently.

- Natroba<sup>®</sup> (spinosad) Topical Suspension: It was recommended that Natroba<sup>®</sup> (spinosad) topical suspension be placed on the DVHA PDL requiring prior authorization with the criteria for approval being the patient has had a documented side effect or allergy to permethrin or treatment failure with two treatments of permethrin.

*Public Comment:* No public comment.

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

- Sprix<sup>®</sup> (ketorolac) Nasal Spray: It was recommended that Sprix<sup>®</sup> (ketorolac tromethamine) nasal spray be placed on the DVHA PDL requiring prior authorization with the approval for criteria being the indication or diagnosis is moderate to moderately severe pain requiring analgesia at the opioid level AND the patient has had a documented inadequate response or intolerance to generic ketorolac tablets AND the patient has had a documented side effect, allergy, or treatment failure to at least TWO additional preferred generic NSAIDs OR the patient has a documented medical necessity for the specialty dosage form (i.e. inability to take medication orally (NPO)). In addition, the following quantity limit was recommended: 5 bottles/5 day supply every 90 days.

*Public Comment:* No public comment.

- **Board Decision:** The Board unanimously voted to modify the approval criteria to: The indication or diagnosis is moderate to moderately severe pain AND the patient has had a documented inadequate response or intolerance to generic ketorolac tablets OR the patient has a documented medical necessity for the specialty dosage form (i.e. inability to take medication orally NPO)). In addition, the following quantity limit was recommended: 5 bottles/5 day supply every 90 days.
- Tradjenta<sup>®</sup> (linagliptin) Oral Tablet: It was recommended that Tradjenta<sup>®</sup> (linagliptin) be added to the DVHA PDL as prior authorization required with the criteria for approval being the patient has had a documented side effect, allergy, contraindication or treatment failure with metformin. This is processed with automatic step therapy at point-of-sale.

*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)

- First Generation Cephalosporins: In recognition of the established safety and efficacy of first generation cephalosporins, consensus clinical guideline recommendations, availability of generics and cost considerations, no changes are recommended to the current DVHA approval criteria.

*Public Comment:* No public comment.

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

- Second Generation Cephalosporins: At this time, all generic second generation cephalosporins are preferred on the DVHA PDL. The brand and generic products that are no longer available have been removed. No additional changes to the current approval criteria for the second generation cephalosporins are recommended.

*Public Comment:* No public comment.

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

- Third Generation Cephalosporins: It was recommended that Suprax<sup>®</sup> (cefixime) suspension should move to PA required and cefpodoxime proxetil suspension should move to preferred. Products that are no longer available will be removed from the table. No additional changes to the current approval criteria for the third generation cephalosporins are recommended.

*Public Comment:* No public comment.

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

- Ketolides: It was recommended that in addition to the current criteria that the following criteria be added for Ketek<sup>®</sup>: **The member has had a documented therapeutic failure with all clinically appropriate alternatives.**

*Public Comment:* No public comment.

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

- Macrolides: A review of Dificid<sup>®</sup> (fidaxomicin) was presented as part of the drug class review. In consideration of the limited FDA approval for Dificid<sup>®</sup>, absence of consensus guideline recommendations on its place in therapy, risk of resistance and the availability of less costly alternatives, it is recommended that Dificid<sup>®</sup> be managed as a Prior Authorization (PA) required drug with the criteria for approval being: the patient's diagnosis or indication is *Clostridium difficile* associated diarrhea (CDAD) AND the patient has had a side-effect, allergy, treatment failure or contraindication to metronidazole OR the prescriber provides a clinically compelling rationale why metronidazole is not appropriate for the patient (e.g. patient has severe *Clostridium difficile* infection, history of recurrent infections) AND the patient has had a side-effect, allergy, treatment failure or contraindication to oral vancomycin capsules (Vancocin<sup>®</sup>). Duration of therapy should be limited to 10 days/30 days. No other changes to the macrolide managed class are proposed.

*Public Comment:* No public comment.

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

- Oxazolidinones: In recognition of the established safety and efficacy of Zyvox<sup>®</sup>, consensus clinical guideline recommendation, unavailability of generics and cost considerations, no changes were recommended to the current DVHA approval criteria.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously voted to change the criteria to: the patient has been started on intravenous or oral linezolid in the hospital and will be finishing the course of therapy in an outpatient setting OR the patient has a documented blood, tissue, sputum, or urine culture that is positive for Vancomycin-Resistant Enterococcus (VRE) species OR the patient has a documented blood or sputum culture that is positive for Methicillin-Resistant Staphylococcus species OR the patient has a documented tissue or urine culture that is positive for Methicillin-Resistant Staphylococcus species

AND the patient has had a documented treatment failure with trimethoprim/sulfamethoxazole OR there is a clinically valid reason that the patient cannot be treated with trimethoprim/sulfamethoxazole.

Penicillins: In recognition of the established safety and efficacy of penicillins, consensus clinical guideline recommendations, availability of generics and cost considerations, no changes were recommended to the current DVHA approval criteria or preferred drugs.

*Public Comment:* No public comment.

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

- Tetracyclines: In recognition of the established safety and efficacy of tetracyclines, consensus clinical guideline recommendations, availability of generics and cost considerations, no changes to the current DVHA approval criteria or preferred drugs were proposed.

*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)

- Glycopeptides: At this time, Vancocin® (vancomycin capsule) is not managed by the DVHA and is currently available without a prior authorization (PA). In recognition of its limited indication, availability of generic alternatives, and cost considerations, it is recommended to move Vancocin® from preferred to non-preferred status with the criteria for approval being: the patient's diagnosis or indication is enterocolitis caused by *Staphylococcus aureus* OR the patient's diagnosis or indication is antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile* AND the patient has had a therapeutic failure, adverse reaction or contraindication to metronidazole OR the prescriber provides a clinically compelling rationale why metronidazole is not appropriate for the patient. (e.g. patient has severe *Clostridium difficile* infection, history of recurrent infections). Note: IV vancomycin products are not recommended to be managed at this time.

*Public Comment:* No public comment.

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

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

- Atypical Antipsychotics: Long Acting Injectable Products: Deferred until next meeting.

#### **11. General Announcements Diane Neal, RPh, MHP**

##### **FDA Safety Alerts**

- Reminder to healthcare providers and patients to enroll in the Avandia-Rosiglitazone Medicines Access Program: The FDA is reminding healthcare providers and patients about the need to enroll in the Avandia-Rosiglitazone Medicines Access Program by November 17, 2011, in order to continue prescribing and receiving rosiglitazone-containing medicines (Avandia, Avandamet, and Avandaryl). After November 18, 2011, rosiglitazone medicines will no longer be available through retail

pharmacies and will only be available by mail order through specially certified pharmacies participating in the program.

*Public Comment:* No public comment.

**Board Decision:** None needed.

- Review update of Trilipix (fenofibric acid) and the ACCORD Lipid trial: The FDA is informing the public that the cholesterol-lowering medicine Trilipix (fenofibric acid) may not lower a patient's risk of having a heart attack or stroke. This is based on data from the Action to Control Cardiovascular Risk in Diabetes (ACCORD) Lipid trial, which evaluated the efficacy and safety of fenofibrate plus simvastatin combination therapy versus simvastatin alone in patients with type 2 diabetes mellitus. FDA reviewed this trial as part of its ongoing investigation of the safety and efficacy of Trilipix.

*Public Comment:* No public comment.

**Board Decision:** None needed.

- UPDATE on Tumor Necrosis Factor (TNF) blockers and risk for pediatric malignancy: The FDA is updating the public about its ongoing safety review of Tumor Necrosis Factor (TNF) blockers and malignancy (cancer) in children, adolescents, and young adults (30 years of age or younger). FDA is requiring the manufacturers of TNF blockers to perform enhanced safety surveillance for these products.

*Public Comment:* No public comment.

**Board Decision:** None needed.

**12. Adjourn:** Meeting adjourned at 9:02 p.m.

### **Next DUR Board Meeting**

Tuesday, January 10, 2012

7:00 - 9:00 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 6:30 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.