



**Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 07/30/2013**

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
Halle Sobel, MD

Absent:

Jeanne Greenblatt, MD

Mario Sarafini, DO

Staff:

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

Michelle Sirois, Catamaran
Mary Beth Bizzari, RPh, DVHA
Aaron French, DVHA

Nancy Miner, Catamaran
Nancy Hogue, PharmD, DVHA
Michael McAdoo, DVHA

Guests:

Rita Baglini, APS
Glen Ehret, Sunovion
Julia Hoff, NovoNordisk
Marie Roache, Pfizer
Timothy Chatas, UCB
Gillian Black-Noller, Pfizer

Mario Carnovale, Novartis
Amy Finn, Merck
James Kokoszyna, Allergan
Angelo Valeri, Biogen
Carl Possidente, Pfizer
John Holtz, Pfizer

Thomas Currier, Purdue
Rod Francisco, Sunovion
Peter Persico, Otsuka
Scott Williams, J&J
Tom Algozzine, Novartis
Mark Veerman, JNJ

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 May, 2013 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- Introductions of Dr. Thomas Simpatico, Chief Medical Officer, and Aaron French, Deputy Commissioner, were made.
- The CMS Annual Report for DUR activities submitted for FFY2012 was discussed and a link will be forwarded to the DUR Board members.

- There will be a public meeting in Montpelier on August 14, 2013, about the legislative mandate to develop a uniform prior authorization form between payers for both medical claims and drugs.

4. Medical Director Update:

- Dr. Simpatico described the roles of the Chief Medical Officer and the Medical Director.

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

- Pediatric Antipsychotic Medications: Changes to target symptoms and diagnosis criteria were recommended.

Public Comment: No public comment.

Board Decision: Dr. Lasek requested that this topic be deferred to a later meeting when Dr. Greenblatt can attend.

- Second Reconsiderations (general) by Medical Director: A draft form was submitted to the Board for comments. This form would be used by prescribers who wish to have a second reconsideration by the Medical Director of a denied prior authorization request. It is designed to provide more clinical information to DVHA for consideration.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the form. Dr. Batra would like to see the form available on the internet for completion and submission.

- Second Reconsiderations (buprenorphine or buprenorphine/naloxone) by Medical Director: A draft form was submitted to the Board for comments. This form would be used by prescribers who wish to prescribe a beneficiary either a non-preferred dosage form or daily dose greater than 16 mg/day. The wording is still in draft form and will be finalized by DVHA and the Substance Abuse Unit. The clinical criteria were updated to reflect that all grandfathering based upon prior claims history will be removed and all requests for alternate dosage forms and daily doses greater than 16 mg/day will be forwarded to Substance Abuse Unit for review with Medical Director. The quantity limit for the 2 mg/0.5 mg buprenorphine/naloxone film will be reduced to 1 film/day now that multiple other dosage strengths of film are available to encourage dose consolidation.

Public Comment: No public comment.

Board Decision: The Board approved the clinical criteria changes proposed but did not want the statement about review by Substance Abuse Unit included as part of the clinical criteria.

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

- Buprenorphine with concomitant opiates, opiate combinations or tramadol: A summary of beneficiaries who had filled buprenorphine or buprenorphine/naloxone claims of at least 28 days and an opiate, opiate combinations or tramadol claims of 11 days or more was presented. Within a 6 month time period there were 107 members who met these criteria. This was then broken down to

look at the therapy within the same calendar month – with this further refinement there were 51 members that met criteria (for at least one month), with 8 members meeting this criteria for each of the 6 individual months.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations with the following change: All claims for opiates or opiate combination medications submitted within 14 days of a Suboxone or buprenorphine/naloxone or buprenorphine mono claim will reject at the pharmacy counter if submitted for > 5 days' supply. Reject message to explain maximum days' supply of 5 days (greater than 5 days' supply requires PA). Letters will be sent to the prescribers of current members meeting these criteria so that PA can be obtained in advance of the coding change.

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

Abbreviated New Drug Reviews:

- Giazo[®] (balsalazide disodium) Oral Tablet: It was recommended that Giazol[®] be added to the PDL as prior authorization required with the following approval criteria: The diagnosis is ulcerative colitis AND the patient is male and ≥ 18 years old AND the patient has a documented intolerance to generic balsalazide. There will be a quantity limit of 6 tablets per day.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Ilevro[®] (nepafenac 0.3%) Ophthalmic Suspension: It was recommended that Ilevro[®] 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 Acular[®] or Acular LS[®].

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Onmel[®] (itraconazole) 200 mg Oral Tablet: It was recommended that Onmel[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has a diagnosis of a toenail onychomycosis infection (confirmed with a positive KOH stain, PAS stain, fungal culture or physician clinical judgement) AND has a documented side-effect, allergy, contraindication, or treatment failure to oral terbinafine AND there is a clinical reason that itraconazole 100 mg generic capsules cannot be used AND meets at least one of the following criteria: pain to affected area that limits normal activity, Diabetes Mellitus, patient has significant vascular compromise. 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.

- Oxtellar XR[®] (oxcarbazepine) ER Oral Tablet: It was recommended that Oxtellar XR[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has been unable to be compliant with or tolerate twice daily dosing of the generic oxcarbazepine immediate release product.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Quillivant XR[®] (methylphenidate) ER Oral Suspension: It was recommended that Quillivant XR[®] be added to the PDL as preferred. There will be a quantity limit of 12 ml (60 mg) per day.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Tobi Podhaler[®] (tobramycin) Capsules for Inhalation: It was recommended that Tobi Podhaler[®] be added to the PDL as prior authorization required with the following approval criteria: The diagnosis or indication is cystic fibrosis. There will be a quantity limit of 224 capsules per 56 days (4 capsules twice daily for 28 days, then 28 days off).

Public Comment: Tom Algozzine ~ Novartis - Available to answer questions and had Podhaler available for demonstration.

Board Decision: The Board unanimously approved the above recommendation.

- Uceris[®] (budesonide) ER Oral Tablets: Deferred until next meeting.

Full New Drug Reviews:

- Eliquis[®] (apixaban) Oral Tablet: It was recommended that Eliquis[®] be added to the PDL as prior authorization required with the following approval criteria: The diagnosis or indication is nonvalvular atrial fibrillation. A quantity limit of two tablets per day was proposed.

Public Comment: Gillian Black-Noller ~ Pfizer - Highlighted some of the attributes of Eliquis[®].

Board Decision: The Board unanimously approved the above recommendation.

- Fulyzaq[®] (crofelemer) Delayed Release Oral Tablet: It was recommended that Fulyzaq[®] be added to the PDL as prior authorization required with the following approval criteria: The patient has HIV/AIDS and is receiving anti-retroviral therapy AND the patient is at least 18 years of age AND patient requires symptomatic relief of noninfectious diarrhea AND infectious diarrhea (e.g. cryptosporidiosis, c. difficile, etc.) has been ruled out AND patient has tried and failed at least one anti-diarrheal medication (i.e. loperamide or atropine/diphenoxylate). A quantity limit of 2 tablets per day was proposed. Initial authorizations will be granted for 3 months. Reauthorizations for continued use shall be reviewed yearly. Renewal criteria shall confirm that patient has had an objective response to therapy, defined as improvement in diarrhea symptoms. It is also proposed that a new therapeutic category is created with the title of "Antidiarrheals: HIV/AIDS".

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Nesina[®], Oseni[®], & Kazano[®] (alogliptin, alogliptin/pioglitazone & alogliptin/metformin) Oral Tablets: Deferred until next meeting.
- Tecfidera[®] (dimethyl fumarate) Oral Capsule: It was recommended that Tecfidera[®] be added to the PDL as preferred. A quantity limit of two capsules per day; maximum 30 day supply per fill was proposed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Xeljanz[®] (tofacitinib) Oral Tablet: It was recommended that Xeljanz[®] be added to the PDL as prior authorization required with the following approval criteria: Patient has a diagnosis of RA and has already been stabilized on Xeljanz[®] OR patient age ≥ 18 years AND diagnosis is RA AND patient has documentation of an inadequate response, adverse reaction or allergic response to methotrexate, or if methotrexate is contraindicated, at least 1 non-biologic DMARD (other DMARDs include leflunomide, sulfasalazine, hydroxychloroquine, azathioprine, and cyclosporine) AND the prescriber must provide a clinically valid reason why either Humira[®] or Enbrel[®] cannot be used. A quantity limit of two tablets per day was proposed.

Public Comment: John Holtz~ Pfizer - Highlighted some of the attributes of Xeljanz[®].

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)

- Immunomodulators: It was recommended that Humira[®] for the treatment of Ulcerative Colitis (new indication) be added to the PDL as preferred after clinical criteria are met. Remicade will also be listed as preferred after clinical criteria are met.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Multiple Sclerosis Agents: It was recommended that the requirement for Gilenya[®] that the patient has had a documented side effect, allergy, inadequate response, or contraindication to at least one preferred self-injectable MS drug be removed.

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

Board Decision: The Board unanimously approved the above recommendation.

- Oral Anticoagulants: There were updates recommended to the current approval criteria for Coumadin[®], Innohep[®], Pradaxa[®], and Xarelto[®].

Public Comment: Mark Veerman ~ JNJ – Highlighted some of the attributes of Xarelto[®].

Board Decision: The Board unanimously approved the above recommendations with the addition of a quantity limit change for Xarelto[®] 15mg to 2 tablets per day for 21 days initially when prescribed for the treatment of DVT or PE.

9. New Managed Therapeutic Drug Classes:

- None this meeting.

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

Diane Neal, RPh, Catamaran

- Crinone[®]: Deferred until next meeting.
- Makena[®]: Deferred until next meeting.
- Second Generation Cephalosporins: Deferred until next meeting.
- Short Acting Beta Agonist Inhalers (for 1/1/14 implementation): It was recommended that Xopenex[®] HFA be moved to PA required on the PDL with the following approval criteria: The patient must have had a documented side effect, allergy, or treatment failure to two preferred short acting metered dose inhalers.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

11. General Announcements:

FDA Safety Alerts

- 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 8:55 p.m.

Next DUR Board Meeting

Tuesday, September 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.