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**Vermont Health Access  
Pharmacy Benefit Management Program  
DUR Board Meeting Minutes: 02/12/08**

**Board Members:**

Michael Scovner, M.D., Chair  
Andrew Miller, R. Ph.  
Cheryl Gibson, M.D.

Norman Ward, M.D.  
Kathleen Boland, Pharm.D.  
Virginia Hood, M.D.

Lynne Vezina, R.Ph.  
Frank Landry, M.D.

**Staff:**

Ann Rugg, OVHA  
Diane Neal, R.Ph., (MHP)  
Robin Farnsworth, OVHA

Nancy Miner, (MHP)  
Stacey Baker, OVHA  
Jennifer Mullikin, OVHA

Erin Cody, M.D., OVHA  
Judy Jamieson, OVHA

**Guests:**

Carl Pepe, GSK  
Keith Osburn, Sepracor

Matt Badalucco, Merck  
Michael Deorsey, Abbott

Terence Lee, Gilead  
Vince Matteo, Eli Lilly

Frank Landry, M.D., Acting Chair, called the meeting to order at 7:12 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 January 2008 minutes were accepted as printed.

*Public Comment:* No public comment.

**3. OVHA Pharmacy Administration Updates: Ann Rugg - Deputy Director, OVHA**

- State Medicaid Budget SFY 2009: The budget was presented to the House Appropriations Committee last week. The full document is available on the web. The Pharmacy Best Practices and Cost Control Report for 2008 is contained in one of the appendices.

**4. Medical Director Update: Erin Cody, M.D., OVHA**

Clinical Programs Update: No updates to report.

Prescriber Comments: No comments to report.

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

- Vytorin<sup>®</sup> & Zetia<sup>®</sup> - ENHANCE study and FDA Early Communication about Ongoing Data Review: The FDA provided healthcare professionals with an early communication about an ongoing data review for Ezetimibe/Simvastatin (marketed as Vytorin<sup>®</sup>), Ezetimibe (marketed as Zetia<sup>®</sup>), and Simvastatin (marketed as Zocor<sup>®</sup>). Merck/Schering Plough Pharmaceuticals reported preliminary results from the Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia (ENHANCE) trial. Once FDA receives the final study report, FDA estimates it will take approximately 6 months to fully evaluate the data.
- Erythropoiesis Stimulating Agents Communication to Prescribers:  
Deferred until next meeting.

*Public Comment:* No public comment.

**Board Decision:** The Board requested that they be updated as any new information is released regarding the ENHANCE study and the data review.

**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.

- Alli<sup>®</sup> (orlistat OTC): Recommended to be placed with all other anti-obesity agents (PA required). Coverage would require PA with the criteria for approval being that the patient is > 12 years old and the patient's Body Mass Index (BMI) is (1)  $\geq 30 \text{ kg/m}^2$  or (2)  $\geq 27 \text{ kg/m}^2$  with co-morbid condition of Hypertension, Obstructive Sleep Apnea, Type 2 Diabetes Mellitus, Dyslipidemia, or Coronary Heart Disease (history of MI, angina, coronary artery procedures) and the patient has failed to lose weight after 6 months on a weight loss regimen of low calorie diet, increased physical activity, and nutritional counseling and the medication will be used as part of a total treatment plan including a calorie and fat restricted diet and exercise regimen and the agent is not to be used in combination with another anti-obesity agent and the patient does not have any contraindications to use.

*Public Comment:* No public comment

**Board Decision:** The Board approved the MHP recommendations as described but requested that before approval of Xenical<sup>®</sup> (orlistat Rx), the patient must have already had 3 month trial of Alli<sup>®</sup> which did not result in 5 lb or more weight loss.

**7. Review of Newly-Developed/Revised Clinical Coverage Criteria:** *Diane Neal, R.Ph. (MHP)*  
(Public comment prior to Board action)

- Analgesics: Long Acting Narcotics (abbreviated review of Kadian<sup>®</sup>):  
An abbreviated review of Kadian<sup>®</sup> was presented for discussion of whether it could serve as an additional PDL preferred product. The category was divided into oral and transdermal products. The criteria for approval of non-preferred oral products were strengthened with the addition of a required trial of morphine sulfate ER before approval.

*Public Comment:* No public comment.

**Board Decision:** The Board voted to retain Kadian<sup>®</sup> as a non-preferred product requiring PA but agreed with the other recommendations for changes to the clinical criteria.

▪ Anti-Infectives: Anti-Fungal: Allylamines:

This category of anti-fungals was previously included in the category “Anti-infectives: Ani-fungals: Onychomycosis” but there were limitations to this categorization since only the indication of onychomycosis was addressed. The indications were expanded to also include *Tinea capitis* infection and *Tinea pedis*, *Tinea cruris*, or *Tinea corporis* infection. Terbinafine and brand name Lamisal<sup>®</sup> continue to be PA required with criteria for approval dependent on the indication. It was recommended that the quantity limit remain 30 tablets/30 days.

*Public Comment:* No public comment.

**Board Decision:** The new subcategory and revised criteria were accepted by the Board. The criteria for the brand Lamisil<sup>®</sup> was requested to be reworded to read “a documented intolerance” to the generic product. It was recommended that this be the standard wording for approval of brands where the generic exists.

▪ Anti-Infectives: Anti-Fungal: Topical: Onychomycosis:

This category of anti-fungals was previously included in the category “Anti-infectives: Ani-fungals: Onychomycosis” and has been sub-categorized to only include the topical product ciclopirox solution and brand name Penlac<sup>®</sup> Nail Lacquer. Both products would remain PA required with a quantity limit of 6.6 mls (1 bottle) per 90 days.

*Public Comment:* No public comment.

**Board Decision:** The Board requested that physician clinical judgment be included as criteria for diagnosis of onychomycosis in all categories of anti-fungals. The new sub-category was approved by the Board.

▪ Anti-Infectives: Anti-Fungal: Azoles:

This category of anti-fungals was previously included in the category “Anti-infectives: Ani-fungals: Onychomycosis” but there were limitations to this categorization since only the indication of onychomycosis was addressed and the only azole anti-fungal listed was itraconazole/Sporanox<sup>®</sup>. The criteria were expanded to include the indications of invasive aspergillosis, blastomycosis, or histoplasmosis. Fluconazole and ketoconazole are preferred. Itraconazole, Sporanox<sup>®</sup>, VFend<sup>®</sup>, Diflucan<sup>®</sup>, Nizoral<sup>®</sup> and Noxafil<sup>®</sup> are PA required. Criteria were developed for each medication and/or indication.

*Public Comment:* No public comment.

**Board Decision:** The Board approved the expanded table and revised clinical criteria as recommended.

▪ Anti-Infectives: Genital Antivirals:

It was recommended that Condylox<sup>®</sup> Gel move to PA required with a required trial of Aldara<sup>®</sup>.

*Public Comment:* No public comment.

**Board Decision:** The revised PDL preferred and non-preferred products and clinical criteria were unanimously accepted.

- Hepatitis C Agents (PA Length):  
Deferred until next meeting.
- Pulmonary: Antihistamines: 2<sup>nd</sup> Generation:  
It was recommended that for all non-preferred oral swallow tablets/capsules, a trial of both loratadine and cetirizine be tried, followed by a trial of fexofenadine. For approval of a non-preferred oral syrup/suspension, both loratadine and cetirizine must be tried.

*Public Comment:* No public comment.

**Board Decision:** The revised clinical criteria were unanimously approved.

**New Drug Classes:**

- Contraceptives: Vaginal Ring (Nuvaring<sup>®</sup>):  
Recommended for addition to the PDL.

*Public Comment:* No public comment.

**Board Decision:** The new drug class was unanimously accepted.

- Topical: Scabicides and Pediculicides:  
Ovide<sup>®</sup>, lindane and brand name Elimate<sup>®</sup> would be PA required with the criteria for approval being a documented side effect, allergy, or treatment failure with two treatments of permethrin. All other brand and generic scabicides and pediculicides would be preferred.

*Public Comment:* No public comment.

**Board Decision:** The new drug class and clinical criteria were unanimously accepted.

- Vitamins: Prenatal Multivitamins:  
It was recommended that generic prenatal vitamins be preferred while all brands be PA required. For approval of non-preferred products the prescriber must provide a clinically valid reason for the use of the requested medication including reasons why any of the generically available preparations would not be a suitable alternative.

*Public Comment:* No public comment.

**Board Decision:** The new drug class and clinical criteria were unanimously accepted.

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

**Cost Savings/Clinical Analysis of Prior Initiatives:**

- Cough and Cold Products:  
An analysis of the six months utilization 10/01/05 – 3/31/06 of branded cough and cold preparations prior to PDL management to a six month period 10/01/06 – 3/31/07 after PDL management showed an increase in generic utilization from 73.04 % to 87.65 % with a resultant 6 month cost savings of \$ 38,628.04.

*Public Comment:* No public comment.

**Board Decision:** None needed.

- Skeletal Muscle Relaxants:

An analysis of the 3 months utilization 04/01/06 – 06/30/06 of skeletal muscle relaxants prior to PDL management to a 3 month period 04/01/07 – 06/30/07 after PDL management showed a per member per month (PMPM) cost decrease from \$ 0.33 PMPM to \$ 0.21 PMPM with a resultant annualized cost savings of \$ 155,654. The management of the category was primarily the promotion of generic products.

*Public Comment:* No public comment.

**Board Decision:** None needed.

- Carisoprodol Prior Authorization:

All products containing carisoprodol were moved to PA required as of 11/01/06. This change was made due to concerns of safety and diversion. Utilization decreased from 1,215 claims in the 6 month period 04/0/06 – 09/30/06 prior to the change to 324 claims in the period 04/01/07 – 9/30/07 after the PA implementation. This is 73.3 % reduction in utilization.

*Public Comment:* No public comment.

**Board Decision:** None needed.

- Topical Immunomodulator Intervention:

After an FDA alert regarding use of topical immunomodulators (TIM) and concerns regarding safety, particularly in children, criteria were adopted that required a trial of topical corticosteroids, quantity limits were instituted and PA was required for all children less than 2 years old. An analysis of the 6 month period 04/01/06 – 09/30/06 prior to implementation of these criteria to the 6 month period 04/01/07 – 09/30/07 after the implementation resulted in a 48% decrease in total number of unique patients receiving a TIM agent, a 46% decrease in total number of unique patients under age 2 receiving a TIM agent, a 79% decrease in total number of unique patients receiving > 90gms of a TIM in 6 months and a 64% decrease in total TIM drug expenditures which calculates to an annual savings of \$ 62,684.

*Public Comment:* No public comment.

**Board Decision:** None needed.

- Acne Drug Program:

An analysis of the six months utilization 04/01/06 – 09/30/06 of branded acne products prior to PDL management to a six month period 04/01/07 – 09/30/07 after PDL management showed a decrease in branded utilization from 46.67 % to 2.51 % with the resultant per member per month (PMPM) expenditure decreasing from \$ 0.49 PMPM to \$ 0.25 PMPM and an annualized cost savings of \$ 311,308.

*Public Comment:* No public comment.

**Board Decision:** None needed.

- **Mental Health Medication Dose Consolidation:**  
Quantity limits and dose consolidation were implemented for the lower strengths of select mental health medications designed for once daily administration. A comparison of the six months utilization 04/01/06 – 09/30/06 prior to quantity limits to a six month period 04/01/07 – 09/30/07 after quantity limits showed an overall decrease in the average units per day from 1.28 units/day to 1.19 units/day. Annualized cost avoidance was calculated to be \$ 621,359 had quantity limits not been implemented.

*Public Comment:* No public comment.

**Board Decision:** The Board requested that this information and the results of the other cost savings and clinical initiatives be shared with providers and the legislature.

**Discussion of Planned/Ongoing evaluations:**

Ongoing RetroDUR analyses include a proposal to study smoking cessation products and also an analysis of drug therapy in patients with either an inpatient or ER admission due to an asthma exacerbation.

*Public Comment:* No public comment.

**Board Decision:** None needed.

**10. New Drug Product Plan Exclusions (Consent agenda topic): Diane Neal, R.Ph, (MHP)**

- New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. As approved by the DUR Board, drug products that appear to be illogical combinations, kits containing non-drug items or very expensive dosage forms where inexpensive alternatives exist are blocked. The presented table highlights drug products blocked from drug files dated 01/03/08 - 01/31/08. DUR Board members were asked to comment if they felt that a drug product should not be blocked.

*Public Comment:* No public comment.

**Board Decision:** The Board approved the excluded products as presented.

**11. Updated New-to-Market Monitoring Log: Diane Neal, R.Ph, (MHP)**

- 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.

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

**FDA Safety Alerts**

- Cough and Cold Preparations in Children less than 2 years old - safety concerns: FDA informed consumers and healthcare professionals that the FDA has completed its review of information regarding the safety of over-the-counter (OTC) cough and cold medicines in children under 2 years of age and recommends that these drugs not be used to treat children in this age group because serious and potentially life-threatening side effects can occur. Products designed for infants and small children have already been blocked (for example, infant drops). It was recommended that the alert be posted on the OVHA pharmacy web site.

*Public Comment:* No public comment.

**Board Decision:** The Board requested that a FAHC pediatrician be consulted to advise whether all other cough and cold products (in addition to infant drop cough and cold products) should be blocked for children less than 2 years old.

- OrthoEvra Contraceptive Transdermal Patch - blood clots: FDA modified the prescribing information for the Ortho Evra Contraceptive Transdermal (Skin) Patch to include the results of a new epidemiology study that found that users of the birth control patch were at higher risk of developing serious blood clots, also known as venous thromboembolism (VTE), than women using birth control pills. The recommendation is that no action is required on the part of the DUR Board in response to this alert. It was recommended that the alert be posted on the OVHA pharmacy web site.

*Public Comment:* No public comment.

**Board Decision:** The Board approved all MHP recommendations.

- Antiepileptic Drugs - suicidal behavior or ideation: FDA informed healthcare professionals that the Agency has analyzed reports of suicidality (suicidal behavior or ideation) from placebo-controlled clinical studies of eleven drugs used to treat epilepsy as well as psychiatric disorders, and other conditions. In the FDA's analysis, patients receiving antiepileptic drugs had approximately twice the risk of suicidal behavior or ideation (0.43%) compared to patients receiving placebo (0.22%) The recommendation is that no action is required on the part of the DUR Board in response to this alert. The alert will be posted on the OVHA pharmacy web site.

*Public Comment:* No public comment.

**Board Decision:** The Board approved all MHP recommendations.

- Varenicline (Chantix<sup>®</sup>) - neuropsychiatric symptoms: FDA informed healthcare professionals and consumers of important revisions to the WARNINGS and PRECAUTIONS sections of the prescribing information for Chantix regarding serious neuropsychiatric symptoms experienced in patients taking Chantix. These symptoms include changes in behavior, agitation, depressed mood, suicidal ideation, and attempted and completed suicide. The recommendation is that no action is required on the part of the DUR Board in response to this alert. The alert will be posted on the OVHA pharmacy web site.

*Public Comment:* No public comment.

**Board Decision:** The Board approved all MHP recommendations.

13. **Adjourn:** Meeting adjourned at 8:58 p.m.

**Next DUR Board Meeting**

**\*\* PLEASE NOTE\*\*:** NO meeting in March, date change for April

Tuesday, April 01, 2008

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.