



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 09/10/2013**

Board Members:

Present:

Jaskanwar Batra, MD
Kim Ladue, NP
Amanda Kennedy, PharmD

Gary Starecheski, RPh
James Marmar, RPh
Joseph Lasek, MD, Chair

Mark Pasanen, MD
Janet Farina, RPh
Jeanne Greenblatt, MD

Absent:

Halle Sobel, MD

Mario Sarafini, DO

Staff:

Diane Neal, RPh, Catamaran
Stacey Baker, DVHA
Jennifer Egelhof, DVHA

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

Nancy Miner, Catamaran
Nancy Hogue, PharmD, DVHA

Guests:

Thomas Algozzine, Novartis
Wendy Pollinger, Eli Lilly
Robert Pitasi, Otsuka
Carol Spelman, Aegerion

Rita Baglini, APS Healthcare
Carl Possidente, Pfizer
Brad Zettler, Takeda
Dennis Jacobsen, Genzyme

Elizabeth Brewer, Sanofi
Andrew Dean, Otsuka
Gordon Maher

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. 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 July, 2013 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- A summary of the Common PA Form public meeting was given. It was decided that a common PA form for prescriptions will not eliminate administrative burden; therefore, efforts are being made to find other ways to do this such as creating a common formulary document to highlight similarities with no restrictions among all insurers in the state.

4. **Medical Director Update:**

- A Medical Director has been chosen and will begin work in December.

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

- **Pediatric Antipsychotic Medications:** The final status (approved/denied) of the pediatric antipsychotic PA requests received since implementation of the PA requirement was discussed. Changes to target symptoms and diagnosis criteria were also recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved leaving the target symptoms and diagnoses as previously approved at the July meeting (no general aggression or mood instability listed as target symptoms).

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

- **Discussion of Possible Topics for Coming Year:** The DUR Board was asked to suggest possible RetroDUR topics for the upcoming year. Reports of high volume and/or high cost medications and therapeutic classes were distributed.

Public Comment: No public comment.

Board Decision: The Board suggested the following topics as a possibility for the upcoming year: buprenorphine with concomitant benzodiazepine use, slow release melatonin coverage to reduce the usage of other sedative/hypnotics, ADHD medications in children and adults, and continued review of antipsychotic medications in children and adults.

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

Abbreviated New Drug Reviews:

- **Abilify[®] Maintena (aripiprazole) Intramuscular Injection:** It was recommended that Abilify[®] Maintena be added to the PDL as prior authorization required with the following approval criteria: The patient has been started AND stabilized on the requested medication or medical necessity for a specialty dosage form has been provided (non-compliance with oral medications, etc) AND the prescriber must also provide clinical rationale why Risperdal Consta[®] or Invega Sustenna[®] is not a suitable option for this patient AND tolerability has been established previously with oral aripiprazole.

Public Comment: *Dr. Bob Pitasi ~ Otsuka* - Highlighted some of the attributes of Abilify Maintena[®].

Board Decision: The Board requested that haloperidol decanoate and fluphenazine decanoate be added as acceptable step drugs (along with Risperdal Consta[®] and Invega Sustenna[®]) (with rewording of the criteria) and also that started and stabilized be added as an acceptable clinical criterion for approval. The Board would like to review the criteria for other long-acting injectables next meeting.

- Lotemax[®] (loteprednol) Ophthalmic Gel: It was recommended that Lotemax[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has had a documented side effect, allergy, or treatment failure to one preferred generic ophthalmic corticosteroid.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Uceris[®] (budesonide) ER Oral Tablet: It was recommended that Uceris[®] be added to the PDL as preferred. There will be a quantity limit of 1 tablet per day.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation and would like to review usage in six months to look at diagnosis for treatment.

Full New Drug Reviews:

- Gattex[®] (teduglutide) Subcutaneous Injection: It was recommended that Gattex[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has had a diagnosis of short bowel syndrome AND the patient is receiving specialized nutritional support administered intravenously (i.e. parenteral nutrition) AND the patient is 18 years of age or older AND the patient does not have an active gastrointestinal malignancy (gastrointestinal tract, hepatobiliary, pancreatic), colorectal cancer, or small bowel cancer AND the DVHA Medical Director has reviewed the clinical case for approval. Therapy will be limited to 30 day supply per fill.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Juxtapid[®] (lomitapide) Oral Capsule: It was recommended that Juxtapid[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) AND Juxtapid[®] will be used as adjunct to a low-fat diet and other lipid-lowering treatments AND the patient does not have any of the following contraindications to therapy: Pregnancy, Concomitant use with strong or moderate CYP3A4 inhibitors, Moderate or severe hepatic impairment or active liver disease including unexplained persistent abnormal liver function tests AND the patient has tried and had an inadequate response, intolerance or contraindication to both atorvastatin and Crestor[®] AND the DVHA Medical Director has reviewed the clinical case for approval. The following quantity limits were proposed: one tablet per day for both the 5 mg and 10 mg tablet and three tablets per day for the 20 mg tablet. Therapy will be limited to 28 day supply per fill.

Public Comment: Carol Spelman ~ Aegerion - Highlighted some of the attributes of Juxtapid[®]. It was also explained that the annual cost would be capped by the manufacturer if multiple units of the 20 mg tablet are used on a daily basis.

Board Decision: The Board unanimously approved the above recommendations.

- Kynamro[®] (mipomersen) Subcutaneous Injection: It was recommended that Kynamro[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has a

diagnosis of homozygous familial hypercholesterolemia (HoFH) AND Kynamro[®] will be used as adjunct to a low-fat diet and other lipid-lowering treatments AND the patient does not have the following contraindications to therapy: Moderate or severe hepatic impairment or active liver disease including unexplained persistent abnormal liver function tests AND the patient has tried and had an inadequate response, intolerance or contraindication to both atorvastatin and Crestor AND the DVHA Medical Director has reviewed the clinical case for approval. The following quantity limits were proposed: 200mg syringe: 4 syringes per 28 days.

Public Comment: Dennis Jacobsen ~ Genzyme – Was available for questions about Kynamro[®].

Board Decision: The Board unanimously approved the above recommendation.

- Nesina[®], Oseni[®], & Kazano[®] (alogliptin, alogliptin/pioglitazone & alogliptin/metformin) Oral Tablets: It was recommended that Nesina[®], Oseni[®], and Kazano[®] be added to the PDL as prior authorization required with the following approval criteria: Nesina[®]: 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, or treatment failure with at least one preferred DDP-4 agent; Oseni[®]: The patient is unable to take Nesina[®] and Actos[®] (pioglitazone) as the individual separate agents (after meeting clinical criteria for each individual agent); Kazano[®]: The patient has had a documented side effect, allergy or treatment failure with at least one preferred DDP-4 combination agent. The following quantity limits were proposed: Nesina[®]: 1 tablet per day; Oseni[®]: 1 tablet per day; Kazano[®]: 2 tablets per day.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Signifor[®] (pasireotide) Subcutaneous Injection: It was recommended that Signifor[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of (pituitary) Cushing's disease AND the patient is 18 years of age or older AND pituitary surgery is not an option or has not been curative AND the DVHA Medical Director has reviewed the clinical case for approval. A quantity limit of 2 ml/day, maximum 60 ml/30 days was proposed. Upon reauthorization in 6 months, use shall be reviewed to confirm the patient has experienced an objective response to therapy (i.e. clinically meaningful reduction in 24-hour urinary free cortisol levels and/or improvement in signs/symptoms of the disease).

Public Comment: Tom Algozzine ~ Novartis – Highlighted some of the attributes of Signifor[®].

Board Decision: The Board unanimously approved the above recommendations.

- Vascepa[®] (icosapent ethyl) Oral Capsule: It was recommended that Vascepa[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has been started and stabilized on this medication (note: samples are not considered adequate justification for stabilization) OR the patient has triglyceride levels >500mg/dl AND the patient has a documented contraindication, side effect, allergy, or treatment failure to a fibric acid derivative and niacin. A quantity limit of 4 capsules per day was recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

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

- Antivirals: Oral: It was recommended that generic famciclovir be preferred before brand (both after PA)(switch of current coding). The criteria for approval of the generic would be: The patient has a documented side effect, allergy, or treatment failure (at least one course of ten or more days) with acyclovir AND valacyclovir.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Antivirals: Topical: It was recommended that generic acyclovir ointment be added to the PDL as prior authorization required with the following approval criteria: If prescribed for the treatment of oral herpes simplex infection, the patient has had a documented side effect, allergy, or treatment failure (at least one course of four or more days) with Denavir[®]. In addition, for approval of Zovirax[®] Ointment, the patient has a documented intolerance to generic acyclovir ointment.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

9. New Managed Therapeutic Drug Classes:

- Epinephrine: Auto-injector: It was recommended that Epipen[®] and Epipen[®] Jr. be added to the PDL as preferred with all other branded and generic products added as prior authorization required with the following approval criteria for non-preferred products: There is a documented clinical indication to use an alternative product.

Public comment: Elizabeth Brewer ~ Sanofi – Highlighted some of the attributes of Auvi-Q[®].

Board Decision: The Board unanimously approved the above recommendation.

10. Review of Newly Developed/Revised Clinical Coverage Criteria and/or Preferred Products:
Diane Neal, RPh, Catamaran

- Crinone[®]: A category for infertility products (not covered by DVHA) will be created to allow approval of Crinone[®] in patients who are pregnant who have a short cervix.
- Makena[®]: No changes recommended after all. No discussion occurred.
- Second Generation Cephalosporins: It was recommended that there be an update to the approval criteria for Ceftin[®] suspension: The patient has had a documented side effect, allergy, or treatment failure to cefprozil suspension OR the indication for use is Lyme disease.

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: Deferred until next meeting.
- 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 8:47 p.m.

Next DUR Board Meeting

Tuesday, October 22, 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.