



**Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 12/08/2009**

Board Members:

Michael Scovner, M.D., Chair
Lynne Vezina, R.Ph.
Stuart Graves, M.D.

Norman Ward, M.D.
Andrew Miller, R. Ph

Cheryl Gibson, M.D.
Richard Harvie, R. Ph.
Virginia Hood, M.D.

Staff:

Cynthia LaWare, OVHA
Diane Neal, R.Ph., (MHP)
Michael Farber, M.D. OVHA

Nancy Miner, (MHP)
Nancy Hogue, Pharm.D. (MHP)

Jennifer Mullikin, OVHA
Stacey Baker, OVHA
Judy Jamieson, OVHA

Guests:

Heidi Belden, Ortho-McNeil Janssen
Christina Carmody, Endo
Michael Deorsey, Abbott
Amy Finn, Merck

James Kokoszyna, Allergan
Terry Lee, Gilead Sciences
Tim Nies, GSK

Susan Royal, Genentech
Bill Sanborn, Novartis
Angelo Valeri, Novartis

Michael Scovner, M.D. Chair, called the meeting to order at 7:03 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 November 2009 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: *Cynthia LaWare, Director of Pharmacy Benefit Programs, OVHA*

- OIG Audit: OVHA will be audited by the Office of Inspector General in relation to the 402 Demonstration Project. This was the period of time in early 2006 when Medicare Part D was introduced and for the period of time January through March OVHA paid claims on behalf of the Federal Government. The states then billed CMS for reimbursement. Compliance will be evaluated to determine that OVHA billed and was reimbursed correctly.

4. Medical Director Update: *Michael Farber, MD, Medical Director, OVHA*

- Clinical Programs Update: No updates to report.

- Prescriber Comments: No prescriber comments received.

5. Follow-up items from Previous Meeting: Diane Neal, R.Ph., MedMetrics Health Partners (MHP)

- Vectical® (calcitriol) Topical Ointment: A dermatologist was consulted to advise the DUR Board on appropriate step therapy prior to approving Vectical®. It was recommended that calcitriol ointment require prior-authorization with the criteria for approval being the patient is ≥ 18 years of age AND the patient has a diagnosis of mild-to-moderate plaque psoriasis AND the patient has demonstrated inadequate response, adverse reaction or contraindication to calcipotriene. If approved, a quantity limit of 200 g/week (2 tubes/week) is recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

6. Clinical Update: Drug Reviews: Diane Neal, R.Ph. (MHP)

(Public comment prior to Board action)

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

Abbreviated New Drug Reviews

- Fibricor® (fenofibric acid) Tablet: It was recommended that Fibricor® be added to the PDL as prior authorization required with the criteria for approval being that the patient is taking a statin concurrently and has had a documented side effect, allergy, or treatment failure with Tricor® or TriLipix® OR the patient has had a documented side effect, allergy, or treatment failure to gemfibrozil and Tricor® or TriLipix®. Additionally, a quantity limit of one capsule per day is recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Zipsor® (diclofenac potassium) Capsule: It was recommended that Zipsor® (diclofenac potassium) be added to the PDL as prior authorization required with the approval criteria being the patient has had a documented intolerance to diclofenac tablets AND the patient has had a documented side effect, allergy or treatment failure with two additional generic NSAIDs.

Public Comment: No public comment.

Board Decision: The Board requested that the proposed criteria be amended to read “AND the patient has had a documented side effect, allergy or treatment failure with FOUR additional generic NSAIDs”.

Full Drug Reviews

- Besivance® (besifloxacin) Ophthalmic Suspension: It was recommended that Besivance® be added to the PDL as prior authorization required with the approval criteria being the patient has had a documented side effect, allergy or treatment failure with ciprofloxacin or ofloxacin.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Samsca[®] (tolvaptan) Tablet: It was recommended that tolvaptan be added to the PDL as prior authorization required with the approval criteria being the agent is being used for the treatment of euvolemic or hypervolemic hyponatremia AND the treatment will be initiated or is being reinitiated in a hospital setting where serum sodium can be monitored. If Samsca[®] is approved, a quantity limit of one tablet per day for the 15 mg tablet and two tablets per day for the 30 mg tablet was proposed.

Public Comment: No public comment.

Board Decision: The Board requested that in addition to the above criteria the following criteria be included “Despite optimal fluid restriction, the patient’s serum sodium is < 120 mEq/L or the patient is symptomatic with a serum sodium < 125 mEq/L”.

7. Drug Classes-Annual Review: *Diane Neal, R.Ph, (MHP)*
(Public comment prior to Board action)

- Androgens including Topical Testosterone Products:
The oral, injectable and topical products were reviewed. It was recommended that there was not a need to actively manage the oral and injectable products. No changes were recommended to the topical testosterone class preferred products, clinical criteria or quantity limits.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Anticonvulsants (including abbreviated review of Lamictal[®] (lamotrigine) ODT, Lamictal[®] (lamotrigine) XR, Sabril[®] (vigabatrin) and Vimpat[®] (lacosamide)):
Lamictal[®] (lamotrigine) XR: Recommended to require prior authorization with the criteria for approval being the patient has been unable to be compliant with or tolerate twice daily dosing of lamotrigine IR.
Lamictal[®] (lamotrigine) ODT: Recommended to require prior authorization with the criteria for approval being medical necessity for a specialty dosage form has been provided and lamotrigine chewable tablets cannot be used.
Sabril[®] (vigabatrin): Recommended to require prior authorization with the following criteria: Diagnosis is infantile spasms or the patient is an adult and the indication is adjunctive therapy in refractory complex partial seizures after failure of THREE other preferred anticonvulsants.
Vimpat[®] (lacosamide): Recommended to require prior authorization with the criteria for approval being the patient has been started and stabilized on the requested medication or the diagnosis is adjunctive therapy of partial-onset seizures and the patient has had a documented side effect, allergy, treatment failure/inadequate response or a contraindication to at least TWO preferred anticonvulsants.
Felbatol[®] (felbamate): Due to safety concerns, it was recommended to be moved to require prior authorization with the criteria for approval being the patient has been started and stabilized on the requested medication or the diagnosis is adjunctive therapy of partial-onset seizures or Lennox-Gastaut seizures and the patient has had a documented side effect, allergy, treatment failure/inadequate response or a contraindication to at least THREE preferred anticonvulsants. No other changes were recommended to the current clinical criteria and preferred/non-preferred products.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above. The Board requested that Lamictal[®] XR utilization be evaluated in six months. The Board also requested that in addition to the proposed criteria for Sabril[®], an additional criterion of “The prescriber and patient are registered with the SHARE program” be added. In addition, it was requested that a criterion for Felbatol[®] include reference to hepatic dysfunction.

- Antipsychotics (including abbreviated review of Invega[®] Sustenna (paliperidone palmitate IM ER and Saphris[®] (asenapine maleate)):
Atypical Antipsychotics:
Invega Sustenna[®] (paliperidone palmitate): Recommended to require prior authorization. In addition to criteria for long acting injection (Medical necessity for a specialty dosage form has been provided (swallowing disorder, non-compliance with oral medications, etc.)), patient has had a documented side effect, allergy or treatment failure with Risperdal Consta[®].
Saphris[®] (asenapine): Recommended to require prior authorization with the criteria for approval being the same as the other non-preferred tablets in this category (the patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization.) OR the patient has had a documented side effect, allergy or treatment failure with at least two preferred products).
Abilify[®] Discmelt: It was recommended that the quantity limit for 10 mg and 15 mg dosage forms be increased from 1.5 to 2 tablets per day.
Typical Antipsychotics: No changes were recommended for this drug class.

Public Comment: Heidi Belden, Ortho-McNeil Janssen Commented on the clinical studies, dosing regimens and some of the advantages of Invega[®] Sustenna.

Board Decision: The Board unanimously approved the MHP recommendations noted above. The Board requested that long acting typical antipsychotics be clearly outlined in the table.

- Benign Prostatic Hyperplasia (BPH) Treatments (Alpha Blockers and Androgen Hormone Inhibitors):
Alpha Blockers:
No changes were recommended to the preferred/non-preferred products or clinical criteria. It was recommended that a quantity limit of 2 capsules/day be added for Flomax[®], a quantity limit of one tablet/day be added for Uroxatral[®] and a quantity limit of one tablet per day be added for Cardura[®] XL.
Androgen Hormone Inhibitors: No changes were recommended for this category.

Public Comment: No public comment.

Board Decision: The Board approved the addition of the recommended quantity limits and no changes to either preferred products or clinical criteria.

- Urinary Antispasmodics (including abbreviated review of Gelnique[®] (oxybutynin gel):
Gelnique[®] (oxybutynin) topical gel: Recommended to require prior authorization with the criteria for approval being the patient is unable to swallow a solid oral formulation (e.g. patients with dysphagia) OR the patient is unable to be compliant with solid oral dosage forms. A quantity limit of 30 sachets per 30 days is recommended.
Sanctura[®] (trospium): Recommended to move to prior authorization required. The criteria for approval would be the patient has had a documented side effect, allergy, or treatment failure with oxybutynin. AND the patient has had a documented side effect, allergy, or treatment failure with 2 preferred long-acting agents (one of which would be Sanctura XR).

Oxytrol® (oxybutynin transdermal): Recommended that criteria for approval be the same as that proposed for Gelnique above. The criteria for approval being the patient is unable to swallow a solid oral formulations (e.g. patients with dysphagia) OR the patient is unable to be compliant with solid oral dosage forms.

Public Comment: No public comment.

Board Decision: The Board approved the recommendations as noted above.

8. RetroDUR: *Diane Neal, R.Ph, (MHP)*

▪ Xolair® (omalizumab) for persistent asthma:

Currently Xolair® requires prior authorization. This requirement was implemented in October 2003. A retrospective drug analysis of Xolair® was performed to review utilization and evaluate the appropriateness of the current prior authorization criteria. Claims data for Xolair® was reviewed from October 1, 2008 to September 30, 2009. The examined claims data included unique utilizers, number of paid claims, average cost per claim, and total plan cost. The data was reviewed for trends in utilization. In addition, a sample of prior authorization requests for Xolair®, submitted from October 1, 2008 to September 30, 2009, was reviewed for appropriateness of the current prior authorization criteria. During the review period from October 1, 2008 to September 30, 2009, there were a total of 137 paid pharmacy claims and 10 paid medical claims for Xolair® for 18 and 3 unique utilizers, respectively. The total plan cost during this time period was \$312,082.98. The average cost per pharmacy claim was \$2,164.88 and the average cost per medical claim was \$1,549.50. The results indicate appropriate utilization based on the current approval criteria. In addition, there were a total of 53 prior authorization requests for 19 unique utilizers with an overall denial rate of 11%. The prior authorization requests for 11 of the 14 members reviewed were for renewal requests. Although the review demonstrated a high rate of appropriate Xolair® utilization, due to the high cost and risk of inappropriate prescribing, it is recommended that Xolair® remain available via prior authorization. However, most of the prior authorizations were renewal requests and many of the members had multiple prior authorizations in the review period. In addition, while a specialist consult is required yearly, the current authorization period is 3 months. Therefore, it is recommended that the current authorization approval criteria for initial requests remain the same, and length of authorization for renewals requests increased to 1 year. Also, it was recommended that the prior authorization form be revised to help prescribers provide all the necessary information.

Public Comment: No public comment.

Board Decision: The Board approved the recommended change in length of prior authorization.

9. Updated New-to-Market Monitoring Log (Consent agenda topic): *Diane Neal, R.Ph, (MHP)*

- The log is posted on the web site. This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

Board Decision: None needed.

10. General Announcements: *Diane Neal, R.Ph, (MHP)*

FDA Safety Alerts

- Meridia[®] - (sibutramine Hydrochloride): Early communication about an ongoing safety review
FDA notified healthcare professionals and patients that it is reviewing preliminary data from a recent study suggesting that patients using sibutramine have a higher number of cardiovascular events (heart attack, stroke, resuscitated cardiac arrest, or death) than patients using a placebo (sugar pill). These findings highlight the importance of avoiding the use of sibutramine in patients with a history of coronary artery disease (heart disease), congestive heart failure (CHF), arrhythmias, or stroke, as recommended in the current sibutramine labeling. This drug currently requires Prior Authorization. It was recommended that the Board wait for further information from the FDA before making further changes.

Public Comment: No public comment.

Board Decision: The Board approved waiting for more information before making any criteria changes.

- Clopidogrel and Omeprazole-Drug interaction
FDA notified healthcare professionals of new safety information concerning an interaction between clopidogrel (Plavix[®]), an anti-clotting medication, and omeprazole (Prilosec[®]/Prilosec[®] OTC), a proton pump inhibitor (PPI) used to reduce stomach acid. New data show that when clopidogrel and omeprazole are taken together, the effectiveness of clopidogrel is reduced. Patients at risk for heart attacks or strokes who use clopidogrel to prevent blood clots will not get the full effect of this medicine if they are also taking omeprazole. Separating the dose of clopidogrel and omeprazole in time will not reduce this drug interaction. It was recommended that this information be posted on the web site.

Public Comment: No public comment.

Board Decision: The Board recommended waiting for more outcomes information before making any criteria changes.

11. Adjourn: Meeting adjourned at 9:14 p.m.

Next DUR Board Meeting

Tuesday, January 12, 2009

7:00 - 9:00 p.m.*

EDS Building, OVHA 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.