



Department of Vermont Health Access  
Pharmacy Benefit Management Program  
DUR Board Meeting Minutes: February 24, 2015

**Board Members:**

**Present:**

Joseph Lasek, MD, Chair  
Janet Farina, RPh

Mark Pasanen, MD  
Michael Biddle, PharmD

James Marmar, RPh

**Absent: Jaskanwar Batra, MD**

**Staff:**

Michael Ouellette, RPh,  
GHS/Emdeon

Laureen Biczak, DO, GHS/Emdeon

Jason Pope, DVHA

Scott Strenio, MD, DVHA  
Thomas Simpatico, MD, DVHA  
Aaron French, DVHA

Mary Beth Bizzari, RPh, DVHA  
Carrie Germaine, DVHA

Jennifer Egelhof, DVHA  
Stacey Baker, DVHA

**Guests:**

Rick Angeli, Merck  
Kristen Chopas, Gilead  
Christine Dube, MedImmune  
Jim Pitt, Lundbeck  
Brad Martin, Lundbeck  
Lisa Schilling, HP

Kristen Beuno-Doherty, AstraZeneca  
Thomas Currier, Purdue  
Rod Francisco, Sunovion  
Arlene Price, Janssen  
Brian Malloy, DSI

Timothy Chatas, UCB, Inc  
Dave Downey, Abbott Labs  
Kevin Kobylinski, Merck Vaccines  
Wolfgang Zeigenhagen, Genetech  
James Hayes, Abbvie

Joseph Lasek, MD, Chair, called the meeting to order at 6:30 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.

**2. Introductions and Approval of DUR Board Minutes:**

- Introductions were made around the table.
- The October and January meeting minutes were accepted as printed.

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

- No update at this time

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

- Met with UVM and Hep C treatment team members to discuss criteria. No serious concerns were raised. Will continue current policy/criteria.
- Looking for feedback on setting guidelines for approving early refills of controlled substances. Guidelines may include a plan to check for a history of early refills, multiple prescribers, or multiple narcotics. Please send any comments/suggestions to Dr. Strenio.

**5. Follow-up Items from Previous Meetings: Mike Ouellette, RPh, GHS/Emdeon**

- Lidocaine Viscous
  - Add criteria-  
Due to an FDA safety alert, viscous lidocaine will require prior authorization for children ≤ 3 years of age
- Removal of PA requirement for Auralgan-tableted until next meeting

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation regarding viscous lidocaine.

**6. Retro DUR/DUR**

- None at this time

**7. Clinical Update: Drug Reviews: Mike Ouellette, RPh, GHS/Emdeon**

**Abbreviated new Drug Reviews**

- **Vimpat (lacosamide) tablet & oral solution**
  - Reason for review: new indication for monotherapy
  - Indications and Usage: As monotherapy or adjunctive therapy in patients with partial onset seizures.

**Recommendation:** Vimpat is to remain non-preferred and the language on the PDL will be modified to include the monotherapy indication.

*Public Comment:* No public comment.

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

**Full New Drug Reviews: Laureen Biczak, DO, GHS/Emdeon**

- **Cerdelga (eliglustat) 84mg capsules**

Cerdelga is indicated for the long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as

detected by an FDA-cleared test. Cerdelga is an option for the treatment of Gaucher's disease, particularly in those unwilling or unable to tolerate enzyme replacement therapy.

**Recommendation:** To make Cerdelga non-preferred on the PDL. Criteria will require submission of testing to verify CYP2D6 metabolism as well as the diagnosis of Gaucher disease type 1 confirmed by molecular or enzymatic testing. There will be a quantity limit of two capsules daily.

*Public Comment:* No public comment.

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

- **Invokamet(canagliflozin/Metformin) tablet**

Invokamet is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (DM) who are not adequately controlled on a regimen containing metformin or canagliflozin, or in patients who are already treated with both canagliflozin and metformin. Use is not recommended in those with type 1 DM or for the treatment of diabetic ketoacidosis. There was no data found that Invokamet is safer or more effective than other more cost-effective medications available within the class, including the individual active ingredients.

**Recommendation:** To make Invokamet non-preferred on the PDL. Add the following criteria: The patient has documentation of failure of therapy with the combination of the single agents Invokana plus metformin.

*Public Comment:* No public comment.

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

- **Jardiance (empagliflozin) tablet**

Jardiance is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 DM. Use is not recommended for patients with type 1 DM or for the treatment of diabetic ketoacidosis. There was no data found that Jardiance is safer or more effective than other more cost-effective medications available within the class.

**Recommendation:** To make Jardiance non-preferred on the PDL. Add the following criteria: The patient has had a documented side effect, allergy, contraindications, or treatment failure with Invokana.

*Public Comment:* No public comment.

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

- **Kerydin (tavaborole) 5% topical solution**

Kerydin is indicated for the treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*. There was no evidence at this time to support that Kerydin is safer or more efficacious than other more cost effective therapies.

**Recommendation:** To make Kerydin non-preferred on the PDL and require a diagnosis of toenail onychomycosis and meet at least one of the following criteria: pain to affected area that limits normal activity, diabetes mellitus, patient is immunocompromised, patient has a diagnosis of systemic dermatosis or patient has significant vascular compromise AND must have a documented intolerance to generic ciclopirox.

- The Board discussed that the current criteria in the category that require a diagnosis of fingernail/toenail onychomycosis that is confirmed by a positive KOH stain, PAS stain or fungal culture or physician clinical judgment was not really accomplishing any specific purpose as all that is required is physician clinical judgment, therefore they recommended removing this language.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendation and removal of the language as described above.

- **Striverdi Respimat (oldaterol 2.5mcg per actuation) for inhalation**

Striverdi Respimat is indicated for the long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Limitations of use include that Striverdi® Respimat is not indicated to treat acute deteriorations of COPD and it is not indicated to treatment asthma. There was no evidence at this time to support that Striverdi Respimat is safer or more efficacious than other more cost effective therapies.

**Recommendation:** To make Striverdi Respimat Non-Preferred on the PDL. Stiverdi Respimat should be added to the criteria with Arcapta that states: The patient has a diagnosis of COPD (not FDA approved for asthma). AND the patient has a documented side effect, allergy, or treatment failure to either Foradil or Serevent.

*Public Comment:* No public comment.

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

## **8. Therapeutic Drug Classes- Periodic Review: Laureen Biczak, DO, GHS/Emdeon**

- Anticoagulants: The anticoagulant drug class was reviewed with reference to the therapeutic class review that had been provided to the Board. The new oral anticoagulants (NOACs) are indicated for the treatment and prophylaxis of a variety of thromboembolic disorders. It was pointed out that for some indications, such as prophylaxis after hip or knee arthroplasty, they are convenient, cost effective alternatives to subcutaneous fractionated heparin products. For other indications, such as prevention of stroke for those at risk due to atrial fibrillation, they are an evolving alternative to warfarin. Although they are likely overall at least as effective as or minimally more effective than warfarin at stroke prevention and may cause fewer life threatening bleeds, they currently cannot be reversed in case of severe bleeding and are costly.

For those well controlled on a stable dose of warfarin, the data regarding superiority is not clear. The most recent guideline of the American Heart Association/American Stroke Association gives equal weight to recommendations for prevention of stroke in those with non-valvular atrial fibrillation for warfarin or the newer agents with a higher evidence grade supporting continued warfarin use.

**Recommendation:** To leave the current class unchanged which leaves Pradaxa, warfarin and Xarelto 10 mg as preferred. To undertake a “total cost of care” initiative to look at the costs of care beyond drug costs and bring this information back to the Committee in June to reconsider the class with this information.

*Public Comment: Arlene Price Janssen:* Highlighted some of the attributes of Xarelto, reviewing the current indications and mentioning that a product that reverses the drug’s effect was being studied.

**Board Decision:** The Board unanimously approved the above recommendation

### **9. New managed Therapeutic Drug Classes**

#### ▪ **Neurogenic Orthostatic Hypotension**

In this category, Northera was presented as a new drug and midodrine and fludrocortisone were recommended to be added to the PDL class.

#### • **Northera (droxidopa) capsule**

Northera is indicated for the treatment of orthostatic dizziness, lightheadedness or the “feeling that you are about to black out” in adults with symptomatic, neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (Parkinson’s disease (PD), multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency and non-diabetic autonomic neuropathy. The efficacy beyond 2 weeks of treatment has not been established. Assess continued effectiveness periodically.

**Recommendation:** Establish a new PDL category for Neurogenic Orthostatic Hypotension. Include the drugs fludrocortisone and midodrine as preferred. Northera would be non-preferred with criteria as below.

- Quantity Limits
  - Initial 2 week approval
  - Continued therapy approvals based on documentation of continued benefit clinically and as evidenced by positional blood pressure readings
- Clinical Criteria
  - diagnosis of neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson’s disease, multiple system atrophy, or pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy, AND
  - the presentation of symptoms including dizziness, lightheadedness, and the feeling of “blacking out” AND
  - Failure of multiple non-pharmacologic measures as appropriate (e.g. removal of offending medications, compression stockings, increased fluid and salt intake) AND
  - Failure, intolerance or contra-indication to fludrocortisone AND midodrine

- **Allergen Immunotherapy**

In this category, Oralair was presented as a new drug and criteria were recommended for it as well as the drugs presented at the January meeting, Grastek and Ragwitek.

- **Oralair (anthoxanthum odoratum pollen, dactylis glomerata pollen, lolium perenne pollen, phleum pratense pollen, & poa pratensis pollen) tablet**

Oralair is indicated as an allergen extract for immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in this product in persons 10-65 year of age. The grasses include sweet vernal, orchard, perennial rye, timothy and Kentucky blue grass. It is not indicated for the immediate relief of allergy symptoms.

**Recommendation:** That a new category be added to the PDL called Allergen Immunotherapy and that Grastek, Oralair and Ragwitek all be added as non-preferred agents with criteria as below.

- Quantity Limits
  - One tablet daily
- Clinical Criteria

**All agents in class**

- Prescriber must provide the testing to show that the patient is allergic to the components in the prescribed therapy and must provide a clinically valid rationale why single agent sublingual therapy is being chosen over subcutaneous therapy
- Treatment must start 12 weeks before expected onset of pollen season and only after confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen (Ragwitek), timothy grass or cross-reactive grass pollens (Grastek), or any of the 5 grass species contained in Oralair
- Have an auto-injectable epinephrine on-hand

**Grastek additional criteria:** Patient age  $\geq 5$  years and  $\leq 65$  years

**Oralair additional criteria:** Patient age  $\geq 10$  years and  $\leq 65$  years

**Ragwitek additional criteria:** Patient age  $\geq 18$  years and  $\leq 65$  years

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendations for newly managed Therapeutic Drug Classes.

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

The following criteria were presented for drugs that were initially reviewed at the January meeting.

- **Entyvio (vedolizumab) 300mg single-dose vial**

**Recommendation:** That the PDL categories called Crohn’s Disease Injectables and Ulcerative Colitis Injectables be combined into a single category entitled Inflammatory Bowel Disease Injectables since many drugs are approved for both indications. Also, that the criteria for the category be changed to accommodate the new single category as listed below (Entyvio specific changes are highlighted).

Quantity Limits

- CIMZIA: 1 kit/28 days (starter, then regular)
- HUMIRA: 6 syringes/28 days( starter kit), 2 syringes/28 days subsequently
- ENTYVIO: 300 mg X 3/42 days, 300 mg X 1 every 56 days thereafter
- SIMPONI: 3 of 100 mg prefilled syringe or autoinjector X 1, then 100 mg/28days

Clinical Criteria (Crohn’s Disease)

**Humira, Remicade, Cimzia, Tysabri, Entyvio:**

- Patient has a diagnosis of Crohn’s disease and has already been stabilized on the medication. OR
- 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): aminosaliclates, antibiotics, corticosteroids, and immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate. Note: Humira and Cimzia have been shown to be effective in patients who have been treated with infliximab but have lost response to therapy.

**Cimzia additional criteria:**

- Patient age > 18 years AND
- The prescriber must provide a clinically valid reason why Humira cannot be used.

**Tysabri additional criteria:**

- The patient has a documented side effect, allergy, treatment failure, or contraindication to BOTH, Remicade and Humira.

**Entyvio additional criteria:**

- Patient age > 18 years AND
- The patient has a documented side effect, allergy, treatment failure (including corticosteroid dependence despite therapy), or contraindication to BOTH Remicade and Humira

**Clinical Criteria (Ulcerative Colitis)**

**Humira, Remicade,**

- Patient has a diagnosis of Ulcerative Colitis and has already been stabilized on the medication. OR
- The patient has a diagnosis of Ulcerative Colitis and has had a documented side effect, allergy, or treatment failure with at least 2 of the following 3 agents: aminosaliclates (e.g. sulfasalazine, mesalamine, etc.), corticosteroids, or immunomodulators (e.g. azathioprine, 6-mercaptopurine, cyclosporine, etc.).

**Entyvio:**

- Patient has a diagnosis of ulcerative colitis and has already been stabilized on the drug OR
- age > 18 years AND a diagnosis of ulcerative colitis AND
- has demonstrated corticosteroid dependence or has had an inadequate response to or failed to tolerate oral aminosaliclates, oral corticosteroids, azathioprine, or 6-

mercaptopurine. AND the prescriber must provide a clinically valid reason why Humira and Remicade cannot be used.

**Simponi:**

- Patient has a diagnosis of Ulcerative Colitis and has already been stabilized on Simponi OR
- Patient age > 18 years AND Patient has a diagnosis is Ulcerative Colitis and has demonstrated corticosteroid dependence or has had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine. AND The prescriber must provide a clinically valid reason why Humira® cannot be used.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendations.

▪ **Jublia (efinaconazole) 10% topical solution**

**Recommendation:** Add Jublia to the current criteria for Antifungals: Onychomycosis with a quantity limit of 48 weeks and the same criteria as for Penlac and Kerydin requiring an intolerance of generic ciclopirox.

*Public Comment:* No public comment.

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

▪ **Sivextro (tedizolid) 200 mg tablet**

**Recommendation** Add Sivextro Tabs to the current criteria for Anti-infectives Antibiotics: Oxazolidones.

*Public Comment:* No public comment.

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

▪ **Tanzeum (albiglutide) for injection**

**Recommendation** Criteria for Tanzeum would be: Patient has a diagnosis of type 2 diabetes AND patient is at least 18 years of age AND patient has a documented side effect, allergy, contraindication, or treatment failure with metformin. Also, due to the increase in net cost of Byetta relative to other choices in the category, it is recommended that it be made non-preferred as well with current users grandfathered. The criteria for Byetta would be as follows:

**Bydureon/Byetta:** Patient has a diagnosis of type 2 diabetes AND patient is at least 18 years of age AND patient has a documented side effect, allergy, contraindication, or treatment failure with metformin AND patient has a documented side effect, allergy, contraindication, or treatment failure with Victoza.

*Public Comment:* No public comment.

**Board Decision:** The Board unanimously approved the above recommendations

- **Harvoni (90 mg ledipasvir and 400 mg sofosbuvir) tablet**
- **Viekira pak (ombitasvir, paritaprevir, and ritonavir tablet, dasabuvir tablet)**

**Recommendation** Criteria recommended for Harvoni and Viekira pak are as listed below

**Direct Acting Agents: Harvoni, Olysio, Sovaldi and Viekira pak**

- Hep C PA form must be completed and clinical documentation supplied. All requests will be reviewed on a case by case basis by the DVHA Medical Director. Combination therapy will be either approved or denied in its entirety.
- Member must have Metavir fibrosis score of 3 or 4
- Prescriber must be a hepatologist, gastroenterologist or infectious disease specialist
- See PA form for detailed requirements and for documentation required.

*Public Comment:* A representative from AbbVie spoke about the attributes of the Viekira pak reviewing the data about its efficacy, its indications and discussing the packaging.

**Board Decision:** The Board unanimously approved the above recommendations.

**11. General Announcements**

- Selected FDA Safety Alerts
  - None at this time

**13. Adjourn:** Meeting adjourned at 7:27 p.m.