

**MEDICAID DRUG UTILIZATION REVIEW
ANNUAL REPORT INSTRUCTIONS**

FEDERAL FISCAL YEAR

2010

Section 1927 (g)(3)(D) of the Social Security Act requires each State to submit an annual report on the operation of its Medicaid DUR program. Such reports are to include: descriptions of the nature and scope of the prospective and retrospective DUR programs; a summary of the interventions used in retrospective DUR and an assessment of the education program; a description of DUR Board activities; and an assessment of the DUR program's impact on quality of care as well as any cost savings generated by the program.

This report is to cover the period October 1, 2009 to September 30, 2010 and is due for submission to your CMS Central Office by no later than September 30, 2011 . Answering the attached questions and returning the requested materials as attachments to the report will constitute full compliance with the above-mentioned statutory requirement

**If you have any questions regarding the DUR annual report, please contact CMS at :
DURPolicy@cms.hhs.gov**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0659. The time required to complete this information collection is estimated to average 30 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

**MEDICAID DRUG UTILIZATION REVIEW (DUR)
ANNUAL REPORT**

FEDERAL FISCAL YEAR

2010

I. STATE NAME ABBREVIATION

VT

II. MEDICAID AGENCY INFORMATION

1. Identify state person responsible for DUR Annual Report Preparation.

First Name	Nancy		
Middle Name			
Last Name	Hogue		
Address	312 Hurricane Lane Suite 201		
City	Williston	State	50
		Zip Code	05495
E-Mail	nancy.hogue@state.vt.us	Phone	(802) 879-5611

2. Identify pharmacy POS vendor – (Contractor, State-operated, Other).

- Contractor
 State Operated
 Other

Please enter the vendor name or explain:

MedMetrics Health Partners, an SXC company

3. If not State-operated, is the POS vendor also the MMIS Fiscal agent?

- Yes
 No

III. PROSPECTIVE DUR

1. Identify prospective DUR criteria source.

First Data Bank

Other (Specify)

MediSpan FDA Safety Alerts

2. Are new prospective DUR criteria approved by the DUR Board?

Yes No

Please explain:

<p>The Prospective Drug Utilization Review (DUR) process in our claims processing system is designed to check a patients prescription history for possible drug related problems to improve the quality and cost effectiveness of dispensed medications by ensuring adjudicated prescriptions are clinically appropriate. The base DUR system utilizes the Medi-Span Master Drug Database during prescription claim adjudication to check the submitted claim against the patients prescription and demographic profiles.</p> <p>The ProDUR module is table-driven and user-defined. The initial user-defined settings determine which new edits are activated, in which order to perform the edits, and how far back to check member history. Overrides to specific DUR occurrences are determined through the common prior authorization process while others are determined by the dispensing pharmacists professional judgment at POS. The following clinical edits were chosen by DVHA in conjunction with the Vermont DUR Board to be employed in FFY 2010 for POS screening.</p> <ul style="list-style-type: none"> Drug to Drug Interaction Drug to Inferred Disease State Screening Drug Dosing Duration Screening Duplicate Rx Screening Duplicate Therapy Screening Early Fill Screening Drug to Age Caution Drug to Sex Caution <p>In addition to the new MediSpan prospective DUR edits which are added as previously determined, the DUR Board routinely reviews all new FDA Medication Safety alerts to determine whether any additional hard edits need to be added to the ProDUR system in response to those alerts.</p>

3. When the pharmacist receives prospective DUR messages that deny the claim, does your system:

- a) Require preauthorization
- b) Allow the pharmacist to override with the correct "conflict", "intervention" and "outcome" codes?
- c) a) and/or b) above - depending on the situation

Additional Comments:

The ProDUR Services listed provide responses to the dispensing pharmacy concerning potential drug therapy problems. The responses may be:
 Hard Reject: Reject the claim, and do not allow the pharmacy to override a DUR conflict. Only the Clinical or Technical Call Center may override these rejections (may require clinical PA submission).
 Soft Reject: Reject the claim, but allow a pharmacy to override a DUR conflict by submitting conflict, intervention and outcome codes. The Call Centers may also override these types of rejections in certain situations.
 Message: Pay the claim, but send a conflict message back to the pharmacy.
 Extract: Similar to a Message response, except a message is not sent to the pharmacy. The claims system stores the message in the database with the ability to report.

4. Early Refill:

a) At what percent threshold do you set your system edit?

Non-controlled drugs: %

Controlled drugs: %

b) When an early refill message occurs, does the State require prior authorization?

Non-controlled drugs: Yes No

If 'Yes', who obtains authorization?	<input type="radio"/> Pharmacist	<input type="radio"/> Prescriber	<input checked="" type="radio"/> Either
If 'No', can the pharmacist override at the point of service?	<input type="radio"/> Yes	<input type="radio"/> No	

Controlled drugs: Yes No

If 'Yes', who obtains authorization?	<input type="radio"/> Pharmacist	<input type="radio"/> Prescriber	<input checked="" type="radio"/> Either
If 'No', can the pharmacist override at the point of service?	<input type="radio"/> Yes	<input type="radio"/> No	

Additional Comments:

In addition to the early refill thresholds outlined above, DVHA has an 85 % threshold for buprenorphine products.

For stolen controlled drug prescriptions, we require that a police report has been filed. For lost controlled drug prescriptions, DVHA will have a conversation with the prescriber to verify legitimacy.

5. Therapeutic Duplication:

a) When there is therapeutic duplication, does the State require prior authorization:

Non-controlled drugs: Yes No Sometimes

If 'Yes', who obtains authorization? Pharmacist Prescriber Either

If 'No', can the pharmacist override at the point of service? Yes No

If 'Sometimes', please explain:

Controlled drugs: Yes No Sometimes

If 'Yes', who obtains authorization? Pharmacist Prescriber Either

If 'No', can the pharmacist override at the point of service? Yes No

If 'Sometimes', please explain:

Therapeutic duplication of buprenorphine products requires a prior authorization submitted by the pharmacist or prescriber.

Other therapeutic duplications may be overridden at the point of service by the pharmacist who has been instructed to submit conflict, intervention and outcome codes.

See Attachment and Table Supplement

Additional Comments:

Planned hard edits for therapeutic duplication that will be rolled out soon and require prior authorization from the prescriber, include duplicate long acting narcotics and narcotic analgesics in combination with buprenorphine.

6. State has provided DUR criteria data requested on Table 1- Prospective DUR Criteria Reviewed by DUR Board, indicating by problem type those criteria with the most significant severity levels that were reviewed in-depth by the DUR Board in this reporting period.

Yes No

7. State has included Attachment 1 – Prospective DUR Review Summary

Yes No

8. State has included Attachment 2- Prospective DUR Pharmacy Compliance Report, a report on State efforts to monitor pharmacy compliance with the oral counseling requirement.

Yes No

IV. RETROSPECTIVE DUR

1. Identify the vendor that performed your retrospective DUR activities during the time period covered by this report. (company, academic institution or other organization)

Company	MedMetrics Health Partners, an SXC Company
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- a) Is the retrospective DUR vendor also the Medicaid fiscal agent?

Yes No

- b) Is this retrospective DUR vendor also the developer/supplier of your retrospective DUR Criteria?

Yes No

If 'No', please specify:

2. Does the DUR Board approve the retrospective DUR criteria supplied by the criteria source?

Yes No

3. State has provided the DUR Board approved criteria data requested on Table 2 – Retrospective DUR Approved Criteria

Yes No

4. State has included Attachment 3 - Retrospective DUR Screening and Intervention Summary Report

Yes No

V. PHYSICIAN ADMINISTERED DRUGS

The Deficit Reduction Act requires collection of NDC numbers for covered outpatient physician administered drugs. These drugs are paid through the physician and hospital programs. Has your MMIS been designed to incorporate this data into your DUR criteria for both ProDUR and RetroDUR?

Yes No

If 'No', when do you plan to include this information in your DUR criteria?

01-01-2014

Comments:

Our MMIS is separate from our POS claims processing system, which cannot accommodate medical claims. Therefore, we do not believe we can accomplish ProDUR Edits until we implement our new MMIS system in 2014. However, we are evaluating whether we can incorporate HCPCS pharmacy claims into our RetroDUR.

VI. DUR BOARD ACTIVITY

1. State has included a summary report of DUR Board activities and meeting minutes during the time period covered by this report as Attachment 4.- Summary of DUR Board Activities

Yes No

2. Does your State have a Disease Management Program?

Yes No

If 'Yes', is your DUR Board involved with this program?

Yes No

3. Does your State have a Medication Therapy Management Program?

Yes No

If 'Yes', is your DUR Board involved with this program?

Yes No

VII. GENERIC POLICY AND UTILIZATION DATA

1. State has included a description of new policies used to encourage the use of therapeutically equivalent generic drugs as Attachment 5 - Generic Drug Substitution Policies

Yes No

2. Indicate the generic utilization percentage for all covered outpatient drugs paid during this reporting period, using the computation instructions in Table 3 - Generic Drug Utilization

Generic claims	922174	(Non-Innovator Multiple-Source (N))
Total claims	1395139	(Single-Source (S) + Non-Innovator Multiple-Source (N) + Innovator Multiple-Source (I))
Generic Utilization Percentage	66	% (Generic claims % Total claims * 100)

3. Indicate the percentage dollars paid for generic covered outpatient drugs in relation to all covered outpatient drug claims paid during this reporting period using the computation instructions in Table 3 – Generic Drug Utilization

Generic Dollars	19146213	(Non-Innovator Multiple-Source (N))
Total Dollars	117776972	(Single-Source (S) + Non-Innovator Multiple-Source (N) + Innovator Multiple-Source (I))
Generic Expenditure Percentage	16	% (Generic claims % Total claims * 100)

4. Generic Drug Utilization: State Specific Considerations

- a. Do you prefer certain brand drugs over their generic counterparts due to the net cost of the drugs after rebates?

Yes No

Adjusted Generic Utilization Percentage (if available):

- b. Are your Fee-for-service population and drug usage mix impacted by the existence of managed care pharmacy?

Yes No

- c. Do you require or allow the dispensation of a larger days supply for certain generic drugs or require a shorter days supply for certain brand drugs?

Yes No

- d. Do you have a limit on the number of total prescriptions or number of brand prescriptions that a member can receive?

Yes No

- e. Are your member co-pays equal between brand and generic drugs? (e.g. \$3 each or \$0 each)

Yes No

- f. Do you have statutory limitations or program policies which preclude management of select therapeutic classes or certain drugs? (e.g. narrow therapeutic index drugs, mental health drugs, HIV drugs)

Yes No

Other (Please describe below. 2500 Character limit)

Vermont statute requires coverage of Oncology drugs regardless FDA approved indications. For HIV and AIDS-related medications used by individuals with HIV or AIDS, the preferred drug list and any utilization review procedures shall not be more restrictive than the drug list and the application of the list used for the state of Vermont AIDS medication assistance program.

VIII. PROGRAM EVALUATION/COST SAVINGS

1. Did your State conduct a DUR program evaluation/cost savings estimate?

Yes No

2. Who conducted your program evaluation/cost savings estimate? (company, academic institution , other institution)

Company

MedMetrics Health Partners, an SXC Company

3. State has provided the Medicaid program evaluations/cost savings estimates as Attachment 6 – Cost Savings Estimate

Yes No

4. Please state the Estimated net savings amount. \$

31389305

5. Estimated percent impact of your state's cost savings program compared to total drug expenditures for covered outpatient drugs.

Estimated Net Savings Amount / Generic Utilization Data total
 Dollar Amount * 100 = 26

IX. FRAUD, WASTE AND ABUSE DETECTION

1. Do you have a process in place that identifies potential fraud or abuse of controlled drugs by recipients ?

Yes No

If 'Yes', what action(s) do you initiate? Check all that apply.

- a. Deny claim, and require pre-authorization
- b. Refer recipient to lock-in program
- c. Refer to Medicaid Fraud Control Unit (MFCU) or Program Integrity
- d. Other - Please explain

(a) Prior authorization is required when quantity limits are exceeded (especially on long acting narcotics and short acting narcotics in combination with acetaminophen)
 (b) Recipients can be locked in to prescribers, pharmacies or both
 (d) Referrals are also made to law enforcement.

2. Do you have a process in place that identifies possible fraud or abuse of controlled drugs by prescribers ?

Yes No

If 'Yes', what action(s) do you initiate? Check all that apply.

- a. Deny claims written by this prescriber
- b. Refer to MFCU or Program Integrity
- c. Refer to the appropriate Medical Board
- d. Other - Please explain

(a) Prescribers may be removed from our network so claims will be denied.
(d) A record review may be undertaken.

3. Do you have a process in place that identifies potential fraud or abuse of controlled drugs by pharmacy providers ?

Yes No

If 'Yes', what action(s) do you initiate? Check all that apply.

- a. Deny claim
- b. Refer to MFCU or Program
- c. Refer to Board of Pharmacy
- d. Other - Please explain

(d) A record review may be undertaken.

4. Does your State have a Prescription Drug Monitoring Program (PDMP)? See Attachment 7
Prescription Drug Monitoring Program for a description of this program.

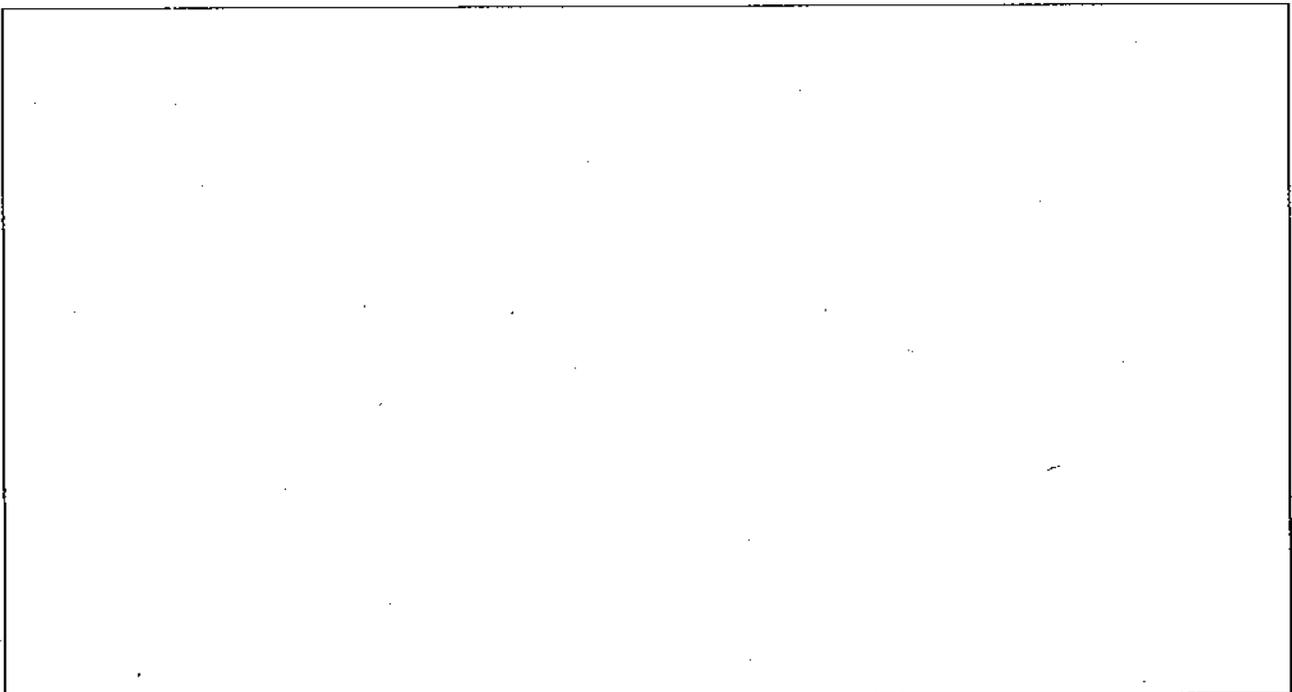
Yes No

If 'Yes', please explain how the State applies this information to control fraud and abuse.

State staff are currently not allowed access to the information in Vermont's PDMP which is called the Vermont Prescription Monitoring System (VPMS). Only physicians and pharmacists with direct care responsibilities are able to view the information. It is expected that prescribers and pharmacies use this regularly. It is a requirement for providers in our Buprenorphine Capitated program to view the VMPS for each beneficiary for whom they prescribe buprenorphine.

If 'No', does your State plan to establish a PDMP?

Yes No



X. INNOVATIVE PRACTICES

1. Have you developed any innovative practices during the past year which you have included in Attachment 8 – Innovative Practices

Yes No

XI. E-PRESCRIBING

1. Has your State implemented e-prescribing?

Yes No

If 'Yes', please respond to questions 2 and 3 below.

If 'No', are you planning to develop this capability?

Yes No

2. Does your system use the NCPDP Origin Code that indicates the prescription source?

Yes No

3. Does your program system (MMIS or pharmacy vendor) have the capability to electronically provide a prescriber, upon inquiry, patient drug history data and pharmacy coverage limitations prior to prescribing?

Yes No

- a) If 'Yes', do you have a methodology to evaluate the effectiveness of providing drug information and medication history prior to prescribing?

Yes No

- b) If 'Yes', please explain the evaluation methodology in Attachment 9 – E-Prescribing Activity Summary.

Yes No

- c) If 'No', are you planning to develop this capability?

Yes No

XII. EXECUTIVE SUMMARY

The Vermont pharmacy best practices and cost control program was authorized in 2000 and established in SFY 2002 by Act 127. This program, as the Vermont Health Access Pharmacy Benefits Management (PBM) Program, is administered by the DVHA.

Central to this program is the Drug Utilization Review Board (composed of physicians and pharmacists) which also serves as the program's Pharmacy and Therapeutics (P&T) Committee.

The goal of the program and the DUR Board is to ensure that clinically appropriate, cost-effective drug therapy is provided to the beneficiaries of the State of Vermont's publicly funded programs. In difficult economic times, this is particularly important, so that these same benefits can be provided to the ever increasing number of beneficiaries.

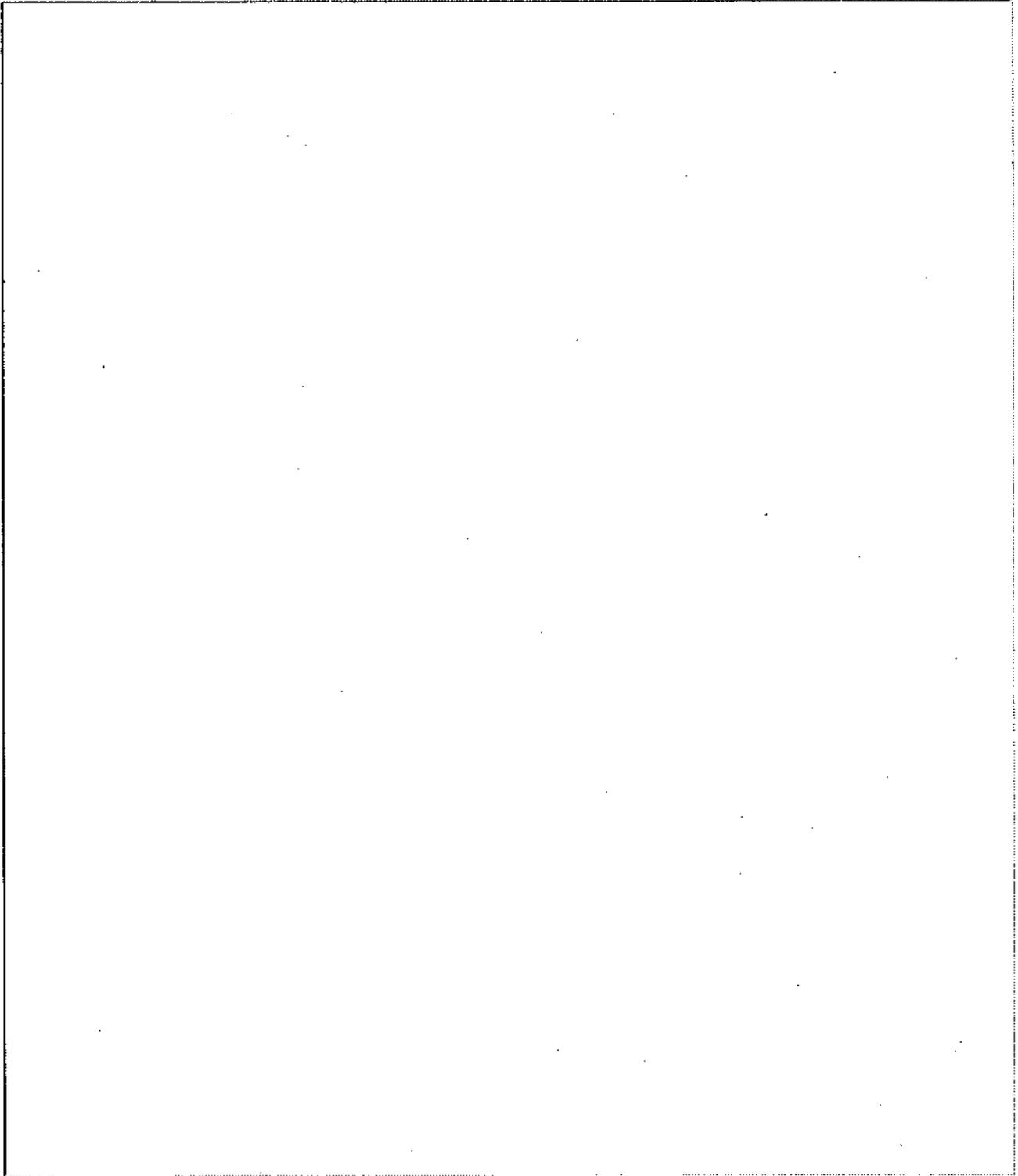
The DUR Board focused on high-cost, high volume medications during FFY 2010 and was particularly active in the areas of buprenorphine (Suboxone/Subutex) and antipsychotic prescribing.

As a result of the ProDUR and RetroDUR review activities of the DUR Board as well as the establishment of clinical criteria and quantity limits for newly reviewed medications, DVHA's PBM MedMetrics' Clinical Call Center is responsible for issuing prior authorization (PA) approval and quantity limit (QL) approval prior to the dispensing of a drug.

The MedMetrics Clinical Call Center processed a total of 28,699 work volume requests October 2009 through September 2010 for DVHA. There were 22,738 clinical requests and 5,961 help desk/informational type requests. Of the 22,738 clinical requests 17,244 were approved, 4,729 were denied and 765 were denied with a change in therapy resulting in an overall approval rate of 79%. The breakdown of clinical requests was 18,689 PA requests and 2,430 QL requests.

The Drug Utilization Review Board met 9 (nine) times in FFY2010. Results of Prospective and Retrospective Drug Utilization reviews are outlined in earlier sections of this report.

Executive Summary contd.



ATTACHMENT AND TABLE SUPPLEMENT

I. ATTACHMENTS

ATTACHMENT 1 - PRODUR REVIEW SUMMARY

This attachment is a year-end summary report on prospective DUR screening. It should be limited to the **Top 20** type/drug combinations which generate the largest number of messages. For each problem type/drug combination included, a denominator must be reported. The denominator is the total number of prescription claims adjudicated (during a given time period) for the drug compared to the number of messages generated for the problem type/drug (incorrect dosage/drug) during the same time period. Denominators permit comparison in percentage terms of the relative frequency of different problem type/drug combinations. For problem type/drug combinations involving more than one drug (e.g., drug/drug interactions), the denominator is the number of prescription claims for the drug submitted for adjudication.

Include for the **Top 20 problem type/drug alerts** with a severity of Level 1:

- * The number of messages generated by the system and a denominator. The number of messages must relate to problem type/drug combinations (incorrect dosage/drug). Report levels of messages by problem type only, incorrect dosage or drug only are not acceptable.
- * The number of messages overridden (i.e., adjudication process carried through to completion even though a message was generated). **
- * The number of reversals/cancellations/denials (i.e., adjudication not carried through to completion) and data on types of interventions by pharmacists and the outcomes of such interventions using applicable NCPDP standards (e.g. Standard Format Version 5.1).
- * The number of refill too soon messages, duplicate prescription messages transmitted and, where applicable, claims denials.

Attachment Name:	Attachment 1_ProDUR and Clinical Call Center Overview.pdf
Description	Top 20 problem type/drug alerts with ProDur savings. Clinical Call Center Overview

ATTACHMENT 2 - PRODUR PHARMACY COMPLIANCE REPORT

This attachment reports the monitoring of pharmacy compliance with all prospective DUR requirements performed by the State Medicaid agency, the State Board of Pharmacy, or other entity responsible for monitoring pharmacy activities. If the State Medicaid agency itself monitors compliance with these requirements, it may provide a survey of a random sample of pharmacies with regard to compliance with the OBRA 1990 prospective DUR requirement. This report details State efforts to monitor pharmacy compliance with the oral counseling requirement. This attachment should describe in detail the monitoring efforts that were performed and how effective these efforts were in the fiscal year reported.

Attachment Name:	Attachment 2_Administrative Rules Vermont Board of Pharmacy.PRODUR and Patient Counselling.pdf
Description	Vermont Board of Pharmacy Rules for Oral Counselling Requirement. Description of responsibilities around these requirements.

ATTACHMENT 3 - RETRODUR SCREENING AND INTERVENTION SUMMARY REPORT

This is a year-end summary report on retrospective DUR screening and interventions. Separate reports on the results of retrospective DUR screening and on interventions are acceptable at the option of the State.

The report(s) should:

- * Report the level of criteria exceptions by drug class (or drugs within the class) and problem type. (An exception is an instance where a prescription submitted for adjudication does not meet the DUR Board-approved criteria for one or more problem types within a drug class.)

NOTE: a) Reporting levels of criteria exceptions by only drug class (drug) or problem type is not acceptable.
 b) Year end summary reports should be limited to the **Top20** problem types with the largest number of exceptions.

- * Include a denominator for each drug class/problem type for which criteria exceptions are reported. A denominator is the number of prescription claims adjudicated for a drug class (or individual drugs in the class) during a given time period compared to the number of criteria exceptions for the drug class (or individual drugs in the class) during that time period.
- * Also report, for each drug class/drug and problem type included in this summary report, the number of interventions (letters, face-to-face visits, etc.) undertaken during the reporting period.
- * States which engage in physician, pharmacy profile analysis (i.e., review prescribing or dispensing of multiple prescriptions for multiple patients involving a particular problem type or diagnosis) or engage in patient profiling should report the number of each type of profile (physician, pharmacy, patient) reviewed and identify the subject(s) (diagnosis, problem type, etc.) involved.

Attachment Name:	Attachment 3_Retrospective DUR Screening and Interventions.pdf
Description	Retrospective DUR evaluations performed during FFY 2010

ATTACHMENT 4 - SUMMARY OF DUR BOARD ACTIVITIES

This summary should be a brief descriptive report on DUR Board activities during the fiscal year reported.

- * Indicate the number of DUR Board meetings held.
- * List additions/deletions to DUR Board approved criteria.
 - a. For prospective DUR, list problem type/drug combinations added or deleted.
 - b. For retrospective DUR, list therapeutic categories added or deleted.
- * Describe Board policies that establish whether and how results of prospective DUR screening are used to adjust retrospective DUR screens. Also, describe policies that establish whether and how results of retrospective DUR screening are used to adjust prospective DUR screens.
- * Describe DUR Board involvement in the DUR education program. (e.g., newsletters, continuing education, etc.) Also, describe policies adopted to determine mix of patient or provider specific intervention types (e.g., letters, face to face visits, increased monitoring).

Attachment Name:	Attachment 4_DUR Board Activity Summary FFY2010.pdf
Description	DUR Board Activity Summary DUR Board Minutes

ATTACHMENT 5 – GENERIC DRUG SUBSTITUTION POLICIES

Describe any policies used to encourage the use of generic drugs such as State maximum/minimum allowable cost (pricing, higher dispensing fee for generic and/or lower co-pay for generics). Include relevant documentation.

Attachment Name:	Attachment 5_Vermont Statutes and PDL Management.Generic Substitution.pdf
Description	Vermont Statutes regarding mandatory generic Generic drug categories on the Preferred Drug List DUR policies regarding new generics

ATTACHMENT 6 - COST SAVINGS ESTIMATE

Include copies of program evaluations/cost savings estimates prepared by State or its contractor noting the methodology used.

Attachment Name:	Attachment 6_Cost Savings Estimates FFY 2010.pdf
Description	Program Evaluations/Cost Savings Estimates for ProDUR and RetroDUR

ATTACHMENT 7 – PRESCRIPTION DRUG MONITORING PROGRAM

In FY 2002, Congress appropriated funding to the U.S. Department of Justice to support Prescription Drug Monitoring Programs (PDMPs). These programs help prevent and detect the diversion and abuse of pharmaceutical controlled substances, particularly at the retail level where no other automated information collections system exists. States that have implemented PDMPs have the capability to collect and analyze data on filled and paid prescriptions more efficiently than those without such programs, where the collection of prescription information can require a time-consuming manual review of pharmacy files. If used properly, PDMPs are an effective way to identify and prevent diversion of the drugs by health care providers, pharmacies, and patients.

Attachment Name:	Attachment 7_Vermont Prescription Monitoring System.pdf
Description	Description of Vermont Prescription Monitoring System and outline of those who may access.

ATTACHMENT 8 - INNOVATIVE PRACTICES NARRATIVE

Please describe in detailed narrative form any innovative practices that you believe have improved the administration of your DUR program, the appropriateness of prescription drug use and/or have helped to control costs. (e.g. disease management, academic detailing, automated pre-authorizations, continuing education programs).

Attachment Name:	Attachment 8_Innovative Practices.pdf
Description	<p>Spent much of FFY 2010 examining buprenorphine prescribing and utilization. Developed educational letter to send to prescribers, established "pharmacy home" for patients on buprenorphine (one pharmacy) and dosing limits as well as maximum 14 day fill. Letter sent to prescribers at end of FFY 2010. Buprenorphine is number one medication in terms of dollars and prescription volume.</p> <p>Partner with AHEC (Area Health Education Programs) from the University of Vermont and their Vermont Academic Detailing Program.</p>

ATTACHMENT 9 – E-PRESCRIBING ACTIVITY SUMMARY

Please describe all development and implementation plans/accomplishments in the area of e-prescribing. Include any evaluation of the effectiveness of this technology (e.g. number of prescribers e-prescribing, percent e-prescriptions to total prescriptions, relative cost savings).

Attachment Name:	Attachment 9_ePrescribing Activity Report.pdf
Description	Current percentage of prescriptions received electronically and future plans for expansion.

TABLE I

Prospective DUR Criteria Reviewed by Board

* TC - Therapeutic Category

Problem Type	AHFS TC (Level 2)	AHFS TC (Level 6)	AHFS TC (Level 6)	Drug Name	Disease	Criteria Implemented
Drug Disease	Central Nervous System Agents	Anorexigenics & Resp & Cereb Stimulants	All	sibutramine (Meridia)	cardiovascular disease	Y
Contraindication	Central Nervous System Agents	Analgesics and Antipyretics	Opiate Agonists	tramadol		Y
Inappropriate Dose	Central Nervous System Agents	Psychotherapeutic Agents	All	Olanzapine (Zyprexa)	Use in adolescents	Y
Other	Miscellaneous Therapeutic Agents	Immunosuppressive Agents	All	natalizumab (Tysabri)	Multiple sclerosis, crohn's	Y
Inappropriate Duration	Blood Formation, Coagulation & Thrombosis		Platelet-Aggregation Inhibitors	clopidogrel/omeprazole		Y

TABLE II

Retrospective DUR Board Approved Criteria

KEY

DD = Insufficient Dose	DDI = Drug/Drug Interaction	DD = Increased Duration
OU = Over Utilization	AG = Appropriate Use of Generics	OU = Over Utilization
DD = Inappropriate Duplication	DDC = Drug Disease Contraindication	OU = Appropriate Dosing
O2 = Appropriate Indication/Diagnosis	O3 = Drug/Age Advisory	

Drug Problem Type

* IC - Therapeutic Category

Therapeutic Category	AHES-IC (Level 1)	AHES-IC (Level 2)	AHES-IC (Level 3)	ID	IDU	OU	DD	DDC	DD	AG	O1	O2	O3
Central Nervous System Analgesics and Agents			Opiate Agonists			Y			Y				
Central Nervous System Analgesics and Agents			Opiate Partial Agonists			Y			Y			Y	
Miscellaneous Therapeutic Agents			All			Y			Y			Y	
Central Nervous System Psychotherapeutic Agents			Anorexigenics & Resp & Cereb. Stim, Misc			Y			Y			Y	Y
Gastrointestinal Drugs			Proton-pump Inhibitors			Y							Y

On-Line POS ProDUR Top 20 Encounters by Problem Type (October 2009 - September 2010)

Drug - Drug Interactions (DDI)												
Submitted Drug Name	Diagnosis Description	History - Drug Name	Total Claim Count	Total Alerts	Number Paid	\$ Amt Paid	Number Reversed	\$ Amt Reversed	Number Rejected	\$ Amt Rejected	ProDUR \$ Savings	
WARFARIN	N/A	SIMVASTATIN	12,041	4,928	4,272	\$39,664.36	169	\$1,458.07	487	\$5,177.12	\$6,635.19	
SIMVASTATIN	N/A	WARFARIN	42,825	3,842	3,380	\$31,911.77	70	\$905.20	392	\$3,686.27	\$4,591.47	
WARFARIN	N/A	LEVOTHYROXINE	9,738	2,625	2,220	\$18,002.53	103	\$852.08	302	\$2,206.95	\$3,059.03	
LEVOTHYROXINE	N/A	WARFARIN	32,024	1,786	1,549	\$13,387.21	48	\$660.64	189	\$1,470.10	\$2,130.74	
RISPERIDONE	N/A	FLUOXETINE HCL	12,115	1,753	1,429	\$123,744.27	77	\$13,801.33	247	\$25,772.50	\$39,573.83	
TRAMADOL HCL	N/A	CITALOPRAM	15,416	1,693	1,421	\$15,204.89	61	\$703.04	211	\$1,975.91	\$2,678.95	
METHADONE HCL	N/A	CLONAZEPAM	6,351	1,616	1,219	\$18,528.70	18	\$446.69	379	\$1,209.65	\$1,656.34	
FLUOXETINE HCL	N/A	RISPERIDONE	21,247	1,603	1,376	\$34,166.33	57	\$1,340.31	170	\$3,201.68	\$2,573.63	
CLONAZEPAM	N/A	DIVALPROEX	42,772	1,411	1,200	\$13,970.54	50	\$750.44	161	\$1,823.19	\$4,541.97	
DILTIAZEM HCL	N/A	SIMVASTATIN	3,794	1,408	1,220	\$33,938.14	39	\$1,540.66	149	\$5,951.23	\$7,491.91	
SIMVASTATIN	N/A	DILTIAZEM HCL	40,346	1,363	1,203	\$12,096.52	30	\$406.28	130	\$1,600.95	\$2,007.23	
TRAMADOL HCL	N/A	DULOXETINE HCL	15,052	1,329	1,139	\$17,997.48	42	\$1,379.96	148	\$2,027.02	\$3,406.98	
CLONAZEPAM	N/A	METHADONE HCL	42,841	1,280	1,121	\$10,569.69	26	\$642.39	133	\$1,341.22	\$1,983.61	
TRAMADOL HCL	N/A	SERTRALINE HCL	14,995	1,272	1,127	\$10,931.31	28	\$243.91	117	\$1,481.76	\$1,725.67	
CYCLOBENZAPRINE HCL	N/A	DULOXETINE HCL	16,005	1,258	1,042	\$9,642.36	40	\$379.08	176	\$1,171.26	\$1,550.34	
DIVALPROEX	N/A	CLONAZEPAM	8,922	1,251	897	\$113,765.94	87	\$18,721.79	267	\$17,553.77	\$36,275.56	
FENOFIBRATE	N/A	SIMVASTATIN	3,013	1,085	902	\$135,415.12	45	\$10,023.31	138	\$18,032.31	\$28,055.62	
TRAMADOL HCL	N/A	VENLAFAXINE HCL	14,777	1,054	914	\$12,234.98	40	\$524.24	100	\$848.56	\$1,372.80	
TRAMADOL HCL	N/A	FLUOXETINE HCL	14,733	1,010	878	\$9,656.20	27	\$322.58	105	\$995.28	\$1,317.86	
SIMVASTATIN	N/A	FENOFIBRATE	39,943	960	808	\$11,553.41	24	\$538.49	128	\$1,750.32	\$2,288.81	
											Total Top 20	\$154,917.54

Drug - Inferred Disease State Screen (DRUG - DIS)												
Submitted Drug Name	Diagnosis Description	History - Drug Name	Total Claim Count	Total Alerts	Number Paid	\$ Amt Paid	Number Reversed	\$ Amt Reversed	Number Rejected	\$ Amt Rejected	ProDUR \$ Savings	
BUPROPION HCL	DX:CONVULSIVE DIS	N/A	20,321	5,103	4,355	\$542,556.05	297	\$46,331.77	451	\$58,627.93	\$104,959.70	
MELATONIN	DX:DEPRESSION	N/A	6,319	2,243	1,961	\$17,088.79	98	\$919.84	184	\$1,923.12	\$2,442.96	
AMPHET-DEXTROAMPH	DX:OPIATE DEPI/ABUSE	N/A	15,703	1,519	1,392	\$246,519.19	46	\$9,343.35	81	\$12,972.57	\$22,315.92	
METHYLPHENIDATE HCL	DX:ANXIETY	N/A	26,969	1,462	1,349	\$92,855.65	39	\$1,879.36	74	\$3,973.68	\$5,853.04	
BUPRENOR-NALOX	ADDERALL XR 20MG	N/A	43,796	1,070	1,005	\$122,770.30	11	\$1,163.51	54	\$5,074.48	\$6,237.99	
CLONAZEPAM	BUPROPION 150MG SR	N/A	42,373	1,012	872	\$8,055.99	48	\$356.26	92	\$921.16	\$1,277.42	
BUPRENOR-NALOX	TRAMADOL 50MG	N/A	43,581	855	791	\$98,102.90	15	\$1,534.70	49	\$6,809.10	\$8,343.80	
CLONAZEPAM	WELLBUTRIN XL 300MG	N/A	42,073	712	626	\$5,564.96	31	\$273.45	55	\$677.97	\$951.42	
CLONAZEPAM	WELLBUTRIN XL 150MG	N/A	42,014	653	551	\$4,646.54	26	\$335.56	76	\$574.19	\$909.75	
GABAPENTIN	BUPROPION 150MG SR	N/A	18,241	609	524	\$11,827.89	28	\$788.82	57	\$1,140.42	\$1,928.24	
METOCLOPRAMIDE HCL	DX:CONVULSIVE DIS	N/A	1,886	583	533	\$5,712.86	18	\$221.86	32	\$610.73	\$832.59	
PNV W/ FER - FOLIC	DX:CHF	N/A	4,312	582	501	\$7,365.26	53	\$908.44	28	\$385.07	\$1,283.51	
CYCLOBENZAPRINE HCL	ADDERALL XR 30MG	N/A	15,325	578	527	\$4,294.85	15	\$137.08	36	\$310.41	\$447.49	
BUPRENOR-NALOX	DX:OPIATE DEPI/ABUSE	N/A	43,267	541	508	\$65,478.99	12	\$2,309.26	21	\$3,246.35	\$5,555.61	
LISDEXAMFETAMINE	DX:OPIATE DEPI/ABUSE	N/A	6,669	532	493	\$54,405.96	14	\$1,340.07	25	\$3,357.05	\$4,697.12	
CITALOPRAM	MELATONIN 3MG	N/A	26,492	515	440	\$4,920.43	18	\$216.31	57	\$959.01	\$1,175.32	
BUPRENOR-NALOX	AMPHETAMINE 20MG	N/A	43,208	482	456	\$76,057.90	6	\$1,063.27	20	\$2,179.26	\$3,262.53	
TRAMADOL HCL	DX:OPIATE DEPI/ABUSE	N/A	14,160	437	383	\$4,564.35	30	\$365.02	24	\$248.77	\$613.79	
TRAZODONE HCL	MELATONIN 3MG	N/A	13,688	424	374	\$3,050.03	13	\$141.72	37	\$270.33	\$412.05	
PROPRANOLOL HCL	DX:ASTHMA	N/A	3,564	420	322	\$10,195.51	23	\$633.95	75	\$1,616.03	\$2,449.98	
											Total Top 20	\$175,961.23

On-Line POS ProDUR Top 20 Encounters by Problem Type (October 2009 - September 2010)

Dosing - Duration Screening (DOS - DUR)										
Submitted Drug Name	Total Claim Count	Total Alerts	Number Paid	\$ Amt Paid	Number Reversed	\$ Amt Reversed	Number Rejected	\$ Amt Rejected	ProDUR \$ Savings	
PEG 3350	8,724	4,943	4,297	\$126,289.90	314	\$12,434.15	332	\$10,001.35	\$22,435.50	
AMPHET-DEXTROAMPH	18,762	4,578	4,229	\$1,333,801.63	145	\$49,592.96	204	\$58,880.68	\$108,473.64	
CITALOPRAM	29,716	3,739	3,223	\$34,565.15	219	\$2,537.41	297	\$3,387.87	\$5,925.28	
METHYLPHENIDATE HCL	28,772	3,265	3,060	\$372,897.44	70	\$10,962.48	135	\$17,591.54	\$28,554.02	
BUPRENORPHINE-NALOXONE	45,912	3,186	2,891	\$287,618.03	96	\$9,093.39	199	\$17,325.26	\$26,418.67	
AMOXICILIN	31,250	2,880	2,672	\$26,480.73	136	\$1,416.59	72	\$799.48	\$2,216.07	
ESITALOPRAM OXALATE	14,762	2,585	2,270	\$377,386.26	108	\$17,430.80	207	\$38,403.39	\$55,834.19	
DULOXETINE HCL	11,952	2,583	2,215	\$323,383.02	157	\$23,744.54	211	\$34,129.81	\$57,874.35	
ZOLPIDEM TARTRATE	21,381	2,517	2,153	\$44,999.82	147	\$3,306.34	217	\$7,453.77	\$10,760.11	
AMOXICILIN & POT CLAV	10,738	2,512	2,291	\$91,129.20	143	\$7,103.97	78	\$4,150.43	\$11,254.40	
QUETIAPINE FUMARATE	17,832	2,208	1,939	\$347,407.67	99	\$28,304.16	170	\$28,774.13	\$58,078.29	
CEFEDINIR	4,910	2,104	1,955	\$206,735.22	117	\$13,730.84	32	\$2,481.73	\$16,212.57	
BUPROPION HCL	17,314	2,096	1,821	\$100,615.06	115	\$10,003.51	160	\$8,949.83	\$18,953.34	
HYDROCODONE-APAP	53,843	1,902	1,740	\$42,028.80	48	\$1,212.41	114	\$3,664.35	\$4,876.76	
LITHIUM CARBONATE	5,325	1,831	1,560	\$23,518.57	123	\$2,165.88	148	\$2,990.79	\$5,156.67	
CHOLECALCIFEROL	10,928	1,790	1,525	\$10,917.87	137	\$1,258.51	128	\$879.75	\$2,138.26	
FLUCONAZOLE	6,690	1,721	1,554	\$11,343.25	82	\$881.09	85	\$501.02	\$1,382.11	
AMITRIPTYLINE HCL	8,920	1,711	1,459	\$9,931.56	105	\$693.25	147	\$862.94	\$1,556.19	
OXYCODONE HCL	19,633	1,645	1,526	\$332,425.02	45	\$3,767.07	74	\$14,518.64	\$28,285.71	
NYSTATIN (MOUTH-THROAT)	2,561	1,532	1,414	\$20,562.65	81	\$1,340.34	37	\$502.89	\$1,843.23	
Total Top 20									\$468,229.36	

Duplicate Rx Screening (DUPRX)										
Submitted Drug Name	Total Claim Count	Total Alerts	Number Paid	\$ Amt Paid	Number Reversed	\$ Amt Reversed	Number Rejected	\$ Amt Rejected	ProDUR \$ Savings	
CLONAZEPAM	44,994	3,633	1,327	\$12,986.33	441	\$4,606.44	1,865	\$16,225.88	\$20,832.32	
LORAZEPAM	42,074	1,994	962	\$9,234.90	255	\$3,028.04	777	\$7,293.43	\$10,321.47	
BUPRENORPHINE-NALOXONE	44,682	1,956	578	\$115,055.55	16	\$1,693.49	1,362	\$204,177.51	\$205,871.00	
CITALOPRAM	27,842	1,865	246	\$3,458.71	30	\$932.26	1,589	\$24,826.78	\$25,759.04	
LEVAlBUTEROL TARTRATE	34,126	1,703	243	\$14,974.52	22	\$1,386.30	1,438	\$94,181.68	\$95,567.98	
SERTRALINE HCL	24,867	1,680	201	\$2,188.84	18	\$165.24	1,461	\$17,960.62	\$18,125.86	
LISINAPRIL	29,204	1,558	180	\$1,315.65	24	\$148.68	1,354	\$13,773.20	\$13,921.88	
LEVOTHYROXINE	31,718	1,480	181	\$3,201.26	34	\$802.41	1,265	\$27,440.93	\$28,243.34	
HYDROCODONE-APAP	53,212	1,471	248	\$3,347.73	10	\$100.61	1,213	\$16,675.57	\$16,776.18	
METHYLPHENIDATE HCL	26,976	1,469	275	\$17,200.58	16	\$939.30	1,178	\$130,600.21	\$131,539.51	
FLUOXETINE HCL	21,087	1,443	190	\$5,347.67	23	\$430.62	1,230	\$34,385.32	\$34,815.94	
QUETIAPINE FUMARATE	17,041	1,417	232	\$63,646.82	26	\$10,423.00	1,159	\$419,670.84	\$430,093.84	
SIMVASTATIN	40,364	1,381	215	\$2,611.36	42	\$763.55	1,124	\$23,494.83	\$24,258.38	
OXYCODONE W/ APAP	34,703	1,210	285	\$8,904.68	4	\$103.32	921	\$26,009.62	\$26,112.94	
TRAZODONE HCL	14,455	1,191	180	\$1,391.12	16	\$121.02	995	\$10,491.62	\$10,612.64	
CLONIDINE HCL	7,893	1,174	124	\$1,843.15	15	\$692.77	1,035	\$20,839.44	\$21,532.21	
GABAPENTIN	18,698	1,066	210	\$6,079.39	23	\$529.67	833	\$27,528.82	\$28,058.49	
OXYCODONE HCL	18,993	1,005	255	\$35,513.54	6	\$994.27	744	\$95,571.34	\$96,565.61	
OMEPRAZOLE MAGNESIUM	25,244	978	181	\$7,168.80	72	\$3,401.85	725	\$36,606.75	\$40,008.40	
ALPRAZOLAM	16,970	962	359	\$4,491.51	101	\$1,332.18	502	\$7,605.09	\$8,937.27	
Total Top 20									\$1,287,954.30	

On-Line POS ProDUR Top 20 Encounters by Problem Type (October 2009 - September 2010)

Duplicate Therapy Screening (DUP'THER)

Submitted Drug Name	Total Claim Count	Total Alerts	Number Paid	\$ Amt Paid	Number Reversed	\$ Amt Reversed	Number Rejected	\$ Amt Rejected	ProDUR \$ Savings
CLONAZEPAM	76,122	34,761	24,758	\$237,614.21	2,473	\$31,357.33	7,530	\$66,099.54	\$97,456.87
HYDROCODONE-APAP	66,237	14,496	10,296	\$124,332.14	494	\$6,696.84	3,706	\$55,615.44	\$62,312.28
LISINAPRIL	41,682	14,046	10,045	\$89,583.71	630	\$5,632.34	3,371	\$30,885.46	\$36,517.80
TRAZODONE HCL	26,164	12,900	10,062	\$87,044.82	564	\$7,522.07	2,274	\$22,959.04	\$30,481.11
CITALOPRAM	38,727	12,750	8,646	\$96,320.39	668	\$10,256.03	3,416	\$51,802.50	\$62,058.53
FLOXETINE HCL	31,545	11,901	8,417	\$180,101.92	736	\$17,431.19	2,748	\$74,224.96	\$91,556.15
SERTRALINE HCL	35,017	11,880	8,151	\$86,999.51	536	\$7,346.20	3,143	\$38,926.72	\$46,272.92
BUPRENORPHINE-NALOXONE	54,263	11,537	9,467	\$875,096.77	230	\$22,135.61	1,820	\$291,086.77	\$313,222.38
BUPROPION HCL	26,443	11,225	8,494	\$1,018,313.81	735	\$94,852.84	1,996	\$250,610.13	\$345,462.77
OXYCODONE W/ APAP	44,520	11,027	8,782	\$246,170.49	229	\$5,488.20	2,016	\$61,180.38	\$66,638.58
LORAZEPAM	50,264	10,174	8,014	\$66,897.17	641	\$6,422.36	1,519	\$14,101.85	\$20,524.21
FUROSEMIDE	23,887	9,298	7,514	\$43,066.01	362	\$2,450.61	1,422	\$11,483.49	\$13,934.10
HYDROCHLOROTHIAZIDE	24,578	8,977	6,625	\$35,372.59	363	\$2,471.36	1,989	\$12,284.34	\$14,755.70
METHYLPHENIDATE HCL	33,712	8,205	6,899	\$644,081.39	167	\$18,856.34	1,139	\$128,255.32	\$147,111.66
DIAZEPAM	22,975	8,104	6,154	\$44,614.75	496	\$3,759.45	1,454	\$13,044.37	\$16,803.82
OXYCODONE HCL	26,050	8,062	7,188	\$1,145,120.24	221	\$39,437.76	653	\$93,824.27	\$133,262.03
FLUTICASON-SALMETEROL	22,707	7,744	4,322	\$1,556,346.09	591	\$236,993.15	2,831	\$1,223,409.74	\$1,460,402.89
VENLAFAXINE HCL	22,240	7,638	6,062	\$953,066.98	516	\$102,759.89	1,050	\$207,982.86	\$310,742.75
LEVAlBUTEROL TARTRATE	40,051	7,628	5,426	\$333,817.14	454	\$29,213.06	1,748	\$107,148.60	\$136,361.66
QUETIAPINE FUMARATE	22,567	6,943	5,360	\$1,465,905.47	313	\$128,166.29	1,270	\$443,036.65	\$571,202.94
Total Top 20									\$3,977,181.15

Early Fill Screening (TOO SOON)

Submitted Drug Name	Total Claim Count	Total Alerts	Number Paid	\$ Amt Paid	Number Reversed	\$ Amt Reversed	Number Rejected	\$ Amt Rejected	ProDUR \$ Savings
BUPRENORPHINE-NALOXONE	43,921	1,195	45	\$3,989.38	2	\$96.04	1,148	\$68,331.06	\$68,427.10
CLONAZEPAM	42,390	1,029	48	\$1,174.48	3	\$22.42	978	\$4,961.08	\$5,003.50
LEVAlBUTEROL TARTRATE	33,445	1,022	62	\$3,771.23	6	\$663.93	954	\$49,732.19	\$50,396.12
TRAMADOL HCL	14,516	793	10	\$106.14	0	\$0.00	783	\$6,748.00	\$6,748.00
CITALOPRAM	26,669	692	26	\$270.16	1	\$28.44	665	\$5,355.59	\$5,384.03
OMEPRAZOLE MAGNESIUM	24,950	684	14	\$600.54	0	\$0.00	670	\$21,225.85	\$21,225.85
HYDROCODONE-APAP	52,328	587	14	\$182.00	0	\$0.00	573	\$5,347.53	\$5,347.53
GLUCOSE BLOOD	22,424	571	23	\$3,602.11	1	\$307.84	547	\$99,697.34	\$100,005.18
LORAZEPAM	40,639	559	31	\$306.21	1	\$19.55	527	\$2,764.23	\$2,773.78
GABAPENTIN	18,175	543	24	\$957.26	1	\$36.05	518	\$12,427.32	\$12,463.37
SERTRALINE HCL	23,724	537	32	\$448.33	2	\$24.90	503	\$3,968.82	\$3,991.72
ZOLPIDEM TARTRATE	19,401	537	14	\$410.62	1	\$5.86	522	\$10,193.14	\$10,199.00
BUPROPION HCL	15,739	521	16	\$1,937.85	1	\$0.00	504	\$51,524.91	\$51,524.91
FLOXETINE HCL	20,146	502	25	\$651.26	1	\$85.75	476	\$8,353.12	\$8,438.87
LORATADINE	25,865	488	6	\$65.39	0	\$0.00	482	\$3,653.72	\$3,653.72
QUETIAPINE FUMARATE	16,106	482	55	\$23,264.83	2	\$78.81	425	\$107,334.97	\$107,413.78
LISINAPRIL	28,127	481	11	\$118.52	2	\$18.49	468	\$3,184.29	\$3,202.78
SIMVASTATIN	39,461	478	16	\$294.45	0	\$0.00	462	\$6,318.20	\$6,318.20
PANTOPRAZOLE	19,464	464	14	\$5,974.38	1	\$213.37	449	\$101,151.43	\$101,364.80
LEVOTHYROXINE	30,699	461	16	\$469.99	1	\$29.05	444	\$6,909.13	\$6,938.16
Total Top 20									\$570,820.42

On-Line POS ProDUR Top 20 Encounters by Problem Type (October 2009 - September 2010)

Drug - Age Caution Screening (DRUG - AGE)										
Submitted Drug Name	Total Claim Count	Total Alerts	Number Paid	\$ Amt Paid	Number Reversed	\$ Amt Reversed	Number Rejected	\$ Amt Rejected	ProDUR \$ Savings	
PROMETHAZINE W/CODEINE	758	131	126	\$1,188.22	4	\$40.20	1	\$9.23	\$49.43	
ANTIPYRINE-BENZO-POLYCOS	85	23	14	\$902.57	3	\$179.11	6	\$950.19	\$1,129.30	
PROMETHAZINE HCL	5,976	20	17	\$148.80	2	\$13.01	1	\$4.98	\$17.99	
MINOCYCLINE HCL	1,693	9	9	\$148.35	0	\$0.00	0	\$0.00	\$0.00	
VALGANCICLOVIR HCL	100	9	7	\$3,693.06	2	\$2,478.84	0	\$0.00	\$2,478.84	
HISTRELIN ACETATE (CPP)	9	4	1	\$15,543.03	2	\$31,086.06	1	\$15,543.03	\$46,629.09	
PHENYLEPH-PROM W/ COD	40	4	4	\$38.62	0	\$0.00	0	\$0.00	\$0.00	
SPECIALTY VIT PRODUCTS	166	4	3	\$88.38	1	\$29.46	0	\$0.00	\$29.46	
PROMETHAZINE & PHENYL	11	3	1	\$10.15	1	\$10.15	1	\$10.15	\$20.30	
PROMETHAZINE-DIV	61	1	1	\$8.29	0	\$0.00	0	\$0.00	\$0.00	
Total Top 20									\$50,354.41	

Drug - Sex Caution Screening (DRUG - SEX)										
Submitted Drug Name	Total Claim Count	Total Alerts	Number Paid	\$ Amt Paid	Number Reversed	\$ Amt Reversed	Number Rejected	\$ Amt Rejected	ProDUR \$ Savings	
EFLORNITHINE HCL	138	15	7	\$482.17	2	\$131.32	6	\$0.00	\$131.32	
FINASTERIDE	1497	3	2	\$38.22	0	\$0.00	1	\$15.89	\$15.89	
Total Top 20									\$147.21	

Drug - Sex Caution Screening (DRUG - SEX)										
Submitted Drug Name	Total Claim Count	Total Alerts	Number Paid	\$ Amt Paid	Number Reversed	\$ Amt Reversed	Number Rejected	\$ Amt Rejected	ProDUR \$ Savings	
EFLORNITHINE HCL	138	15	7	\$482.17	2	\$131.32	6	\$0.00	\$131.32	
FINASTERIDE	1497	3	2	\$38.22	0	\$0.00	1	\$15.89	\$15.89	
Total Top 20									\$147.21	

SUMMARY: On-Line POS ProDUR for ALL ENCOUNTERS (October 2009 - September 2010)

Problem Type	Total Claim Count	Total Alerts	Number Reversed	Alert % Reversed	\$ Amt Reversed	Number Rejected	Alert % Rejected	\$ Amt Rejected	Total ProDUR Savings
DDI	11,525,034	117,491	4,280	3.64%	\$316,270.97	15,779	13.43%	\$696,709.03	\$1,012,980.00
DRUG - DIS	10,199,479	42,039	2,124	5.05%	\$240,755.02	3,693	8.78%	\$279,647.89	\$520,402.91
DOS - DUR	2,012,720	128,723	8,502	6.60%	\$1,584,663.36	9,480	7.36%	\$1,813,848.66	\$3,398,511.92
DUPRX	2,253,419	86,781	3,397	3.91%	\$181,065.69	65,511	75.49%	\$7,247,519.70	\$7,428,585.39
DUPRTH	2,692,490	669,437	33,442	5.87%	\$3,122,768.04	127,411	22.37%	\$11,902,737.57	\$15,025,505.61
TOO SOON	2,133,486	35,773	97	0.27%	\$9,898.03	33,998	95.04%	\$2,630,048.70	\$2,639,946.73
DRUG - AGE	8,899	208	15	7.21%	\$33,836.83	10	4.81%	\$16,517.68	\$50,354.41
DRUG - SEX	1,635	18	2	11.11%	\$131.32	7	38.89%	\$15.89	\$147.21
TOTAL	30,827,162	980,470	51,859	5.29%	\$5,489,389.26	\$255,889.00	26.10%	\$24,587,044.92	\$30,076,434.18



Vermont Clinical Call Center Total Monthly Activity Overview

Month	Oct-09	Nov-09	Dec-09	Jan-10	Feb-10	Mar-10	Apr-10	May-10	Jun-10	Jul-10	Aug-10	Sep-10	Total	YTD
Total Clinical Call Center Work Volume	2,592	2,257	2,377	2,361	2,202	2,703	2,494	2,242	2,297	2,154	2,423	2,597	28,090	28,392
Total Clinical Requests	2,017	1,774	1,884	1,864	1,716	2,129	1,918	1,791	1,813	1,710	1,972	2,150	22,156	22,656
Clinical Requests Approved	1,506	1,280	1,421	1,409	1,283	1,592	1,498	1,379	1,394	1,314	1,519	1,859	17,244	17,457
Approval Rate	75%	73%	75%	76%	74%	75%	78%	77%	77%	77%	77%	77%	77%	76%
Clinical Requests Change In Therapy	102	91	94	52	58	77	28	47	34	60	58	64	705	711
Change in Therapy Rate	5%	5%	5%	3%	3%	4%	1%	3%	2%	4%	3%	3%	3%	3%
Clinical Requests Denied	409	393	369	403	395	460	392	385	385	338	335	427	4,728	4,994
Denial Rate	20%	22%	20%	22%	23%	22%	20%	20%	21%	20%	20%	20%	21%	21%
Total Non-Clinical Requests	575	483	493	497	488	574	576	451	484	444	451	447	5,961	5,997
Performance Standard (% in 24 hours)	100%	100%	99.95%	100%	100%	99.95%	99.95%	100%	99.71%	98.94%	100%	99.90%	100%	100%

Comparison and Analysis	Oct-09	Nov-09	Dec-09	Jan-10	Feb-10	Mar-10	Apr-10	May-10	Jun-10	Jul-10	Aug-10	Sep-10	Total	YTD
Total Informational Calls	22%	21%	21%	21%	22%	21%	23%	20%	21%	21%	19%	17%	21%	21%
Quantity Limit Clinical Calls	8%	8%	9%	8%	8%	9%	10%	8%	8%	9%	9%	8%	9%	9%
Prior Authorization Clinical Calls	70%	70%	70%	71%	69%	70%	67%	72%	71%	70%	73%	75%	71%	71%

Claims by Type/Month	Oct-09	Nov-09	Dec-09	Jan-10	Feb-10	Mar-10	Apr-10	May-10	Jun-10	Jul-10	Aug-10	Sep-10	Total	YTD
Total Informational Calls	575	483	493	497	488	574	576	451	484	444	451	447	5,961	5,997
Number of Calls Resolved	575	483	493	497	488	574	576	451	484	444	451	447	5,961	5,997
Resolution Rate	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Number of Calls Pending	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pending Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Total Requests for Prior Authorizations	1,803	1,658	1,678	1,870	1,530	1,893	1,660	1,012	1,536	1,607	1,766	1,816	20,285	20,690
Requests Approved	1,327	1,139	1,242	1,251	1,118	1,407	1,281	1,244	1,242	1,165	1,347	1,497	15,290	15,712
Approval Rate	74%	72%	74%	75%	73%	74%	77%	77%	78%	77%	76%	77%	75%	75%
Requests Change in Therapy	91	79	80	45	48	48	22	33	27	39	49	53	614	611
Change in Therapy rate	5%	5%	5%	3%	3%	3%	1%	2%	2%	3%	3%	3%	3%	3%
Requests Denied	385	370	351	374	364	438	357	337	367	303	370	395	4,411	4,566
Denial Rate	21%	23%	21%	22%	24%	23%	22%	21%	22%	20%	21%	20%	22%	22%
Total Requests for Quantity Limit	211	186	211	154	181	177	177	117	177	177	177	177	2,111	2,111
Requests Approved	179	151	179	159	145	185	217	135	152	149	172	182	1,954	1,954
Approval Rate	84%	81%	85%	81%	78%	78%	84%	78%	86%	73%	83%	79%	92%	92%
Requests Change in Therapy	11	12	14	7	10	29	6	14	7	21	9	11	151	151
Change in Therapy rate	5%	6%	7%	4%	5%	12%	2%	8%	4%	10%	4%	5%	7%	7%
Requests Denied	24	23	18	20	31	22	35	28	18	33	25	32	318	318
Denial Rate	11%	12%	9%	15%	17%	9%	14%	16%	10%	16%	12%	15%	15%	15%

Prior Authorization Detail

All fractions of percentages rounded to nearest whole number

Administrative Rules Vermont Board of Pharmacy
(effective October 1, 2009)

8.15 Inspection of Drug Outlets

(a) Biennially, a Board member, a representative appointed by the Board, or an employee of or contractor with the Office of Professional Regulation, shall inspect a drug outlet in Vermont during regular business hours, for compliance with these rules. Deficiencies shall be handled in the manner set forth in Rule 7.2(l)

9.29 Prospective Drug Review

(a) A pharmacist shall review the patient record and each prescription drug order presented for dispensing for purposes of promoting therapeutic appropriateness by identifying:

- (1) Over-utilization or under-utilization;
- (2) Therapeutic duplication;
- (3) Drug-disease contraindications;
- (4) Drug-drug interactions (including serious interactions with non-prescriptive or over-the-counter drugs);
- (5) Incorrect drug dosage or duration of drug treatment;
- (6) Drug-allergy interactions; and
- (7) Clinical abuse or misuse.

(b) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the practitioner.

9.30 Patient Counseling

(a) Patient counseling is the effective oral consultation by the pharmacist, in the exercise of his or her professional judgment and consistent with state statutes and Board rules regarding confidential information, with the patient or care giver, in order to improve therapy by ensuring the proper use of drugs and devices.

(b) Upon receipt of a prescription drug order and following a review of the patient's record, a pharmacist may personally initiate discussion of matters which will enhance or optimize drug therapy with each patient or care giver of such patient. Such discussion shall be in person, whenever practicable, or by telephone and shall include appropriate elements of patient counseling. Such elements may include the following:

- (1) The name and description of the drug;
- (2) The dosage form, dose, route of administration, and duration of drug therapy;
- (3) Intended use of the drug and expected action;
- (4) Special directions and precautions for preparation, administration, and use by the patient;
- (5) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- (6) Techniques for self-monitoring drug therapy;
- (7) Proper storage;
- (8) Prescription refill information;

- (9) Action to be taken in the event of a missed dose; and
- (10) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(c) Alternative forms of patient information may be used to replace patient counseling in an emergency situation when verbal face-to-face counseling is not possible. Alternative forms of patient information may be used to supplement patient counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(d) Each pharmacy shall post a notice advising, "You have the right to confidential consultation with a pharmacist about your prescription. If you wish, a confidential consultation will be provided."

(e) Patient counseling, as described above and defined in these rules, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s).

(f) A pharmacist shall not be required to counsel a patient or care giver when the patient or care giver refuses such consultation and such refusal is documented.

VT Medicaid does not actively monitor pharmacy compliance with the oral patient counseling requirements. In addition, the Office of Professional Regulation is a "complaints driven" entity and so that office does not affirmatively go out and monitor or inspect for compliance with the oral counseling requirement.

Retrospective Drug Utilization Review (RetroDUR) Program FFY2010

The goal of the Vermont RetroDUR Program is to promote appropriate prescribing and use of medications. RetroDUR identifies prescribing, dispensing, and consumption patterns which are clinically and therapeutically inappropriate and do not meet the established clinical practice guidelines. A variety of interventions are then employed to correct these situations. MedMetrics' RetroDUR program takes a multilevel approach to identifying, filtering, and communicating important information pertaining to the prescribing and/or consumption of medications. It is an approach that analyzes patterns of utilization at a patient-specific level, as well as the unique prescribing habits and the pharmaceutical care provided by the physician.

All levels of the retrospective DUR process, including the development of the clinical review criteria, the content of the alert letters, and the clinical monographs and questionnaires, are produced by MedMetrics-affiliated professional staff and registered pharmacists. The initiative's criteria as well as research and compilation of data are reviewed and approved by consensus of Vermont's DUR board.

Most medications and therapeutic classes chosen for retrospective drug utilization review in FFY2010 require prior authorization in all cases and so numbers of exceptions to criteria are not calculated.

MHP/DVHA – Retrospective DUR Summary (FFY 2010)

Description
Follow up analyses from FFY 2009 report: <ul style="list-style-type: none"> • Buprenorphine (Suboxone/Subutex) – ongoing review of utilization • Specialty Pharmacy -- ongoing evaluation • Provigil –update of utilization for dose • Synagis – evaluation of new AAP guidelines adopted and PA request review • Medicare Part D Wrap Program – PPI/Statin (1/2010)
Xolair – review of PA requests and utilization (12/2009)
Lunesta – review of PA requests and utilization (1/2010)
Amitiza – review of utilization and PA request (5/2010)
Antipsychotics – prescribing by provider type/specialty, Seroquel dosing (5/2010)
Topical Immunomodulators – duplicate therapy (6/2010)
Duplicate Therapy with Long Acting Narcotics (6/2010)
Mental Health Medication Use in Children

Follow up analyses performed in FFY 2010 from FFY 2009 CMS report DUR activities:

1. Prescribing of buprenorphine – ongoing utilization review

Background and Overview (*initial RetroDUR analysis detailed in FFY 2008 CMS report, first follow-up analysis detailed in FFY 2009 CMS report*)

- Buprenorphine (Subutex) and buprenorphine/naloxone (Suboxone) are FDA approved for the pharmacological treatment of opioid addiction. Off-label use for the treatment of pain may also occur if PA criteria are not in place. Buprenorphine/naloxone is the preferred agent as it is less abusable than buprenorphine alone. There are certain situations (such as pregnancy) when buprenorphine “mono” may be preferred.
- Clinical criteria and a PA form for Suboxone and Subutex were presented and initially adopted at the November 2007 DUR Board meeting.
- Quantity limits of 3 tablets per day (all strengths of both Subutex and Suboxone) were adopted effective June 1, 2009 in an effort to encourage dose consolidation and limit maximum daily doses. Prescribers requesting to exceed the quantity limit were asked to outline a tapering dose plan for their patient.
- Prescribers requesting Subutex (rather than Suboxone) for patients due to Suboxone allergy now asked to verify that the allergic reaction was witnessed by a healthcare professional.

Methods

- Buprenorphine utilization is tracked and graphed on a monthly basis and was an agenda topic at 5 of the DUR Board meetings in FFY 2010.
- Daily dose and days' supply were examined for the period 3/10/2010 – 5/10/2010.
- Subutex PAs for the time period 3/31/2009 – 4/21/2010 were examined.
- Cost savings opportunities related to reducing daily dose were calculated and presented.

Results

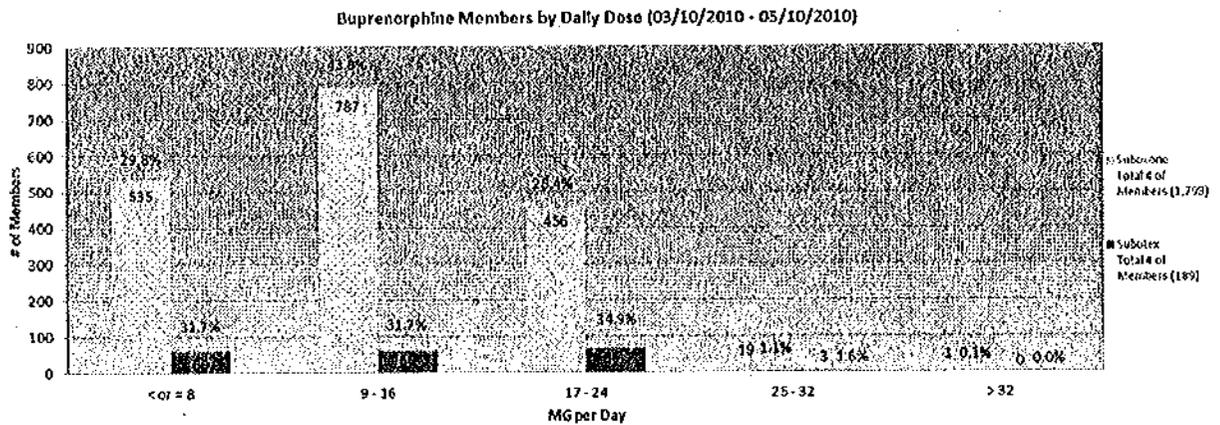
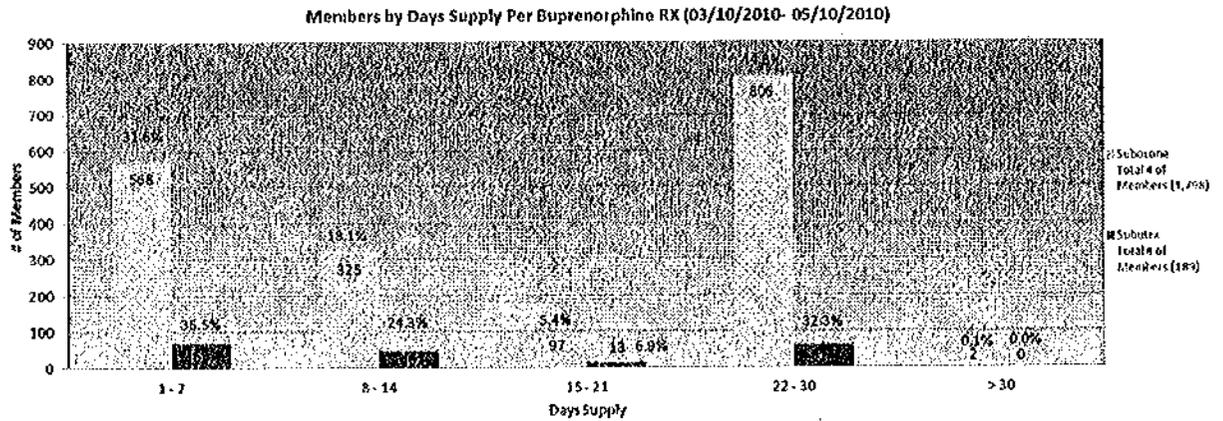
- Suboxone is consistently the top drug (of all drugs in all classes) by both prescription volume and prescription payment as reported on a quarterly basis.
- The percentage of unique utilizers receiving Subutex (of combined Subutex/Suboxone use) has stabilized at 9.31 % as of September 2010. The total unique utilizer count increased from 1674 members in October 2009 to 1773 members in September 2010. The total plan paid amount for the combined Suboxone and Subutex increased from \$ 627,918.12 in October 2009 to \$ 678,298.69 in September 2010.
- The percentage of utilizers with doses per day of ≤ 8 mg, 9 – 16 mg, 17 – 24 mg, 25 – 32 mg or > 32 mg was 29.8%, 43.8%, 25.4%, 1.1% and 0.1% for Suboxone[®] and 31.7%, 31.7%, 34.9%, 1.6% and 0% for Subutex[®] respectively. The percentage of utilizers with days supply per prescription of 1 – 7, 8 – 14, 15 – 21, 22 – 30 or > 30 days were 31.6%, 18.1%, 5.4%, 44.8% and 0.1% for Suboxone[®] and 36.5%, 24.3%, 6.9%, 32.3% and 0% for Subutex[®] respectively.
- If all prescriptions were reduced to 16 mg/day, greater than 1 million dollars could be saved on an annual basis.
- A follow-up RetroDUR will be performed and will be presented in the FFY 2011 CMS Report to track ongoing utilization.

The DVHA DUR board elected to:

- Limit days supply to a maximum of 30 days effective 3/16/2010.
Effective 10/25/2010 (as voted on 5/18/2010)
- Prescriber encouraged to query Vermont Prescription Monitoring System when requesting PA.
- A “pharmacy home” must be selected for buprenorphine patients where all prescriptions will be filled.
- PA requests for Subutex due to pregnancy must be accompanied by a history from the OB Provider.

- PA requests for Subutex due to breastfeeding a methadone dependent baby must be accompanied by a baby history from the neonatologist or pediatrician.
- Quantity limit on Subutex reduced to 16 mg/day.
- Maximum days supply reduced to 14 days.
- PA form required to be faxed rather than requests processed over the phone.

A mailing was sent to all 167 prescribers who had recently prescribed a buprenorphine product. Of these, 31 prescribers received a patient roster of patients that were being prescribed greater than the new maximum dosing. In all, 89 patients were identified who were being prescribed in daily doses greater than the newly established maximums.



**Review of Subutex PA Approvals 3/31/2009 through 4/21/2010
(Note: Patients may be counted twice if PA expired during year)**

	Pregnancy	Breastfeeding Methadone Dependent Baby	Allergy/Intolerance	Total
Approved by MedMetrics Clinical Call Center	270	15	31	316
Approved Second Reconsideration by OVHA Medical Director			22	22
Total	270	15	53	338
Percentage of Approvals	79.9 %	4.44 %	15.66 %	100 %

Potential Cost Savings Scenario for Buprenorphine

Data Includes All DVHA Claims for Suboxone & Subutex

Annualized Cost Savings Based on Utilization in Service Period 03/10/10 to 05/10/10

	Suboxone	Subutex
All Doses > 24 mg/Day reduced to 24 mg/day	\$37,251.30	\$5,847.24
All Doses > 16 mg/Day reduced to 16 mg/day	\$870,473.94	\$176,195.10
 Incremental Cost Savings (All dose > 16 mg/day but ≤ 24 mg/day reduced to 16 mg/day)	 \$833,222.64	 \$170,347.86

2. Specialty Pharmacy

Background and Overview (initial RetroDUR analysis detailed in FFY 2009 CMS report)

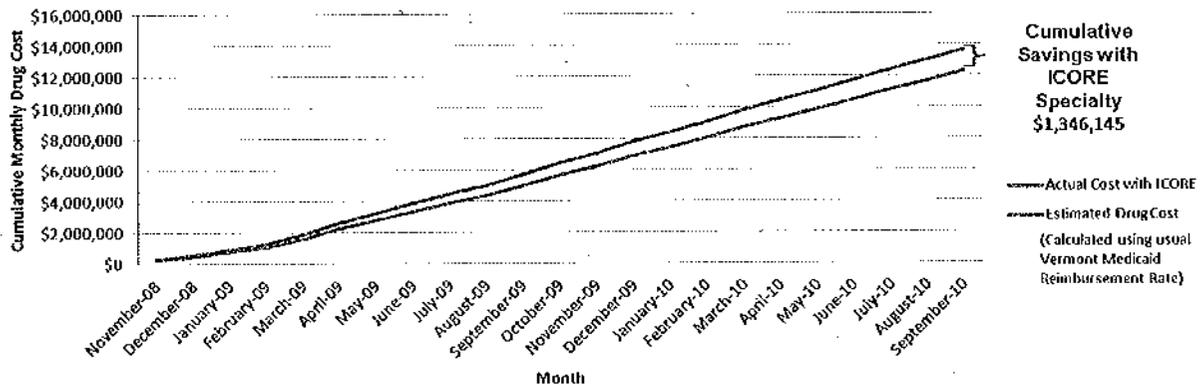
- In October 2008, two specialty pharmacies were selected to serve Medicaid beneficiaries: Wilcox Home Infusion and ICORE Healthcare, LLC, partnering with our pharmacy benefits manager, MedMetrics Health Partners. Wilcox Medical is the specialty pharmacy for Synagis[®] and ICORE Healthcare/MedMetrics is the specialty pharmacy for all other products. Dispensing of identified specialty medications is limited to these pharmacies for Medicaid beneficiaries where Medicaid is the primary insurer.
- The partnership of MedMetrics and ICORE assures the coordination of our pharmacy benefit management initiatives with our specialty pharmacy approach.
- Medications included in this program include Synagis, hemophilia factors, growth hormones, multiple sclerosis self-injectables, hepatitis C (ribavirin and injectables) treatments, self-injectables for rheumatoid arthritis, psoriatic arthritis, juvenile arthritis, psoriasis, Crohn's Disease and ankylosing spondylitis as well as Pulmozyme[®] and Tobin[®] for cystic fibrosis patients.
- In FFY 2010, select oral oncology medications were also added (October 2009).

Methods

- The cost savings realized by mandating dispensing through our specialty pharmacy vendors compared to the usual retail pharmacy rate was calculated.

Results

- In FFY 2010 (October 2009 through September 2010), savings were \$613,454 as compared to the first 11 months of the Specialty Drug Program (November 2008 through September 2009) when savings were \$732,691.
- Effective July 2009, reimbursement on drugs subject to AWP pricing moved from AWP less 11.9% to AWP less 14.2% plus a dispensing fee. Consequently, the relative savings achieved from the specialty pharmacy program were not as great going forward as would have been realized if the rate paid to retail pharmacies had not decreased.
- We believe that additional savings were realized by promotion of the preferred drugs within each drug class, although we have not been able to calculate this number. With a preferred specialty pharmacy vendor relationship, the specialty pharmacy is compelled to adhere more strictly to preferred product selections.



3. Provigil (initial RetroDUR analysis detailed in FFY 2009 CMS report)

Background and Overview

- Provigil® (modafinil) was first approved by the FDA in 1998 for the treatment of excessive sleepiness associated with narcolepsy. In 2003, the labeling for modafinil was expanded to include approval for the treatment of excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome (OSAHS) as adjunct to standard therapy and for the treatment of shift work sleep disorder (SWD). Modafinil is available by prescription only and has been classified as a schedule IV drug due to its potential for abuse.
- For all three approved indications, the recommended starting dose is 200 mg once daily and the maximum recommended dose is 400 mg daily.
- Although not FDA approved for these indications, the use of modafinil for the treatment of attention deficit/hyperactivity disorder (ADHD), fatigue associated with Multiple Sclerosis (MS) and excessive sleepiness associated with the treatment of major depressive disorder (MDD) and schizophrenia has been studied in clinical trials and is often seen in clinical practice.

Methods

- Due to the numerous potential off-label uses of Provigil[®], a retrospective drug utilization analysis was performed in January 2009 to review utilization and to evaluate the appropriateness of current prior authorization (PA) procedures.
- During this review it was discovered that several patients were receiving daily doses of 600 mg or 800 mg per day.
- The DUR Board voted to establish quantity limits for Provigil 100mg tablets of 45/30 days and Provigil 200 mg tablets of 60/30 days. Prescribers of current users were required to obtain PA for quantity limit overrides though no patient was denied the higher dose if previously established.
- A subsequent review was performed to look at high dose users and plan cost in total for Provigil[®].

Results

- Several of the previously identified patients remain on high dose Provigil as the prescriber does not wish to titrate the dose down and risk patient destabilization.
- While the number of unique utilizers and paid claims has decreased, the average cost per prescription has increased significantly due to a 36 % increase in AWP. Consequently, no significant cost savings were achieved but total plan cost increases were avoided.

Provigil[®]: Unique Utilizers, Paid Claims, Average Cost per Prescription and Total Monthly Plan Cost from January 1, 2008 to December 31, 2008.

	1/2008	2/2008	3/2008	4/2008	5/2008	6/2008
Unique Utilizers	102	91	109	88	114	104
Paid Claims	120	103	127	105	122	114
Avg. \$/RX	\$359.21	\$380.33	\$382.14	\$443.01	\$424.89	\$439.16
Plan Cost \$	\$43,105.30	\$39,173.55	\$48,531.21	\$46,516.37	\$51,835.97	\$50,064.59
	7/2008	8/2008	9/2008	10/2008	11/2008	12/2008
Unique Utilizers	103	104	98	100	96	95
Paid Claims	121	124	115	108	109	115
Avg. \$/RX	\$416.72	\$444.77	\$476.20	\$451.77	\$437.77	\$459.12
Plan Cost \$	\$50,422.90	\$55,151.60	\$54,763.38	\$48,790.95	\$47,716.94	\$52,798.26

Provigil[®]: Unique Utilizers, Paid Claims, Average Cost per Prescription and Total Monthly Plan Cost from October 1, 2009 to September 30, 2010.

	Oct-09	Nov-09	Dec-09	Jan-10	Feb-10	Mar-10
Unique Utilizers	88	86	81	80	67	78
Paid Claims	133	102	92	90	74	94
Avg. \$/RX	\$352.21	\$451.87	\$600.61	\$668.62	\$594.88	\$652.71
Plan Cost \$	\$46,843.88	\$46,090.46	\$55,256.05	\$60,176.10	\$44,020.79	\$61,354.92
	Apr-10	May-10	Jun-10	Jul-10	Aug-10	Sep-10
Unique Utilizers	69	83	83	78	69	67
Paid Claims	83	97	96	86	85	76
Avg. \$/RX	\$589.79	\$599.76	\$790.93	\$746.23	\$741.99	\$716.98
Plan Cost \$	\$48,952.46	\$58,176.31	\$75,929.48	\$64,175.47	\$63,068.80	\$54,490.78

4. Synagis

Background and Overview (initial RetroDUR analysis detailed in FFY 2009 CMS report)

- Synagis[®] (palivizumab) was approved by the FDA in 1998 for the prevention of serious lower respiratory tract infection caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV infection.
- The American Academy of Pediatrics (AAP) updated the guidelines for the use of palivizumab in the summer of 2009. In recognition of the greatest risk of hospitalization due to RSV in the first 10 weeks of life, the guidelines now recommend limiting the use of Synagis[®] among infants born at a gestational age between 32 and 35 weeks to the first three months of life (i.e. a maximum of 3 doses). In addition, the guidelines reinforce that a maximum of five Synagis[®] doses should be administered to other appropriate patient groups, regardless of season variability.
- In September 2009, the Department of Vermont Health Access (DVHA) had updated the Synagis[®] approval criteria for the upcoming 2009-2010 RSV season in response to the changes in the American Academy of Pediatrics guideline recommendations on RSV prophylaxis with palivizumab (Synagis[®]), published in the Red Book in July 2009. Total anticipated cost savings of the recommended revised approval criteria was expected to be approximately \$300,577 per each RSV season.

Methods

- The Department of Vermont Health Access (DVHA) claims data for Synagis[®] were reviewed from November 1, 2009 to March 31, 2010. The examined claims data included unique utilizers, number of paid claims, average cost per claim, and total plan cost. The data were reviewed for trends in utilization and compared with the data from the 2008-2009 RSV season (Graphs 1 and 2). Furthermore, the number of doses received per unique utilizer was estimated from the detailed claims data report (Graph 3). In addition, a sample of prior authorization requests for Synagis[®], submitted during the same time period, was reviewed for appropriateness of decision and to assess the need to modify the current approval criteria.

Results

- From November 1, 2009 to March 31, 2010 there were 346 paid claims, for 78 unique members, that cost the plan a total of \$632,536.12. The average cost per prescription was \$1,828.14. There were no paid claims outside of the official DVHA RSV season. Comparing these findings to the results of the previous year's quality assurance analysis, the revised Synagis[®] approval criteria appears to have culminated in cost savings of \$428,518 or 40.4% reduction in DVHA's annual spending on Synagis[®].
- A total of 102 Synagis[®] prior authorization requests were identified from October 1, 2009 to March 31, 2010. These requests include the following:

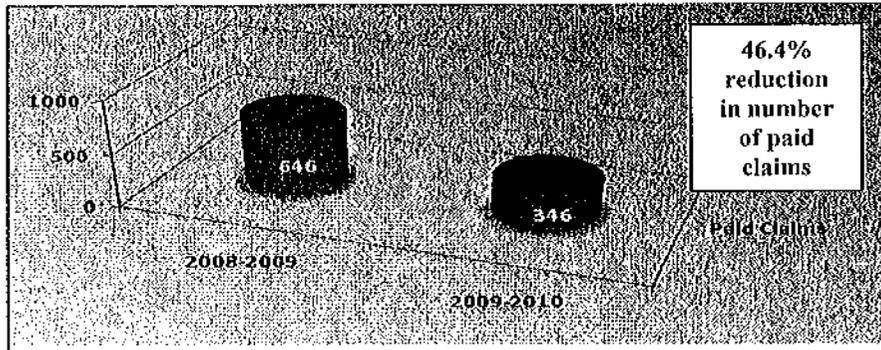
Palivizumab (Synagis[®]) - 102 requests
Number of approvals: 70
Number of denials: 32 (31% denial rate)

- There were no anecdotal reports from the specialty pharmacy vendor or prescribers of clinical issues that were felt to be related to the new guidelines that had been adopted.

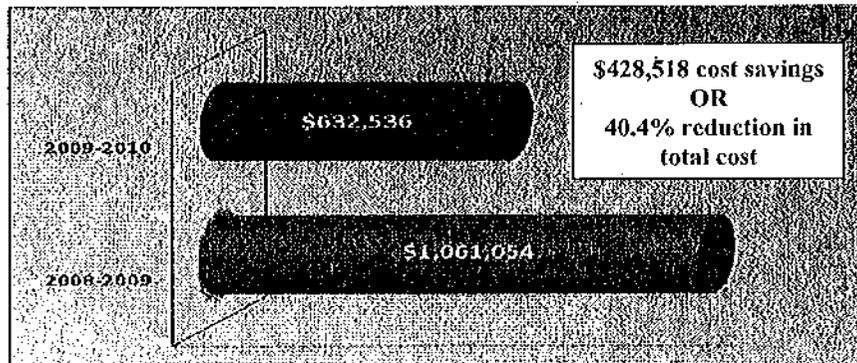
The DVHA DUR board elected to:

- Continue with the revised clinical criteria of Synagis® in accordance with the AAP recommendations for the upcoming 2010-2011 RSV season.

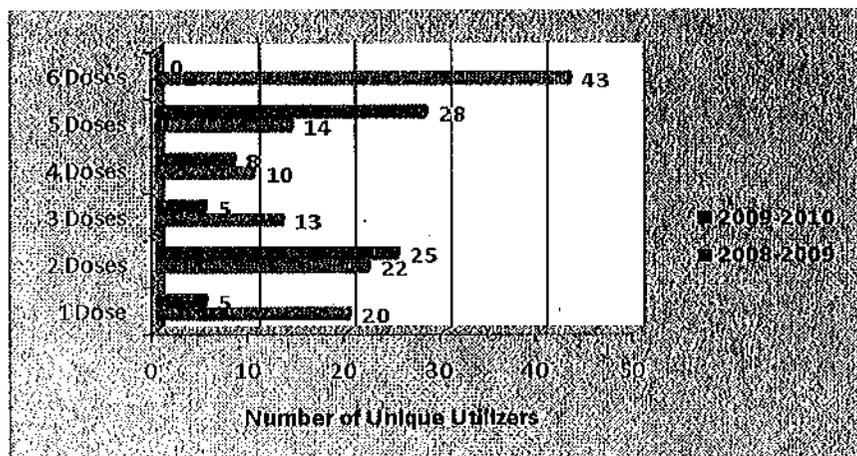
Graph 1: Paid Synagis Claims from the 2008-2009 and 2009-2010 RSV Seasons



Graph 2: Total Plan Cost from the 2008-2009 and 2009-2010 RSV Seasons



Graph 3: Number of Synagis® Doses per Unique Utilizer



5. Therapeutic Equivalency Pilot Program for PPIs and Statins – Medicare Part D Wrap

Background and Overview (*initial RetroDUR analysis detailed in FFY 2009 CMS report*)

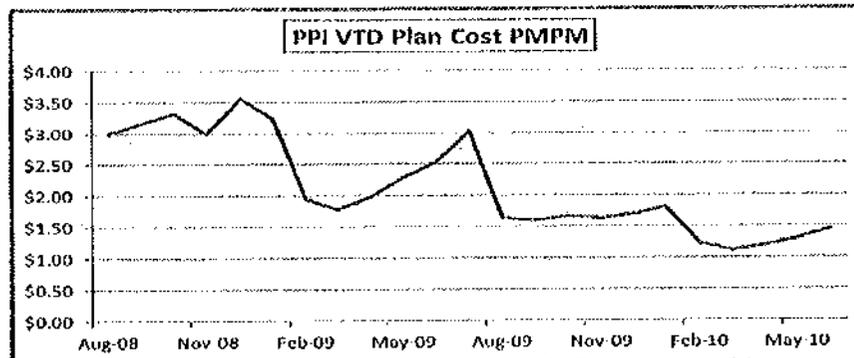
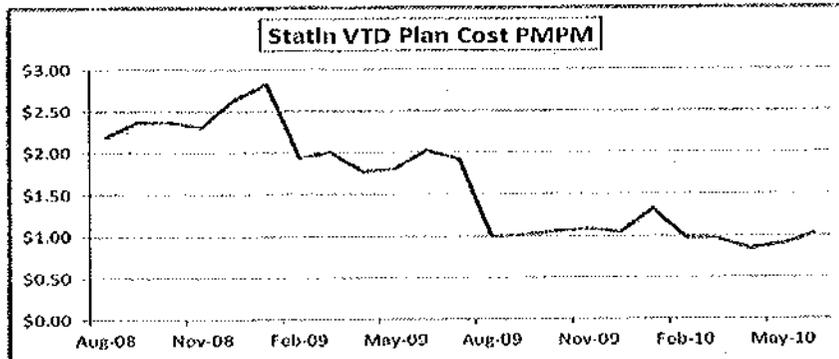
- The General Assembly of the State of Vermont voted, as part of H.441, to implement a pilot program to maximize the use of over-the-counter (OTC) and generic drugs. The pilot applies to the statin and proton pump inhibitor (PPI) drug classes for individuals enrolled simultaneously in a Medicare Part D prescription drug plan and Vermont's VPharm Program.
- Prior to the implementation of the pilot, VPharm covered the majority of cost sharing for these drug classes, whether it was a co-pay on a generic or branded drug or the entire claim cost for patients in the deductible or the Part D coverage gap. As a way to preserve as robust a VPharm benefit as possible without impacting clinical care, the legislature sought cost savings in select drug classes. These two drug classes were chosen as there are significantly less costly generic and over-the-counter (OTC) drug choices available that have been proven to be equally efficacious and well-tolerated compared to the more expensive branded products.
- Within the VPharm program, Vermont spends the greatest amount of money in these two drugs classes. As such, this pilot was projected to save \$500,000 in state fiscal year 2010.

Methods

- The Vermont Therapeutic Equivalency Pilot Program was implemented on August 3, 2009, after which time drug claims submitted by pharmacies for VPharm patients who were not using a preferred product were rejected if no exception had been requested. Although the patient may have had a portion of the claim paid by their Medicare Part D plan, the wrap coverage was not provided. DVHA, in collaboration with the DUR board, was charged with preparing an analysis of the effectiveness of this pilot.

Results

- Total program drug costs for the PPI and statin drug classes were evaluated for a three month "Pre-Program" time period of 4/1/2009 through 6/30/2009 and compared to a three month "Post-Program" time period of 8/1/2009 through 10/31/2009.
- Pre-program preferred PPI prescriptions represented 39 percent of all scripts; post-program that percentage increased to 72 percent. Similarly, pre-program preferred statin prescriptions represented 69 percent of all scripts; post-program that percentage increased to 86 percent.
- Further, the combined drug costs were \$138,150 less in the 3 month follow-up period as compared to the 3 month pre-program period, a decrease of 35.8%. The post-period non-preferred costs include those with prior authorizations from their Part D plans as well as those for whom exceptions were requested. This translates into a projected annualized savings of \$552,600.
- A further analysis through May 2010 demonstrated that the initial 3 month savings have been sustained.



New analyses performed in FFY 2010 from DUR activities:

1. Xolair (omalizumab) for Persistent Asthma

Background and Overview

- Omalizumab (Xolair[®]) was Food and Drug Administration (FDA)-approved in 2003 for adults and adolescents (12 years of age and older) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Guidelines from the National Asthma Education and Prevention Program (NAEPP) and the National Heart, Lung, and Blood Institute (NHLBI) recommend using Xolair[®] in patients at least 12 years old with allergies that require step 5 or 6 therapy for severe persistent asthma.

Methods

- 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

Results

- 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 DVHA DUR board elected to:

- Continue to require prior authorization for Xolair[®]. Although the review demonstrated a high rate of appropriate Xolair[®] utilization, due to the high cost and risk of inappropriate prescribing, it is agreed 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 agreed 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 so that requests would not be denied because all information had not been provided.

2. Lunesta (eszopiclone) for Insomnia

Background and Overview

- Lunesta[®] (eszopiclone) is a nonbenzodiazepine hypnotic agent that is Food and Drug Administration (FDA)-approved for the treatment of insomnia in adults.
- Direct comparison trials of the agents within this class are limited and there is insufficient evidence to demonstrate that any agent in the class is safer or more effective than another. One study, involving 382 patients, found that there were no differences in any of the sleep outcomes when eszopiclone and zolpidem were compared directly.
- Lunesta[®] requires prior-authorization for DVHA. This requirement was implemented on January 5, 2009. Existing users were grandfathered with a 90-day look back for a paid pharmacy claim for Lunesta[®].

Methods

- DVHA claims data for Lunesta[®] from April 1, 2008 to October 31, 2009 was reviewed (9 months prior to and 9 months after prior-authorization implementation). 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 Lunesta[®], submitted from January 5, 2009 to November 5, 2009 was reviewed for appropriateness of the current prior authorization criteria.

Results

- As expected, utilization of Lunesta[®] decreased after the implementation of the prior-authorization requirement. The average number of unique utilizers in the 9 months before and after the implementation of the prior-authorization was 382 and 253, respectively. In addition, a total of 207 prior authorization requests were reviewed between January 5, 2009 and November 5, 2009. Despite a fairly high rate of approval, the overall denial rate was 22%. The results of this quality assurance analysis and review of the denials for the prior-authorization requests indicate that some prescribers were requesting Lunesta[®] without a trial of generic zolpidem.

Savings = \$ 168,115.83/ 9 months

Annualized savings = \$ 224,154.43

Unique Utilizers, Paid Claims, Paid Amounts and Average Costs per Claim for Lunesta before and after Prior Authorization Requirement.

	April 2008- December 2008	February 2009- October 2009
Average Monthly Unique Utilizers	419	253
Paid Claims	3897	2554
Average Plan Cost/Rx	\$141.06	\$149.42
Total Plan Cost	\$549,726.97	\$381,611.08

The DVHA DUR board elected to:

- Maintain current criteria for prior authorization for Lunesta due to the lack of comparative efficacy data demonstrating advantages of Lunesta[®] over other agents in the class, as well as the availability of less costly generic drug products within the class. The Board also voted to maintain the length of authorization for approval at one year.
3. **Amitiza (lubiprostone) for Chronic Idiopathic Constipation/Constipation Predominate Irritable Bowel Syndrome (IBS-C)**

Background and Overview

- Amitiza[®] (lubiprostone) was approved by the Food and Drug Administration (FDA) in 2006 for the treatment of chronic idiopathic constipation in adults. In April 2008, the indication was extended to include the treatment of constipation predominate irritable bowel syndrome (IBS-C) in women at least 18 years of age.
- Amitiza[®] requires prior authorization (PA). This requirement was implemented in February 2007, when only the 24 µg strength was available for the treatment of chronic idiopathic constipation. In July 2008, the Amitiza[®] approval criteria was updated to include the new 8 µg strength FDA-approved for the treatment of IBS-C in women 18 years of age or older. At the same time, a quantity limit of two capsules daily, reflecting FDA-recommended dosing, was implemented.

Methods

- A retrospective drug analysis of Amitiza[®] was performed to review utilization and evaluate the appropriateness of the current PA approval criteria as well as the current approval duration.
- DVHA claims data for Amitiza[®] was reviewed from February 1, 2009 to January 31, 2010. 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 Amitiza[®] submitted from February 1, 2009 to January 31, 2010 was reviewed for appropriateness of the current prior authorization criteria and approval duration.

Results

- From February 1, 2009 to January 31, 2010, there were a total of 122 paid Amitiza[®] 24 µg claims for 32 unique utilizers, costing the plan \$23,737.23 with an average cost per claim of \$195. There

was a monthly average of 9 unique utilizers (range 7-14) of Amitiza[®] 24 µg. The demand for the lower 8 µg Amitiza[®] strength was considerably lower. For the Amitiza[®] 8 µg strength, there were 29 paid claims for a total of 14 unique utilizers (2 unique utilizers per month on average) costing the plan a total of \$5,843.17 per year at \$201 per claim, on average.

- The results indicate appropriate utilization based on the current approval criteria. In addition, there were a total of 80 prior authorization requests for 51 unique utilizers with an overall approval rate of 87.5%. Furthermore, 51% of the received prior authorization requests were renewal requests, 97.56% of which were approved for three months. Approximately 90% of all new Amitiza[®] approvals were one-time PAs, with renewal not being pursued. The most common reason for denying a request for Amitiza[®], regardless of strength, was insufficient information.

The DVHA DUR board elected to:

- Maintain current criteria for prior authorization for Amitiza but recommended that while the current duration of authorization for new requests remains the same, the length of authorization for renewals be increased to 1 year, with recertification authorized upon verification of clinical response.

4. Antipsychotics – Evaluation of who is prescribing and Seroquel Dosing

Background and Overview

- As with most states, there has been considerable interest in the prescribing of antipsychotics. Antipsychotics are the second largest medication category by drug spend for DVHA. DVHA collaborates with AHEC (Area Health Education Centers Program) to provide data to assist in academic detailing projects. In FFY 2010 AHEC was planning an academic detailing program concerning the appropriate prescribing of atypical antipsychotics. DVHA compiled VT Medicaid data on atypical antipsychotics and shared this information with the DUR Board in addition to AHEC.
- At the same time, budgetary constraints within the state Department of Mental Health prompted a request for evaluation of Seroquel dosing.

Methods

- DVHA claims data for the period 4/1/2009 through 3/31/2010 for antipsychotics were examined for prescriber specialty for those patients ≤ 21 years old and > 21 years old.
- DVHA claims for Seroquel for the period 05/13/2009 through 05/13/2010 were evaluated to determine total daily dose for those patients > 18 years old and < 60 years old..

Results

- As to be expected, psychiatrists prescribed the vast majority of antipsychotics for both children and adults with an additional significant amount prescribed by family practice and pediatric medicine.
- 56 % of total claims and 31.6 % of dollars for Seroquel claims were for doses < 150 mg/day that most probably reflects use as an hypnotic or anxiolytic rather than as an antipsychotic.

**DVHA Antipsychotic prescribing
by specialty and provider type
Patient Age > 21 years old
4/01/2009 - 3/31/2010**

Prescribing_Prov_Specialty_Desc	Total Claims	Total Claims %
PSYCHIATRIC	24,157	66.47%
FAMILY PRACTICE	6,156	16.94%
INTERNAL MEDICINE	2,126	5.85%
OTHER CERTIFIED NURSE PRACTITIONER	3,905	10.74%
	36,344	100.00%

**DVHA Antipsychotic prescribing
by specialty and provider type
Patient Age ≤ 21 years old
4/01/2009 - 3/31/2010**

Prescribing_Prov_Specialty_Desc	Total Claims	Total Claims %
PSYCHIATRIC	11,538	70.10%
PEDIATRIC MEDICINE	3,054	18.56%
FAMILY PRACTICE	919	5.58%
OTHER	948	5.76%
TOTAL	16,459	100.00%

Seroquel Analysis (Patient Age > 18 and < 60 years old)

of Claims & Total Plan Paid by Daily Dose Strength

Claims Data: 05.13.09 - 05.13.10

MG Per Day	# of Claims	% of Claims	Total Plan Paid	% of Total Plan Paid
25 MG Once Daily	1,020	8.39%	\$84,124.42	2.48%
50 MG Once Daily	2,435	20.03%	\$339,978.84	10.02%
Other < 150 MG	3,331	27.40%	\$647,974.28	19.10%
≥ 150 MG	5,371	44.18%	\$2,321,207.67	68.41%
	12,157	100.00%	\$3,393,285.21	100.00%

5. Topical Immunomodulators – Duplicate Therapy

Background and Overview

- Elidel[®] (pimecrolimus) and Protopic[®] (tacrolimus) are topical immunomodulators used in the treatment of atopic dermatitis as second line therapy after corticosteroids.
- The MedMetrics Clinical Call Center raised a concern around patients who may be receiving duplicate therapy with both Elidel and Protopic as a way to get around quantity limits that are in place.
- Elidel[®] and Protopic[®] require prior authorization (PA) for patients < 2 years and those without a previous trial of a corticosteroid. Both drugs have quantity limits of 30grams per fill and 90 grams per 6 months. Additionally, patients < 16 years are limited to a Protopic[®] ointment concentration of 0.3%. A retrospective quality assurance analysis of Elidel[®] and Protopic[®] duplicate therapy was performed to review utilization and evaluate the appropriateness of the current PA criteria.

Methods

- DVIIA claims data and PA requests for duplicate topical immunomodulator therapy were reviewed from March 1, 2008 to February 28, 2010.

Results

- During this time period there was only one unique utilizer with 4 months of claims for duplicate Elidel[®] and Protopic[®] therapy, costing the plan a total of \$698.86. Upon further review of the member's prior authorization history, the approvals note that Elidel[®] only worked on one side of the member's body and Protopic[®] worked on the other side but irritated the side of the body on which Elidel[®] worked. No inappropriate duplicate therapy was discovered.

The DVIIA DUR board determined:

- No changes to the current DVIIA prior authorization approval criteria were required.

6. Long Acting Narcotics – Duplicate Therapy

Background and Overview

- DVHA does not have hard reject criteria in place to restrict duplicate long-acting narcotic therapy. Pharmacies will receive soft reject messages that may be overridden with the appropriate codes. Preferred long-acting narcotics are available without a prior authorization and non-preferred LA narcotics pay after PA criteria and quantity limit criteria are met. There is no hard edit in place to prevent the use of multiple LA narcotic products. A retrospective evaluation of LA narcotic utilization was performed to identify current utilization trends and to assess the need for coding implementation that would prevent duplicate LA narcotic claims from paying at the point of sale.

Methods

- Members receiving duplicate LA narcotic therapy were identified through DVIIA claims data if having two or more consecutive claims for long-acting narcotics or Suboxone/Subutex within 30 days from April 1, 2009 to March 31, 2010. Subsequently, claims data were reviewed to confirm therapeutic duplication of long-acting narcotics. Members switching from one form of therapy to another were excluded from the analysis. Claims for different strengths of the same drug were likewise excluded. A summary of the data search results is presented in Table 1. Members identified by the QA analysis were evaluated for current utilization of duplicate LA narcotics, multiple prescribers, and specific LA narcotic combinations prescribed (Figures 1 and 2). Moreover, the examined claims data included unique utilizers by month to evaluate for trends in duplicate LA narcotic utilization (Table 3). In addition, a detailed summary of LA narcotic utilization for 22 members (50%) included in the review is presented in Table 3.

Results

- A review of utilization data from April 1, 2009 to March 31, 2010 has identified 48 members receiving two or more long-acting narcotics concurrently for at least two consecutive months. On average, there were 41 unique members with paid duplicate LA narcotic or LA narcotic/Suboxone® claims monthly within the review period.

Table 1: Data Search for Duplicate LA Narcotics from April 1, 2009 to March 31, 2010.

Data Search Result Summary	Number of Members
Total number of members identified	64
Number of members receiving duplicate LA narcotic therapy	38
Number of members with concomitant LA narcotic/ Suboxone® claims*	10
Number of members with inactive profiles	4
Number of members eligible for inclusion in the detailed summary	44
Number of members with current duplicate LA narcotic claims	13
Number of members with current concomitant LA narcotic/Suboxone® claims	1
Number of members with duplicate LA narcotic claims from multiple prescribers	7
Number of members with concomitant LA narcotic/ Suboxone® claims from multiple prescribers	6
Number of members with only 2 consecutive months of duplicate LA narcotic or concomitant LA narcotic/Suboxone® claims	14

*The data search did not identify any members receiving concurrent Subutex® and LA narcotic therapy.

Figure 1: Types of Duplicate LA Narcotic Regimens

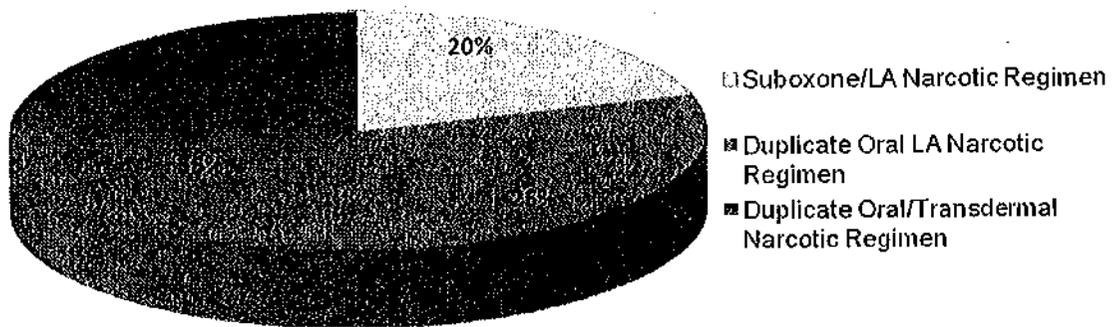
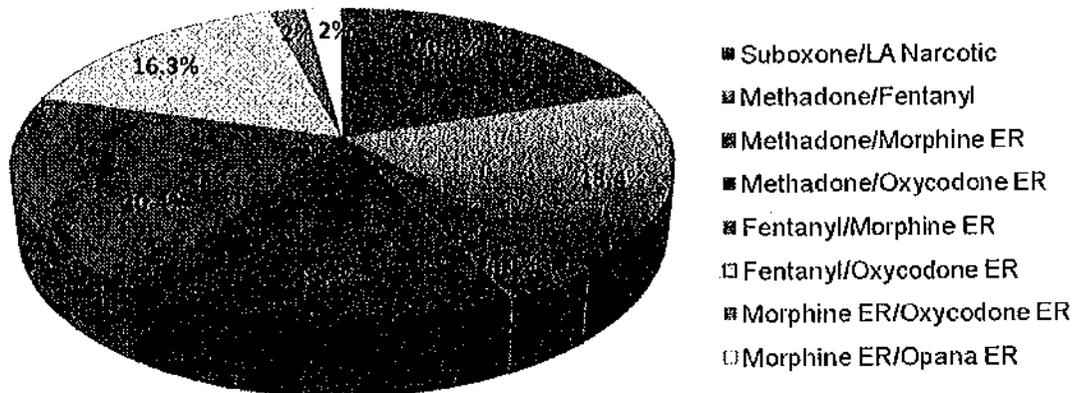


Figure 2: Specific LA Narcotic Combinations



- A regimen consisting of an oral LA narcotic and a transdermal product was the most common (55%) duplicate LA narcotic combination therapy. Fentanyl in combination with morphine sulfate extended-release was the most frequently encountered example of such therapy. Moreover, 20% of the identified duplicate LA narcotic claims were for Suboxone[®] used in combination with a LA narcotic. Patient profiles were reviewed in detail for a random selection (50%) of members (with active profiles) identified by the review. Among these members, chronic back pain was the most common indication, in 36% of patients, for requesting a LA narcotic. Furthermore, malignancy and chronic pain syndrome were listed as diagnoses for 18.2% and 9% of patients, respectively. Diagnoses in remaining members could not be ascertained from a retrospective patient profile review. From the information received during prior authorization review, it appears that five members continued to receive a LA narcotic which the member was reported to have discontinued either due to inadequate therapeutic response or adverse effects. In all five instances, the same prescriber was responsible for both LA narcotic prescriptions. Whether the prescribing physician intended for the patient to receive duplicate LA narcotic therapy or to switch him/her to an alternative LA narcotic is unknown.

- The results of the retrospective QA analysis suggest that a small proportion of LA narcotic utilizers receive duplicate LA narcotic therapy or buprenorphine in combination with a LA narcotic. Current consensus guidelines and evidence-based medicine do not support this practice.

The DVHA DUR board elected to:

- Require prior authorization for duplicate long acting narcotic therapy after 2 consecutive months of combined therapy. The prescriber would need to provide a clinically compelling rationale for the duplicate therapy.
- Ask DVIIA to check with legal staff concerning the information the Clinical Call Center may give to prescribers regarding duplicate therapy.

7. Mental Health Medications in Children

Background and Overview

- An analysis was done at DVIIA in 2007 to look at the use of mental health medications in children singly and in combination. While there has been much discussion on this topic nationally, it was unclear whether the increasing trend had slowed or stopped in Vermont.

Methods

- DVIIA claims data for mental health medications in children for the period 4/1/2010 through 9/30/2010 was compiled and compared to the same analysis done 3 years earlier for the period 4/1/2007 through 9/30/2007.

Results

- While the numbers of covered beneficiaries have increased in all age groups, there was no significant increase in any group of medications or age groups.

See attachment next page



Department of Vermont Health Access

Mental Health Medication
Utilization in Children
Ages 0 - 17 years old
(04/01/07 - 09/30/07 and 04/01/10 - 09/30/10)



One Unique Medication / 6 Months (April through September)

Age	0 - 6 years		7 - 12 years		13 - 17 years	
	2007	2010	2007	2010	2007	2010
Number of OVHA Beneficiaries of this Age as of June of Specified Year	21,601	28,840	15,669	20,460	15,720	16,096
Total Number of Unique Members With Claim(s) for Mental Health Medication(s)	413	352	3,101	2,839	2,737	2,997
Percentage of OVHA Beneficiaries of this Age with Any Mental Health Medication Claim	1.91	1.22	19.79	13.88	17.41	18.62
1 Unique Medication in 6 Months	296	226	2,121	1,863	1,606	1,906
Percentage of Age Group / Percentage of those with Claims	1.37 / 71.42	0.78 / 64.20	13.54 / 68.40	9.11 / 65.62	10.22 / 58.68	11.84 / 63.60
Antidepressant Only / % of Beneficiaries this Age with 1 Unique Medication in 6 Months	39 / 13.22	27 / 11.95	254 / 11.98	278 / 14.92	689 / 42.90	807 / 42.34
Antipsychotic Only / % of Beneficiaries this Age with 1 Unique Medication in 6 Months	41 / 13.90	17 / 7.52	111 / 5.23	70 / 3.76	125 / 7.78	113 / 5.93
ADHD Med Only / % of Beneficiaries this Age with 1 Unique Medication in 6 Months	215 / 72.88	182 / 80.53	1,756 / 82.79	1,515 / 81.32	792 / 49.32	986 / 51.73

Includes Antidepressants, Antipsychotics (includes lithium) and ADHD Medications (Stimulants and Non-Stimulants)
Does **NOT** include any anticonvulsants (some of which may be used as mood stabilizers), anxiolytics or sedative/hypnotics

Completed 11/10/2010

Mental Health Medication
Utilization in Children
Ages 0 - 17 years old
(04/01/07 - 09/30/07 and 04/01/10 - 09/30/10)



Department of Vermont Health Access



Two Unique Medications / 6 Months (April through September)

	0 - 6 years		7 - 12 years		13 - 17 years	
	2007	2010	2007	2010	2007	2010
Number of OSHA Beneficiaries of this Age as of June of Specified Year	21,601	28,840	15,669	20,460	15,720	16,096
Total Number of Unique Members With Claim(s) for Mental Health Medication(s)	413	352	3,101	2,839	2,737	2,997
2 Unique Medications in 6 Months	87	90	675	656	701	702
Percentage of Age Group / Percentage of those with Claims	0.40 / 21.07	0.31 / 25.57	4.31 / 21.77	3.21 / 23.11	4.46 / 25.61	4.36 / 23.42
2 Antidepressants / % of Beneficiaries this Age with 2 Unique Medications in 6 Months	1 / 1.15	2 / 2.22	23 / 3.41	18 / 2.74	118 / 16.83	132 / 18.80
Antidepressant + Antipsychotic / % of Beneficiaries this Age with 2 Unique Medications in 6 Months	3 / 3.45	8 / 8.89	51 / 7.56	47 / 7.16	138 / 19.69	117 / 16.67
Antidepressant + ADHD Med / % of Beneficiaries this Age with 2 Unique Medications in 6 Months	17 / 19.54	13 / 14.44	209 / 30.96	217 / 33.08	216 / 30.81	238 / 33.90
2 Antipsychotics / % of Beneficiaries this Age with 2 Unique Medications in 6 Months	2 / 2.30	1 / 1.11	25 / 3.70	10 / 1.52	45 / 6.42	32 / 4.56
Antipsychotic + ADHD Med / % of Beneficiaries this Age with 2 Unique Medications in 6 Months	31 / 35.63	12 / 13.33	200 / 29.63	142 / 21.65	115 / 16.41	100 / 14.25
2 ADHD Meds / % of Beneficiaries this Age with 2 Unique Medications in 6 Months	33 / 37.93	54 / 60.00	167 / 24.74	222 / 33.84	69 / 9.84	83 / 11.82

Includes Antidepressants, Antipsychotics (includes lithium) and ADHD Medications (Stimulants and Non-Stimulants)
Does **NOT** include any anticonvulsants (some of which may be used as mood stabilizers), anxiolytics or sedative/hypnotics

Mental Health Medication
Utilization in Children
Ages 0 - 17 years old
(04/01/07 - 09/30/07 and 04/01/10 - 09/30/10)



Department of Vermont Health Access



Three Unique Medications / 6 Months (April through September)

Age	0 - 6 years		7 - 12 years		13 - 17 years	
	2007	2010	2007	2010	2007	2010
Number of OSHA Beneficiaries of this Age as of June of Specified Year	21,601	28,840	15,669	20,460	15,720	16,096
Total Number of Unique Members With Claim(s) for Mental Health Medication(s)	413	352	3,101	2,839	2,737	2,997
3 Unique Medications in 6 Months	31	36	305	320	430	389
Percentage of Age Group / Percentage of those with Claims	0.14 / 7.50	0.12 / 10.23	1.95 / 9.84	1.56 / 11.27	2.74 / 15.71	2.42 / 12.98
3 Antidepressants / % of Beneficiaries this Age with 3 Unique Medications in 6 Months	0 / 0	0 / 0	2 / 0.66	1 / 0.31	24 / 5.58	13 / 3.34
Antidepressant(s) + Antipsychotic(s) / % of Beneficiaries this Age with 3 Unique Medications in 6 Months	1 / 3.23	2 / 5.56	34 / 11.15	14 / 4.38	96 / 22.33	77 / 19.79
Antidepressant(s) + ADHD Med(s) / % of Beneficiaries this Age with 3 Unique Medications in 6 Months	6 / 19.35	12 / 33.33	53 / 17.38	86 / 26.88	74 / 17.21	98 / 25.19
3 Antipsychotics / % of Beneficiaries this Age with 3 Unique Medications in 6 Months	0 / 0	0 / 0	0 / 0	4 / 1.25	5 / 1.16	5 / 1.29
Antipsychotic(s) + ADHD Med(s) / % of Beneficiaries this Age with 3 Unique Medications in 6 Months	12 / 38.71	7 / 19.44	58 / 19.02	66 / 20.63	35 / 8.14	39 / 10.03
3 ADHD Meds / % of Beneficiaries this Age with 3 Unique Medications in 6 Months	2 / 6.45	12 / 33.33	11 / 3.61	24 / 7.50	6 / 1.40	0 / 0
Antidepressant + Antipsychotic + ADHD Med / % of Beneficiaries this Age with 3 Unique Medications in 6 Months	10 / 32.26	3 / 8.33	147 / 48.20	125 / 39.06	190 / 44.19	157 / 40.36

Includes Antidepressants, Antipsychotics (includes lithium) and ADHD Medications (Stimulants and Non-Stimulants)
Does **NOT** include any anticonvulsants (some of which may be used as mood stabilizers), anxiolytics or sedative/hypnotics

Drug Utilization Review Board Activity Summary FFY2010

The VT Medicaid (DVHA) DUR Board acting as the program's Pharmacy and Therapeutics (P&T) Committee met 9 (nine) times in FFY2010.

The combined functions of the DUR Board results in the DUR Board having a unique perspective on the evaluation and Preferred Drug List (PDL) placement of newly released drugs. As new drugs are brought forward for evaluation, the DUR Board chooses to manage these medications in a manner that will result in appropriate prescribing from the time of introduction of the drug (prospectively) rather than in a retrospective manner when inappropriate patterns of prescribing may have become ingrained. This results in the early adoption of quantity limits, step therapy and promotion of generic drug choices. At the same time, as new drugs are evaluated, patterns of prescribing for alternative drugs may become apparent and lead the Board to undertake retrospective drug utilization review activities for those other medications. Additionally, the DUR Board will recommend that follow-up RetroDUR be performed of relatively new drugs to ensure that the adopted clinical criteria are appropriate and result in patterns of utilization that are appropriate and cost-effective.

In FFY 2010, the DUR Board activities included:

- 32 New Drug Reviews
- 17 New Dosage Form Reviews
- 18 Revised Clinical Coverage Criteria (including new indications for drugs already on the preferred drug list)
- 4 New Managed Drug Classes
- 28 Therapeutic Class Reviews
- 32 Quantity Limits established for new or previously reviewed drugs
- 26 FDA Safety Alerts reviewed
- 11 RetroDUR Analyses
 - Cough and Cold < 2 years old
 - Xolair for Persistent Asthma
 - Buprenorphine (discussed at 5 meetings)
 - Lunesta for Insomnia
 - Antipsychotics
 - Congestive Heart Failure – Appropriate Medication Use
 - Amitiza
 - Topical Immunomodulators – Duplicate Therapy
 - Long Acting Narcotics – Duplicate therapy
 - Actiq and Fentora
 - Synagis

The Drug Utilization Review (DUR) Board will advise DVHA on how best to educate providers and address the impact of pharmacy manufacturers advertising. In these meetings counter-detailing opportunities are considered. DVHA partners with The Vermont Academic Detailing Program which is a university-based prescriber education and support program that operates out of AHEC (Area Health Education Center Programs) to identify mutual areas of interest. The goal of the Vermont Academic Detailing Program is to promote high quality, evidence-based, patient-centered, and cost-effective treatment decisions by healthcare professionals. AHEC staff visit prescriber offices for person-to-person educational sessions.

In the course of DUR activities, the DUR Board may select certain drugs to target for review in order to ensure that clinical criteria and prescribing patterns are appropriate. Staff makes recommendations for targeted areas and the Board selects those most relevant. The Board then determines if follow-up is appropriate either with the identified prescribers or with a clinical advisory to all providers. In the event a preferred drug is changed to a non-preferred status and specific beneficiaries are affected, prescribers are provided with two tools as recommended by the DUR Board. One is a list of all the patients who were prescribed the specific drug that is being changed. The second is a profile unique to each patient with the drug change listed. This creates a record for use in the patient's file.

To educate providers on general PBM Program coverage activities, various methods are used. Most frequently, mailings are prepared around both general and specific changes and they are targeted to prescribers and pharmacies separately. The mailing topics are generally complimentary so that pharmacies understand the communications that have been sent to prescribers. These mailings are also sent electronically to provider affiliates and representatives so that these organizations can use their proprietary methods to distribute the materials. Examples of these organizations include the Vermont Medical Society and the Vermont Pharmacists Association. Providers may find all general pharmacy benefit management materials posted on the DVHA webpage at <http://dvha.vermont.gov/for-providers>. These materials include the description of the PBM Program; DUR Board information; the Preferred Drug List and Criteria; prior authorization information and forms; bulletins and mailings; and other information, instructions and alerts.



Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 10/13/09

Board Members:

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

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

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

Staff:

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

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

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

Guests:

Mall Badalucco, Merck
Amy Finn, Merck
Mouhamed Gueye, Roche Pharmaceutical
Mark Kaplan, Abbott
Craig Lemley, Amylin

Kelley Mackison, Johnson & Johnson
Paul McDermott, Centecor Ortho Biotech
Steven McRae, Genentech
Bob Meany, Takeda Pharmaceuticals
Chris Michaels, Ilan

Tim Nics, GSK
Carl Possidente, Pfizer
Gary Prevost, PriCara
Wayne Smith, Jazz Pharma
Angelo Valeri, Novartis

Michael Scovner, M.D. Chair, called the meeting to order at 7:00 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(1)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table. Dr. Michael Farber was introduced as the new Medical Director. Dr. Farber comes to Vermont from California Medicaid (MediCal).
- The September 2009 meeting minutes were amended so that the quantity limit on Uloric[®] would read "1 tablet per day". The amended minutes were accepted.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: Vicki Loner - Deputy Director, OVHA

- No administration update.

4. Medical Director Update: Michael Farber, M.D. -- Medical Director

- 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 (MIIP)

- **Kapidex[®] Communications (Proton Pump Inhibitors)**
The Kapidex[®]/Prevacid[®] communication sent to pharmacies was shared with the DUR Board. The Board requested that the communication to be sent to prescribers include dosing information. The Board also asked that MedMetrics ensure that the messaging sent to pharmacies when Prevacid[®] prescriptions are rejected clearly list PDL preferred alternatives.

Public Comment: No public comment.

Board Decision: None needed.

- **Vectical[®] (calcitriol) Topical Ointment**
Deferred until next meeting. Unable to obtain input from a dermatologist to date.

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

- **Aplenzin[®] (bupropion extended release) Tablet:** It was recommended that coverage would require PA with the criteria for approval being that the patient has had a documented inadequate response to Wellbutrin XL AND the patient has had a documented side effect, allergy, or inadequate response to at least 2 different antidepressants from the SSRI, SNRI and/or Miscellaneous Antidepressant categories (may be preferred or non-preferred). A quantity limit of one tablet per day was recommended.

Public Comment: No public comment.

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

Full Drug Reviews

- **Rapaflo[®] (silodosin) Capsule:** It was recommended that coverage would require PA with the criteria for approval being that the patient has had a documented side effect, allergy or treatment failure with two preferred drugs (preferred drugs include doxazosin (generic), terazosin (generic), Flomax[®] and Uroxatral[®]). A quantity limit of one capsule per day was recommended.

Public Comment: No public comment.

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

- **Simponi[®] (golimumab) Prefilled Injection:** It was recommended that coverage would require PA due in part to its lack of proven superiority to other available agents and also to its cost compared to these other agents.

Public Comment: Paul McDermott, Centecor Ortho Biotech – Commented on the cost of Simponi[®] and its clinical attributes and ease of administration.

Board Decision: Due to some inaccuracies in the monthly cost of therapies within this drug category reported in the review, the Board moved to table discussion of Simponi[®] at this time and to continue

discussion next month. The Board also requested that the drugs considered to belong to the DMARD category be outlined clearly.

- Toviaz[®] (fesoterodine) ER Tablet: It was recommended that coverage would require PA with the criteria for approval being that the patient has had a documented side effect, allergy, or treatment failure with oxybutynin (short acting) AND the patient has had a documented side effect, allergy, or treatment failure with 2 preferred long-acting urinary antispasmodic agents. A quantity limit of one tablet per day was recommended.

Public Comment: No public comment.

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

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

- Influenza Medications:
Presented to the DUR Board as information was a letter from CMS to State Health officials concerning vaccinations and antiviral medications for 2009 H1N1. PA criteria have been removed for antivirals at the request of the VT Department of Health though quantity limits remain. A general update on the state of drug supplies and management of the class was presented.

Public Comment: No public comment.

Board Decision: None needed.

- Ossification Enhancers:
See below for individual drug subclasses. In addition, it was recommended that the length of authorization for non-preferred drugs in this class be changed from lifetime to 3 years.

Public Comment: No public comment.

Board Decision: The Board approved the recommended change.

**8. Drug Classes – Annual Review:
(Public comment prior to Board action)**

- Bisphosphonates: Since there is no data to conclusively recommend one oral bisphosphonate over another, no changes are recommended in this category. Alendronate (generic) and Boniva[®] are the preferred oral products. It was recommended that 2 new indications be added to the clinical criteria accepted indications for Reclast[®] injection to also include that the patient is male with a diagnosis of osteoporosis or the patient has a diagnosis of glucocorticoid induced osteoporosis.

Public Comment: No public comment.

Board Decision: The Board approved the changes recommended above.

- Calcitonins: It was recommended that both Miacalcin[®] and Fortical[®] continue to be available as preferred products. The generic formulation that is AB equivalent to Miacalcin[®] should be listed

as non-preferred with the criteria for approval being that the patient has a documented intolerance to the brand product.

Public Comment: No public comment.

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

- **Parathyroid Hormones:** It was recommended that the criteria for approval of Forteo[®] (the only drug in this class) be modified to read “treatment failure is defined as documented continued bone loss or fracture after one or more years of treatment with a preferred bisphosphonate”.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommended change.

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

- **Cough and Cold Products in Children Less than 2 years old**
In January of 2008, the FDA issued a public health advisory, warning of the risk of using cough and cold medications in patients under the age of 2, due to the risk of potentially life threatening adverse effects. Due to this warning, a prior authorization for all cough and cold products was implemented for the Office of Vermont Health Access for patients under 2 years of age. In order for a PA to be approved, the doctor must acknowledge the FDA’s warning regarding the risks of using these medications in children less than 2 years of age, and document that the medical necessity for use of the cough/cold product in their patient outweighs the risks as described in the FDA alert. Since the implementation of the PA, the number of claims has decreased from 62 to 2 per cold season (October 1 through April 30).

Public Comment: No public comment.

Board Decision: The Board agreed that the current criteria for prior authorization for cough and cold products for children under the age of 2 years old are clinically appropriate and that no changes are required.

- **Future Topics:** A discussion of possible future RetroDUR topics was held. There was still considerable interest in going back and looking at short acting beta-agonist overuse in patients who are not on a regularly taken controller medication. The Board was asked to think about other possible topics.

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

This will become a quarterly agenda topic so will be discussed at the December meeting.

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

- 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.

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

FDA Safety Alerts

▪ Sitagliptin – pancreatitis:

FDA is revising the prescribing information for Januvia (sitagliptin) and Janumet (sitagliptin/metformin) to include information on reported cases of acute pancreatitis in patients using these products. Prescribers should be aware of the possibility for and monitor for the emergence of the signs and symptoms of pancreatitis such as nausea, vomiting, anorexia, and persistent severe abdominal pain, sometimes radiating to the back. No changes to clinical criteria are recommended.

Public Comment: No public comment.

Board Decision: None needed

▪ Tysabri - More cases of PML:

The FDA continues to receive reports of progressive multifocal leukoencephalopathy (PML) in patients receiving Tysabri. Tysabri was approved by the FDA for the treatment of relapsing forms of multiple sclerosis (MS) in November 2004 and for moderately to severely active Crohn's disease in January 2008. The risk for developing PML appears to increase with the number of Tysabri infusions received. At this time, the FDA is not requiring changes regarding PML to the Tysabri prescribing information or to the Tysabri risk management plan, called the TOUCH Prescribing Program. No changes to clinical criteria are recommended.

Public Comment: No public comment.

Board Decision: None needed

13. Adjourn: Meeting adjourned at 8:30 p.m.

Next DUR Board Meeting

Tuesday, November 10, 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.



Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 11/10/09

Board Members:

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

Kathleen Boland, Pharm.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)
Robin Farnsworth, OVHA

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

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

Guests:

Ward Bennett, Centocor-OBI
Christina Carmody, Bando
Melanie Crain, J&J OMJ
Mike Delucia, Forest

Michael Deorsey, Abbott
Rod Francisco, Forest
Craig Lemley, Amylin
Steven McRae, Genentech

Danielle Moon, Merck
Tim Nies, GSK
Gary Prevost, PriCara
Vanessa Sciortino, Pricara

Michael Scovner, M.D. Chair, called the meeting to order at 7:02 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 October 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*

- Legislative Committee on Administrative Rules: Discussions are ongoing regarding the 90 day supply rule and the AWP discount rule.
- Co-pay Analysis: There will be a presentation to the Health Access Oversight Committee regarding an analysis of an alternative co-pay structure.

4. Medical Director Update: Medical Director absent.

- Clinical Programs Update: No updates were reported.
- Prescriber Comments: No comments were received.

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

- **Simponi® (golimumab) Prefilled Injection:** It was recommended that coverage would require PA with the criteria for approval being that the patient has a diagnosis of RA, psoriatic arthritis or ankylosing spondylitis and has already been stabilized on Simponi® OR patient age \geq 18 years AND diagnosis is RA, psoriatic arthritis or ankylosing spondylitis, and the patient has documentation of an inadequate response, adverse reaction or allergic response to methotrexate, or if methotrexate is contraindicated, at least 1 DMARD AND the prescriber must provide a clinically valid reason why either Humira® or Enbrel® cannot be used. In addition, it was recommended that initial approval durations should be authorized for 3 months with a quantity limit of 1 syringe/month.

Public Comment: Ward Bennet, Centocor – OBI: Relayed the information that a study was presented at a recent meeting of the American College of Rheumatology that showed a statistically significant slowing of disease progression upon radiographic review compared to methotrexate.

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

- **Vectical® (calcitriol) Topical Ointment**
Deferred until next meeting. Unable to obtain input from a dermatologist to date.

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

- **Exforge HCT® (amlodipine/valsartan/hydrochlorothiazide) Tablet:** Recommended for addition to the PDL as preferred after the following clinical criteria are met: 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 to an angiotensin converting enzyme inhibitor (ACEI), an ACEI combination or any other angiotensin receptor blocker (ARB) or ARB combination. In addition, a quantity limit of 1 (one) tablet per day was recommended.

Public Comment: No public comment.

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

Full Drug Reviews

- **Nucynta® (tapentadol) Tablet:** Recommended for addition to the PDL as Prior-Authorization required with the criteria for approval being the member has had a documented side effect, allergy, or treatment failure to at least two of the following 3 immediate release generic short acting narcotic analgesics -- morphine, hydromorphone or oxycodone. It was also recommended that these same clinical criteria be applied to Opana®.

Public Comment: Melanie Crain, J&J OMJ – Commented on the clinical trials with Nucynta® and mechanism of action.

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

- Nuvigil[®] (armodafinil) Tablet: Recommended for addition to the PDL as prior authorization required with the criteria for approval for narcolepsy and excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome (adjunct to standard treatment) being the patient is ≥ 17 years old AND 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 to a CNS stimulant or has a contraindication for use of these agents (e.g. substance abuse history). It was recommended that Nuvigil[®] not be approved for sleepiness associated with shift work sleep disorder, idiopathic hypersomnolence, excessive daytime sleepiness, fatigue associated with use of narcotic analgesics, or for ADHD. In addition, if Nuvigil[®] is approved, a quantity limit of 60 tablets for 30 days for the 50 mg strength and 30 tablets for 30 days for 150 mg and 250 mg strengths is recommended.

Public Comment: No public comment.

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

- Savella[®] (milnacipran) Tablet: Recommended for addition to the PDL as prior authorization required with the criteria for approval being the diagnosis or indication is treatment of fibromyalgia AND the patient has had a documented side effect, allergy, or treatment failure to TWO drugs from the following: gabapentin, tricyclic antidepressant, SSRI antidepressant, SNRI antidepressant, miscellaneous antidepressant or cyclobenzaprine. In addition, a quantity limit of 2 tablets/day was recommended. Also, it was recommended that Savella[®] be added as an option for prior trial that will allow a patient to meet criteria for use of Lyrica[®] or Cymbalta[®] for the diagnosis of fibromyalgia.

Public Comment: Mike Delucia, Forest – Commented on the mechanism of action, pharmacokinetics, efficacy and safety of Savella[®].

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

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

- Growth Hormones:

A previously presented therapeutic class review of growth hormones determined that all products are equally efficacious. It was recommended that the most cost effective class structure would have Nodritropin[®] and Omnitrope[®] as the preferred products (after clinical criteria are met) within this class. Nutropin[®] would move to non-preferred status after clinical criteria are met. ICORE, the specialty pharmacy vendor for OVHA, will be responsible for contacting physicians and patients' families regarding this change and will ensure that teaching regarding the use of the new products occurs with families. This change was proposed for 01/04/2010.

Public Comment: No public comment.

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

- Lipotropics: Miscellaneous/Combinations (Lovaza[®] and Zetia[®]):

It was recommended that "started and stabilized" be added as an approval criteria for Lovaza[®] so that patients needing ongoing prior approvals could meet criteria (previously the criteria only included an elevated triglyceride level which patients who were responding to therapy would no longer have). A

discussion was held surrounding the approval criteria for Zetia[®] and whether the criteria for approval should remain a trial of both generic simvastatin and Crestor[®].

Public Comment: No public comment.

Board Decision: The DUR Board voted to approve the additional clinical criteria for Lovaza[®] as noted above but declined to change the clinical criteria for Zetia[®].

▪ **Migraine Medications (Triptans):**

It was recommended that regular Maxalt[®] tablets move to prior authorization required. Malaxt[®] MLT would remain preferred. This change was recommended due to a significant net cost difference between the two dosage forms. A patient specific prescriber mailing will be sent to prescribers asking them to change patients on regular Maxalt[®] tablets to Maxalt[®] MLT. This change was proposed for 01/04/2010.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MIIP recommendations noted above

8. **Drug Classes – Annual Review:**

(Public comment prior to Board action)

- **Long Acting Narcotics:** A full therapeutic class review was prepared. The only change to this category is that methadone 40 mg dispersible tablets are no longer allowed to be dispensed at retail and will be removed from the listing. Complaints surrounding the criteria for Duragesic[®]-12 patches were discussed but the criteria were recommended to remain unchanged. The criteria were reworded to be clearer.

Public Comment: No public comment.

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

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

- No RetroDur this month.
- **Future Topics:** Possible future topics were discussed.

Public Comment: No public comment.

Board Decision: None needed.

10. **New Drug Product Plan Exclusions:** Diane Neal, R.Ph, (MIIP)

- This will now be a quarterly agenda topic so was not discussed this month.

11. **Updated New-to-Market Monitoring Log:** 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.

12. General Announcements: Diane Neal, R.Ph, (MHP)
FDA Safety Alerts

- **Byetta[®] - altered kidney function:** FDA notified healthcare professionals of revisions to the prescribing information for Byetta[®] (exenatide) to include information on post-marketing reports of altered kidney function, including acute renal failure and insufficiency. Byetta[®] currently requires prior authorization. No changes to criteria were recommended.

Public Comment: No public comment.

Board Decision: None needed.

- **Rituxan[®] - PML:** Genentech and FDA notified healthcare professionals about a third case of progressive multifocal leukoencephalopathy [PML], the first case of PML in a patient with rheumatoid arthritis [RA] treated with Rituxan[®] who has not previously received treatment with a TNF antagonist. Information to date suggests that patients with RA who receive Rituxan[®] have an increased risk of PML. Physicians should consider PML in any patient being treated with Rituxan[®] who presents with new onset neurologic manifestations. Consultation with a neurologist, brain MRI, and lumbar puncture should be considered as clinically indicated. Rituxan[®] is not currently actively managed in the OVHA benefit and no changes to this are recommended.

Public Comment: No public comment.

Board Decision: None needed.

13. Adjourn: Meeting adjourned at 8:43 p.m.

Next DUR Board Meeting

Tuesday, December 08, 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.



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, Gilcad 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 malcate)):
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, (MIIP)*

- 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, (MIIP)

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.



Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 01/12/2010

Board Members:

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

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

Richard Harvic, 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)
Robin Farnsworth, OVHA

Vicki Loncr, OVHA
Stacey Baker, OVHA
Judy Jamieson, OVHA

Guests:

Steve Berardino, Amgen
Michael Deorsey, Abbott

Glenn E. Doolley, Sr, Sanofi-Aventis
Morrie Olsen, Reckitt Benckiser

Bill Sanborn, Novartis
Brooke Pastore Still, Reckitt Benckiser

Michael Scovner, M.D. Chair, called the meeting to order at 7:05 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 December 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*

- Vermont Prescription Monitoring System: A brown bag lunch presentation discussing this program will be held on Friday February 12th, 2010 at 12 noon. All interested are welcome to attend.
- VPharm PPI/Statin Pilot Program: A draft copy of the "Therapeutic Equivalency Program Legislative Report" was distributed (and later collected) to DUR Board members and discussed. VPharm costs are clearly shifting more toward preferred medications; 39% preferred proton pump inhibitors (PPIs) pre program compared to 72% post program, and 69% preferred statins pre program compared to 86% post-program. In addition, the costs per day for proton pump inhibitors (PPI's) decreased 26% and costs per day for statins decreased 52%. This figure includes the cost of non-preferred products obtained through exception or due to a prior authorization in the Part D plan. The savings for the three-month post period were \$138,000, with a projected annualized savings of \$552,600.

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)*

- Topical Testosterone Products: A DUR Board member had asked about gender edits on these products. There is a gender edit in place and so claims for female patients would reject for prior authorization.

Public Comment: No public comment.

Board Decision: None needed.

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

- Asacol HD[®] (mesalamine) Delayed Release Tablet
Deferred until February meeting.

Full New Drug Reviews

- Effient[®] (prasugrel) Tablet: It was recommended that Effient[®] (prasugrel) be added to the PDL as a preferred product in the platelet inhibitor class. A quantity limit of one tablet per day was recommended to encourage dose consolidation.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MIIP recommendations noted above. In addition, the Board requested a utilization review in six months to monitor for appropriate utilization.

- Ilaris[®] (canakinumab) Vial for Subcutaneous Injection: It was recommended that Ilaris[®] (canakinumab) require prior authorization with the criteria for approval being the member is 4 years old or older AND the member has a diagnosis of CAPS, supported by medical records. In addition, a quantity limit of 1 vial/56 days is recommended. It was also recommended that for approval of Arcalyst[®] (rilonacept) (the only other medication FDA approved for this indication) that a trial of Ilaris[®] would be required first. A new managed category entitled "Cryopyrin-Associated Periodic Syndromes (CAPS) injectables" will be created.

Public Comment: No public comment.

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

- Multaq[®] (dronedarone) Tablet: It was recommended that Multaq[®] (dronedarone) be made available without prior authorization. Due to low utilization within this drug class and no anticipated issues with inappropriate prescribing, it was recommended that the antiarrhythmic drug class did not need to be listed as a managed class.

Public Comment: No public comment.

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

- Onglyza[®] (saxagliptin) Tablet: It was recommended that Onglyza[®] (saxagliptin) be added to the PDL as “preferred after clinical criteria are met”. The criteria for approval would be a documented side effect, allergy, contraindication or treatment failure with metformin. A look-back for prior therapy with metformin would be handled with automated step therapy. In addition, a quantity limit of one tablet per day was recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above. The Board requested that the criteria be worded in a manner that would not discourage combined therapy with metformin.

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

- Scabicides and Pediculicides (includes overview of Ulesfia[®] (benzyl alcohol 5% lotion)):
Deferred until February meeting

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

- Suboxone[®]/Subutex[®] (buprenorphine):
Suboxone[®] and Subutex[®] utilization was discussed. From January 2007 until December 2009 the number of unique monthly utilizers increased from 788 to 1,737. Total payment increased from \$263,248.10 per month to \$702,032.58 per month. Patterns of daily dose amounts, days supply per prescription and numbers of Subutex[®] patients compared to Suboxone[®] patients were discussed. No immediate changes were recommended to the criteria and additional aspects of utilization will be studied.

Public Comment: Morrie Olson, Reckitt Benckiser -- discussed the history of the drug, pharmacology and appropriate use of the medication.

Board Decision: None needed.

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

- Lunesta[®] (eszopiclone) for insomnia: As expected, utilization of Lunesta[®] decreased after the implementation of the prior-authorization requirement. The average number of unique utilizers in the 9 months before and after the implementation of the prior-authorization was 382 and 253, respectively. In addition, a total of 207 prior authorization requests were reviewed between January 5, 2009 and November 5, 2009. Despite a fairly high rate of approval, the overall denial rate was 22%. The results of this quality assurance analysis and review of the denials for the prior-authorization

requests indicate that some prescribers were requesting Lunesta[®] without a trial of generic zolpidem. Due to the lack of comparative efficacy data demonstrating advantages of Lunesta[®] over other agents in the class, as well as the availability of less costly generic drug products within the class, it is recommended that Lunesta[®] remain on prior authorization. It is also recommended that no changes be made to the approval criteria for Lunesta[®] and that the length of authorization for approval remain one year. Some patients at this point remain on therapy without a prior authorization because they were originally grandfathered at the time that Lunesta was moved to non-preferred. It was recommended that the grandfathering continue.

Public Comment: No public comment.

Board Decision: The Board unanimously approved no changes to the criteria but requested that the number of patients remaining on therapy without a prior authorization be determined.

- Cost Savings/Clinical Analysis of Prior Initiatives:
 - Specialty Pharmacy – Hepatitis C and Growth Hormone
Deferred until February meeting.

10. 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.

11. General Announcements: Diane Neal, R.Ph, (MHP)
Deferred until February meeting.

12. Adjourn: Meeting adjourned at 9:30 p.m.

Next DUR Board Meeting

Tuesday, February 09, 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.



Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 02/09/2010

Board Members:

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

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

Stuart Graves, M.D.
Kathleen Boland, Pharm.D.

Staff:

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

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

Jennifer Egelhof, OVHA
Stacey Baker, OVHA

Guests:

Robert Bammons, M.D.
Amy Finn, Merck
Rod Francisco, Forest
Theodore Johnson, M.D.

James Kokoszyna, Allergan
Terry Lee, Gilcad Sciences
Craig Lemley, Amylin
Kelley Mackison, Johnson & Johnson

Jeffrey Olson, Gilcad Medical Affairs
Vik Patel, Amylin
John Renna, Shire
James Soriano, Shire
Mark Walker, Shire

Michael Scovner, M.D. Chair, called the meeting to order at 7:05 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 2010 meeting minutes were accepted as printed.

Public Comment: No public comment.

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

- Pharmacy Best Practices and Cost Control Report 2010 (SFY 2009): This report has been submitted to the legislature. The full report is available on the OVHA website. Net of rebates there was an increase in spend of 6.63% which appears to have been largely driven by an increase in enrollment of 5.16%. Net spending per beneficiary per month increased by 1.4% for all OVHA beneficiaries.

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

- DUR Board Meeting Schedule: A proposal was made to spread the DUR Board meetings from a monthly schedule to an every 6 week schedule. There would be a total of 8 meetings per year.
- Clinical Programs Update: There has been a lot of emphasis placed on examining the buprenorphine program for opiate addiction. This will be discussed in more detail later in the meeting and in the months to come.

- Prescriber Comments: No prescriber comments reported by Dr. Farber.

Robert Emmons, M.D. (private practice psychiatrist) – Dr. Emmons (who is not a Medicaid enrolled provider) was invited by a DUR Board member to speak regarding his experience covering for a colleague for a possible Medicaid patient who needed a prior authorization. It was suggested by Dr. Emmons that the Preferred Drug List should be eliminated and replaced with educational efforts and advice. It was also suggested that there should be a method to track and report harm that might occur as a result of drug coverage policies.

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

- No follow-up items

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

- Acuvail® (ketorolac) Ophthalmic Solution: It was recommended that Acuvail® (ketorolac) require prior authorization as a non-preferred product with the criteria for approval being that the patient has had a documented side effect, allergy, or treatment failure to Acular® or Acular LS® or the patient has a documented hypersensitivity to the preservative benzalkonium chloride. In addition, a quantity limit of 30 unit dose packets per fill was recommended.

Public Comment: No public comment.

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

- Asacol HD® (mesalamine) Delayed Release Tablet: It was recommended that Asacol HD® (mesalamine delayed release tablet) require prior authorization as a non-preferred product with the criteria for approval being that the patient has had a documented side effect, allergy, or treatment failure with two (2) preferred products.

Public Comment: No public comment.

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

- Edluar® (zolpidem tartrate) Sublingual Tablet: ; It was recommended that Edluar® (zolpidem tartrate sublingual) require prior authorization as a non-preferred product with the criteria for approval being that the patient has a medical necessity for a disintegrating tablet formulation (i.e. swallowing disorder). In addition, a quantity limit of one tablet per day was recommended.

Public Comment: No public comment.

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

Full Drug Reviews

- Cetraxal® (ciprofloxacin) Otic Solution: It was recommended that Cetraxal® (ciprofloxacin) otic solution require prior authorization as a non-preferred product with the criteria for approval being that the patient has had a documented side effect, allergy, or treatment failure to one of the following: any generic neomycin/polymixin B/hydrocortisone product, Ciprodex® otic suspension or generic ofloxacin otic solution. In addition, a quantity limit of 14 unit dose packages per fill was proposed. The Otic Anti-Infective managed category table was separated into “anti-infective single agent” products and “anti-infective/corticosteroid combination” products.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above including the restructure of the class table. The Board requested that utilization for some of the alternative otic solutions such as the acetic acid products be brought back to a subsequent meeting.

- Embeda® (morphine sulfate/naltrexone hydrochloride) Capsule (long acting): It was recommended that Embeda® (morphine sulfate/naltrexone hydrochloride) long acting capsule require prior authorization as a non-preferred product with the criteria for approval being that the patient has had a documented side effect, allergy, or treatment failure to generic morphine sulfate SR 12 hour. It was proposed that a history of drug abuse did not warrant approval of Embeda® as it was not clear to what extent this formulation will deter misuse, abuse and diversion.

Public Comment: No public comment.

Board Decision: The Board voted to defer a decision on this product until a subsequent meeting after attaining input from experts in pain management and addiction regarding the role of this drug. The Board also requested to know how many different prescribers were prescribing Avinza® (morphine sulfate).

- Intuniv® (guanfacine) Extended Release Tablet: It was recommended that Intuniv® (guanfacine) extended release require prior authorization as a non-preferred product as stimulants are preferred first line therapies. The recommended criteria for approval were the patient has a diagnosis of ADHD and the patient has been started and stabilized on the requested medication (excludes samples) or the patient has a documented treatment failure due to lack of efficacy to two long acting CNS stimulants and the patient has had a documented treatment failure with guanfacine immediate-release or has been unable to be compliant with or tolerate twice three times daily dosing of guanfacine immediate-release or the patient has a documented side effect, allergy, or direct contraindication (eg. comorbid ties, moderate-to-severe anxiety) to any one long-acting CNS stimulant and the patient has had a documented treatment failure with guanfacine immediate-release or has been unable to be compliant with or tolerate twice three times daily dosing of guanfacine immediate-release. In addition, a quantity limit of one tablet per day was recommended.

Public Comment: Theodore Johnson, M.D., Pediatrician – Discussed the desire for non-stimulant choices in ADHD.

John Renna, Shire – Commented on the situations where immediate release guanfacine might be used (autism, disruptive behavior issues) and also on the properties of Intuniv®.

Board Decision: The Board voted to make Intuniv® non-preferred with the criteria as outlined above but did not want to require a trial of immediate release guanfacine prior to approval. The Board also requested that the drug be approved if there is a history of drug abuse with the patient or in the home.

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

- Scabicides and Pediculicides (includes overview of Ulesfia® (benzyl alcohol 5% lotion)):
It was recommended that the class remain unchanged and that Ulesfia® (benzyl alcohol 5% lotion) be added as non-preferred with the criteria for approval being the same as for other non-preferred products (the patient has had a documented side effect or allergy to permethrin or treatment failure with two treatments of permethrin).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above. It was requested that the statement regarding neurotoxic side effects with other products be clarified at the next Board meeting.

8. New Managed Therapeutic Drug Classes
(Public Comment prior to Board action)

- Pulmonary Arterial Hypertension Agents: It was recommended that Adcirca® (tadalafil) be added to the phosphodiesterase-5 (PDE-5) Inhibitor Medications class as non-preferred with criteria for approval being a clinical diagnosis of pulmonary hypertension and no concomitant use of organic nitrate-containing products. In addition, a quantity limit of 2 tablets per day was recommended. A new category entitled “Pulmonary Arterial Hypertension Medications” was also introduced. There are two subcategories of “endothelial receptor antagonists” and “prostanoids”. All drugs would be preferred with the exception of brand name Flolan® where there is a generic equivalent. In addition, it was recommended that a maximum days supply for all drugs in this class be 30 days due to the high cost of these agents.

Public Comment: No public comment.

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

9. Review of Newly-Developed/Revised Clinical Coverage Criteria
(Public comment prior to Board action)

- Anti-Diabetics: Peptide Hormones (Byetta®): In light of the new FDA approved indication for monotherapy it was recommended that the criteria for approval be changed to require a failure of only one oral antidiabetic agent processed via automated step therapy. Byetta® would move from PA required to preferred agents after clinical criteria are met.

Public Comment: Vik Patel, Amylin – Commented on the clinical efficacy and role of Byetta® in diabetes.

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

- Gastrointestinals: Inflammatory Bowel Agents (Oral and Rectal Products): No need for further discussion as this was covered in the discussion on Asacol IID® where no other changes to the category were recommended.

- Suboxone[®]/Subutex[®] (buprenorphine): It was recommended that days supply be limited to a maximum of 30 days. Additional reports are going to be pulled and further proposals for additional edits will be brought back to the Board.

Public Comment: No public comment.

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

10. RetroDUR: *Diane Neal, R.Ph, (MIIP)*

- **Cost Savings/Clinical Analysis of Prior Initiatives**
 - Specialty Pharmacy – Hepatitis C and Growth Hormone – Overall, the OVHA specialty drug program has resulted in savings of \$796,833 compared to what the reimbursement to pharmacies would have been at the regular retail rate for the period November 2008 through October 2009. Some particular areas to highlight include a savings of \$119,255 just from restricting ribavirin to the generic 200 mg capsule and tablet as opposed to the more costly dosage forms and \$48,151 savings for Synagis[®]. In addition, with the introduction of Specialty pharmacy there has been a shift in patients to preferred products where there is additional savings from increased supplemental rebate collection which is not reflected in the number above.

Public Comment: No public comment.

Board Decision: None needed.

11. 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.

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

- Antipsychotics in Children-NY Times article: Discussed the use of antipsychotics in lower income children. It is expected that there will be a report from a multi-state Medicaid group out later this year.
- **FDA Safety Alerts**
 - Meridia[®] - (sibutramine Hydrochloride): Early communication about an ongoing safety review: FDA notified healthcare professionals that the review of additional data indicates an increased risk of heart attack and stroke in patients with a history of cardiovascular disease using sibutramine. Based on the serious nature of the review findings, FDA requested and the manufacturer agreed to add a new contraindication to the sibutramine drug label stating that sibutramine is not to be used in patients with a history of cardiovascular disease.

Public Comment: No public comment.

Board Decision: The Board would like to revisit the anti-obesity class of medications and review clinical criteria at some point.

- Norpramin[®] (desipramine) – Sudden Cardiac Death: Sanofi-Aventis and FDA notified healthcare professionals of changes to the Warnings and Overdosage sections of the Prescribing Information for Norpramin[®] (desipramine hydrochloride), indicated for the treatment of depression. The new safety information states that extreme caution should be used when this drug is given to patients who have a family history of sudden death, cardiac dysrhythmias, and cardiac conduction disturbances; and that seizures precede cardiac dysrhythmias and death in some patients.

Public Comment: No public comment.

Board Decision: None needed.

- Valproate: – Neural Tube Birth Defects: The FDA notified health care professionals and patients about the increased risk of neural tube defects and other major birth defects, such as craniofacial defects and cardiovascular malformations, in babies exposed to valproate sodium and related products (valproic acid and divalproex sodium) during pregnancy. Healthcare practitioners should inform women of childbearing potential about these risks, and consider alternative therapies, especially if using valproate to treat migraines or other conditions not usually considered life-threatening.

Public Comment: No public comment.

Board Decision: None needed.

- Voltaren Gel[®] (diclofenac) – Hepatic Effects: Endo, Novartis and FDA notified healthcare professionals of revisions to the Hepatic Effects section of the prescribing information to add new warnings and precautions about the potential for elevation in liver function tests during treatment with all products containing diclofenac sodium.

Public Comment: No public comment.

Board Decision: None needed.

- Zyprexa[®] (olanzapine): Use in Adolescents: Lilly and FDA notified healthcare professionals of changes to the Prescribing Information for Zyprexa[®] related to its indication for use in adolescents (ages 13-17) for treatment of schizophrenia and bipolar I disorder [manic or mixed episodes]. The revised labeling states that when deciding among the alternative treatments available for adolescents, clinicians should consider the increased potential (in adolescents as compared with adults) for weight gain and hyperlipidemia. Clinicians should consider the potential long-term risks when prescribing to adolescents, and in many cases this may lead them to consider prescribing other drugs first in adolescents.

Public Comment: No public comment.

Board Decision: None needed.

13. Adjourn: Meeting adjourned at 9:30 p.m.

Next DUR Board Meeting

Tuesday, April 13, 2010

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.



Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 04/13/2010

Board Members:

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

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

Stuart Graves, M.D.
Cheryl Gibson, M.D.

Staff:

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

Nancy Miner, (MHP)
Nancy Hogue, Pharm.D. (MHP)
Michael McAdoo, OVHA

Jennifer Egelhof, OVHA
Stacey Baker, OVHA
Robin Farnsworth, OVHA

Guests:

Steve Berardino, Amgen
Paul Panikos, BIP
Michael Finn, GSK
Rod Francisco, Forest

Bernie Janeczko, Centocor
Mark Kaplan, Abbott
James Kokoszyna, Allergan
Paul McDermott, Johnson & Johnson

Danielle Moon, Merck
Brooke Still, Reckitt Benckiser
Tony Tommasello, Reckitt Benckiser
Angelo Valeri, Novartis

Michael Scovner, M.D., Chair, called the meeting to order at 7:00 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: *Michael Scovner, M.D. Board Chair*

- Introductions were made around the table.
- The February 09, 2010 meeting minutes were accepted as printed.
- Guests were reminded that comments are limited to 3 minutes in duration and a timer will be used to be fair to all. Also, the Medical Director is available for discussion and comments concerning individual patient cases and should be contacted outside the DUR Board meeting.

Public Comment: No public comment.

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

- Director of Pharmacy Benefit Programs Retirement: Cindy LaWare will be retiring at the end of April. Nancy Hogue, Pharm.D, now of MedMetrics Health Partners, has accepted the role.
- Pharmaceutical Marketing Disclosures: The FY09 report from the Vermont Attorney General was presented. Approximately 17% of spending on the top 50 promoted drugs was spent on the marketing of drugs for depression.

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

- **Clinical Programs Update:** OVHA is in the process of forming a new Board called the CURB (Clinical Utilization Review Board) which will specifically look at new technology and technology currently being utilized to determine possible utilization controls and can be viewed as a companion Board to the DUR Board.
- **Prescriber Comments:** No prescriber comments were received.

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

- **Embeda® (morphine sulfate/naltrexone hydrochloride) Capsule (long acting):** Deferred until next meeting as more input is being gathered. Dr. Farber commented that the Medical Letter has just reviewed this drug.
- **Otic Anti-infectives:** Deferred until a later meeting.
- **Ulesfia® (benzyl alcohol 5% lotion):** It was clarified that this is the only benzyl alcohol product in this category. There are other products indicated for the treatment of lice that are also considered non-neurotoxic. Lindane is the only product that is considered neurotoxic.
- **Non Stimulants for ADHD:** It was clarified that a criteria for both Strattera® and Intuniv® is that they may be prescribed when there is a history of drug abuse with either the patient or family.

6. **RetroDUR/Prior Authorization Quality Assurance Analysis:** *Diane Neal, R.Ph., (MHP)*

- **Suboxone®/Subutex® (buprenorphine):** *Michael McAdoo, Managed Care Director, OVHA*
Utilization data was presented. Ideas for strengthening clinical criteria were presented.

Public Comment: Tony Tommasello, Reckitt Benckiser -- Discussed daily dosing requirements and treatment factors that lead to successful opiate addiction treatment.

Board Decision: No action needed as no definitive criteria were presented. More detailed data and recommendations as well as a revised PA form will be presented at the next meeting.

- **Amitiza® (lubiprostone):** Deferred until next meeting.
- **RetroDUR/Educational Activities Currently in Process:**
 - **Antipsychotics:** AHEC (Area Health Education Programs) out of UVM has chosen to target antipsychotic use and prescribing as one of their next projects. OVHA will be providing some utilization data to AHEC to help in the development of academic detailing programs. Dr. Charlie McLean will attend one of the upcoming Board meetings to discuss their program and specifics surrounding this intervention.

Public Comment: No public comment.

Board Decision: None needed.

- **Congestive Heart failure-Are patients on recommended medications?** The OVHA Chronic Care Initiative with APS (who provides telephonic support) will be developing an outreach to prescribers around patients with a diagnosis of CHF for patients who are not receiving a recommended ACEI/ARB and a recommended beta-blocker.

Public Comment: No public comment.

Board Decision: None needed.

- Future Topics?/DUR Board input: A discussion was held with the Board regarding possible RetroDUR topics. One area of interest was overuse of particular drug classes. A draft of the new CMS Annual Report format has been released and will be brought to the DUR Board for discussion.

Public Comment: No public comment.

Board Decision: None needed.

7. 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:

- Ozurdex[®] (dexamethasone) Intravitreal Implant: This drug implant is not available in pharmacies and so should be billed through the Medical Benefit. The OVHA Clinical Unit will be asked to take a look at his product for coverage decisions.

Public Comment: James Kokoszyna, Allergan – Described the implant technique and availability of the product.

Board Decision: None needed.

Full New Drug Reviews:

- Bepreve[®] (bepotastine besilate): It was recommended that Bepreve[®] (bepotastine besilate) ophthalmic solution require prior authorization as a non-preferred product with the criteria for approval being the patient has had a documented side-effect, allergy, or treatment failure to BOTH Optivar[®] and Pataday[®] or Patanol[®] (after a step through OTC ketotifen). A quantity limit of one bottle per month was recommended.

Public Comment: No public comment.

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

- Dysport[®] (abobotulinumtoxinA) Injection: It was recommended that Dysport[®] (abobotulinumtoxinA) require prior authorization as a non-preferred product with the criteria for approval being the patient has a diagnosis of a cervical dystonia or spasmodic torticollis and the patient is ≥ 18 years of age and the patient has had a documented side effect, allergy, or treatment failure with Botox[®].

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above but asked that the wording of the criteria be changed to treatment failure with Botox[®] (remove reference to side effect and allergy).

- Onsolis[®] (fentanyl) buccal soluble film: It was recommended that Onsolis[®] (fentanyl) require prior authorization as a non-preferred product with the criteria for approval being the same as the other fentanyl breakthrough pain products. The criteria would be the patient has an indication of cancer breakthrough pain (no approval for acute pain or postoperative pain) and documentation that the patient is opioid tolerant and the member is on a long-acting opioid formulation and the member has had a documented treatment failure with or intolerance to 2 of the following 3 immediate-release breakthrough pain treatment options: morphine, hydromorphone or oxycodone OR the member is unable to use tablet or liquid formulations. It was recommended that the definition of opioid tolerant be modified as in the fentanyl black box warning (oral morphine \geq 60 mg daily, transdermal fentanyl \geq 25 mcg/hour, oral oxycodone \geq 30 mg daily, oral hydromorphone \geq 8 mg daily or an equianalgesic dose of another opioid daily for a week or longer).

Public Comment: No public comment.

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

- Stelara[®] (ustekinumab) Subcutaneous Injection: It was recommended that Stelara[®] (ustekinumab) require prior authorization as a non-preferred product with the criteria for approval being the prescription must be written by a dermatologist AND the patient has a documented diagnosis of moderate to severe plaque psoriasis and has already been stabilized on Stelara[®] OR the prescription must be written by a dermatologist AND the patient has a documented diagnosis of moderate to severe plaque psoriasis affecting $>$ 10% of the body surface area (BSA) and/or has involvement of the palms, soles, head and neck, or genitalia and has had a documented side effect, allergy, inadequate treatment response, or treatment failure to at least 2 different categories of therapy [i.e. at least 2 topical agents and at least 1 oral systemic agent, (unless otherwise contraindicated)] from the following categories: (1) Topical agents: emollients, keratolytics, corticosteroids, calcipotriene, tazarotene, etc. (2) Systemic agents: methotrexate, sulfasalazine, azathioprine, cyclosporine, tacrolimus, mycophenolate mofetil, etc. (3) Phototherapy: ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA, narrow band ultraviolet B (NUVA), etc. AND the prescriber must provide a clinically valid reason why either Enbrel[®] or Humira[®] cannot be used. A quantity limit of one dose per fill was recommended and patients \leq 100 kg would be limited to 45 mg doses.

Public Comment: Paul McDermott, Johnson & Johnson – Discussed the method of action of Stelara[®] and a brief overview of the drug.

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

- Valturna[®] (aliskiren/valsartan) Tablet: It was recommended that Valturna[®] (aliskiren/valsartan) require prior authorization as a non-preferred product with the criteria for approval being the patient has a diagnosis of hypertension AND the patient has had a documented treatment failure with the combination of a preferred Angiotensin Receptor Blocker (ARB) and Tekturna[®]. A quantity limit of one tablet per day was recommended.

Public Comment: Angelo Valeri, Novartis – Proposed altering the approval criteria above to be changed to “OR” rather than “AND”.

Board Decision: The Board approved the MIIP recommendations noted above with one abstention.

8. Therapeutic Drug Classes – Periodic Review

Deferred until next meeting.

9. New Managed Therapeutic Drug Classes

No new drug classes this month.

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

Diane Neal, R.Ph., (MHP)

- Anti-Diabetics: Insulin Due to the discontinuation of some insulin pen products (Novolin N[®], Novolin R[®] and Novolin 70/30[®]), it was recommended that the corresponding IHumulin products be moved to preferred status.

Public Comment: No public comment.

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

- Byetta[®] and Symlin[®] Fact Sheets: When Byetta[®] and Symlin[®] were originally reviewed by the DUR Board in 2006, information fact sheets were developed and are still being sent to prescribers. It was recommended that these sheets are no longer necessary and the practice should be discontinued.

Public Comment: No public comment.

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

- Suboxone[®]/Subutex[®] (buprenorphine):
Will be brought back for discussion next month (see RetroDUR above).

11. 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.

12. General Announcements

(1) **Selected FDA Safety Alerts** Deferred until next meeting.

(2) **Board Member Resignation** *Michael Scovner, M.D. Board Chair*

It was announced that Rich Harvie R.Ph., a 17 year member of the Board has resigned. Rich was recognized for his many years of service.

13. Adjourn: Meeting adjourned at 9:15 p.m.

Next DUR Board Meeting

Tuesday, May 18, 2010

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.



Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 05/18/2010

Board Members:

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

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

Kathleen Boland, Pharm.D.

Staff:

Diane Neal, R.Ph., (MHP)
Michael Farber, M.D., OVHA
Nancy Miner, (MHP)

Nancy Hogue, Pharm.D., OVHA
Michael McAdoo, OVHA

Jennifer Egelhof, OVHA
Stacey Baker, OVHA

Guests:

Matt Badalucco, Merck
Susan Campbell, Acorda Therapeutics
Thomas Carattini, Acorda Therapeutics
Rod Francisco, Forest

Bernie Jancezko, Centocor
James Kokoszyna, Allergan
Danielle Moon, Merck

Christy Owens, Novartis
Jennifer Roan, Acorda Therapeutics
Angelo Valeri, Novartis

Michael Scovner, M.D. Chair, called the meeting to order at 7:00 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 April 2010 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: Nancy Hogue, Pharm.D., Director of Pharmacy Services, OVHA

- Health Care Reform: OVHA continues to monitor how health care reform may impact the bottom line for drug spend and how it may impact decisions that are made by the DUR Board. At this point in time details are unclear and State Medicaid programs are seeking clarification from CMS.
- FUL (Federal Upper Limit) Calculation: The FUL calculation is being changed to improve reimbursement to pharmacies.

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

- Clinical Programs Update:
DUR Board: OVHA is continuing to seek additional new members to fill vacancies and will also have Board membership and rules clarified in statute next legislative session.

CURB: The Clinical Utilization Review Board will begin meeting soon and has been asked to find 4 million dollars in savings this coming fiscal year.

- Prescriber Comments: No prescriber comments were received.

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

- Embeda[®] (morphine sulfate/naltrexone hydrochloride) Capsule (long acting): It was recommended that Embeda[®] (morphine sulfate/naltrexone hydrochloride) require prior authorization as a non-preferred product with the criteria for approval being the patient has a diagnosis or condition that requires a continuous around-the-clock analgesic and the patient has had a documented side effect, allergy, or treatment failure to morphine sulfate SR 12 hr. Additionally, a history of substance abuse does not warrant approval of Embeda[®] since a clear advantage of this product over other morphine products in this population has not been established. A quantity limit of 2 capsules per day was also recommended.

Public Comment: No public comment.

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

- Valturna[®] (aliskiren/valsartan) Tablet: It was recommended that the clinical criteria adopted last meeting be revised for the sake of clarity to be the patient has a diagnosis of hypertension AND the patient has had a documented side effect, allergy, or treatment failure to an angiotensin converting enzyme inhibitor (ACEI), an ACEI combination or any other angiotensin receptor blocker (ARB) or ARB combination OR the patient has had a documented treatment failure with Tekturna[®] alone.

Public Comment: No public comment.

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

6. RetroDUR/Prior Authorization Quality Assurance Analysis: *Diane Neal, R.Ph., (MIIP)*

- Suboxone[®]/Subutex[®] (buprenorphine): Buprenorphine utilization from 3/10/2010 – 5/10/2010 was presented. The percentage of utilizers with doses per day of ≤ 8 mg, 9 – 16 mg, 17 – 24 mg, 25 – 32 mg or > 32 mg was 29.8%, 43.8%, 25.4%, 1.1% and 0.1% for Suboxone[®] and 31.7%, 31.7%, 34.9%, 1.6% and 0% for Subutex[®] respectively. The percentage of utilizers with days supply per prescription of 1 – 7, 8 – 14, 15 – 21, 22 – 30 or > 30 days were 31.6%, 18.1%, 5.4%, 44.8% and 0.1% for Suboxone[®] and 36.5%, 24.3%, 6.9%, 32.3% and 0% for Subutex[®] respectively. Subutex[®] prior authorization approvals were examined for the period 3/31/2009 through 4/21/2010. PAs were granted for pregnancy (79.9%), breastfeeding a methadone dependent baby (4.44%) or allergy/intolerance (15.66%). Cost savings opportunities related to reducing daily doses was presented. If all daily doses > 16 mg/day were reduced to 16 mg/day the potential annualized cost savings based on utilization from 3/10/2010 – 5/10/2010 would be \$870,473.84 for Suboxone[®] and \$176,195.10 for Subutex[®]. A number of changes to the clinical criteria and PA form were recommended. These include (a) the prescriber must query the Vermont Prescription Monitoring System (VPMS) to review the patient's Schedule II-IV medication history when requesting a new PA (b) the patient must identify a "pharmacy home" where all prescriptions will be filled (c) PA requests for Subutex due to pregnancy must be accompanied by a history from the OB Provider (d) PA requests for Subutex due to breastfeeding a methadone dependent baby must be accompanied by a baby history from the neonatologist or pediatrician (e) quantity limit on Subutex reduced to 16 mg/day

(f) maximum days supply reduced to 14 days and (g) PA form to be faxed rather than requests be processed over the phone.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above and asked that the quantity limit for Suboxone of 3 tablets per day be clarified that it apply to both 2 mg and 8 mg tablets. Also, the PA form will be modified to clarify that prescribers may call after faxing the PA form for urgent requests.

- Amitiza[®] (lubiprostone): The Office of Vermont Health Access (OVHA) claims data for Amitiza[®] was reviewed from February 1, 2009 to January 31, 2010. 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 Amitiza[®] submitted from February 1, 2009 to January 31, 2010 was reviewed for appropriateness of the current prior authorization criteria and approval duration. The results indicate appropriate utilization based on the current approval criteria. During the selected review period, there were a total of 122 paid pharmacy claims for Amitiza[®] 24 µg with an average cost per claim of \$195. The demand for the lower 8 µg Amitiza[®] strength was considerably lower. There were a total of 29 paid claims at \$201 per claim, on average. The total annual plan cost for Amitiza[®] coverage was \$29,580.40. There was no significant variation in the numbers of unique utilizers or paid claims during the review period. In addition, there were a total of 80 prior authorization requests for 51 unique utilizers with an overall approval rate of 87.5%. Furthermore, 51% of the received prior authorization requests were renewal requests, 97.56% of which were approved for three months. Approximately 90% of all new Amitiza[®] approvals were one-time PAs, with renewal not being pursued. The most common reason for denying a request for Amitiza[®], regardless of strength, was insufficient information. No changes to the current OVHA prior authorization approval criteria are recommended. It was recommended that while the current duration of authorization for new requests remains the same, the length of authorization for renewals be increased to 1 year, with recertification authorized upon verification of clinical response.

Public Comment: No public comment.

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

- Congestive Heart Failure: Deferred until next meeting as letter to prescribers is still being finalized.
- Antipsychotics: As a follow-up to prior discussion on work with AHIEC and academic detailing, some data provided to AHIEC was shared. A summary of specialty and provider type of prescribers for antipsychotics was presented for ages 21 years old and under and over 21 years old. An analysis of Seroquel[®] daily dose was presented (> 18 and < 60 years old) was presented. It appears that 56% of total claims and 31.6% of dollars were for doses < 150 mg/day that most probably reflects use as an hypnotic or anxiolytic.

Public Comment: No public comment.

Board Decision: None needed.

7. **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

- Extavia® (interferon beta-1b) Injection: It was recommended that Extavia® require prior authorization as a non-preferred product with the criteria for approval being the patient has a diagnosis of multiple sclerosis and the provider must provide a clinical reason why Betaseron® cannot be prescribed.

Public Comment: No public comment.

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

- Metozolv® (metoclopramide) Orally Disintegrating Tablet: It was recommended that Metozolv® require prior authorization as a non-preferred product with the criteria for approval being the patient has a medical necessity for a disintegrating tablet formulation (i.e. swallowing disorder, inability to take oral medications) AND generic metoclopramide oral solution cannot be used. In addition, the following quantity limit is recommended: 4 tablets/day for both strengths. The duration of authorization is recommended to be up to 3 months; continuation of therapy requests should not be approved.

Public Comment: No public comment.

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

- Renvela® (sevelamer carbonate) Powder for Oral Suspension Packet: It was recommended that Renvela® require prior authorization as a non-preferred product with the criteria for approval being the patient has a requirement for a liquid dosage form. A quantity limit of 2 packets per day of the 0.8g strength packet was recommended to encourage dose consolidation.

Public Comment: No public comment.

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

- Twynsta® (amlodipine/telmisartan) Tablet: It was recommended that Twynsta® require prior authorization as a non-preferred product with the criteria for approval being the patient has had a documented side effect, allergy, or treatment failure to an angiotensin converting enzyme inhibitor (ACEI), an ACEI combination or any other angiotensin receptor blocker (ARB) or ARB combination AND the patient is unable to take the individual components (amlodipine and Micardis®) separately. A quantity limit of one tablet/day was recommended.

Public Comment: No public comment.

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

- Zenpep® (pancrelipase) Delayed Release Capsule: It was recommended that Zenpep® be added as a preferred product without any restrictions.

Public Comment: No public comment.

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

Full Drug Reviews

- Ampyra® (dalfampridine) Extended Release Tablet: It was recommended that Ampyra® require prior authorization as a non-preferred product with the criteria for approval being the patient has a diagnosis of multiple sclerosis and the patient is ≥ 18 years old. In addition, a quantity limit of 2 tablets/day with a maximum 30 day supply was recommended.

Public Comment: No public comment.

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

- Fanapt® (iloperidone) Tablet: It was recommended that Fanapt® require prior authorization as a non-preferred product with the criteria for approval being 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. In addition, a quantity limit of 2 tablets/day was recommended.

Public Comment: Christy Owens, Novartis – Discussed the relative lack of extrapyramidal side effect with this drug.

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

8. Therapeutic Drug Classes – Periodic Review: Diane Neal, R.Ph, (MHIP) (Public comment prior to Board action)

- Acne Medications: Topical: Anti-infectives: No changes were recommended to this class.

Public Comment: No public comment.

Board Decision: Approved no changes.

- Acne Medications: Topical: Retinoids: No changes were recommended other than listing some combination products that are not covered as the individual components may be prescribed separately.

Public Comment: No public comment.

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

- Acne Medications: Topical: Rosacea: No changes were recommended to this class.

Public Comment: No public comment.

Board Decision: Approved no changes.

- Dermatological Agents: Corticosteroids: No changes were recommended to this class.

Public Comment: No public comment.

Board Decision: Approved no changes.

9. New Managed Therapeutic Drug Classes:

- No New Drug Classes

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

Diane Neal, R.Ph, (MHP)

- Atypical Antipsychotics for MDD: Upon review, it became apparent that our criteria for MDD as written applied to all antipsychotics rather than the select few that were intended. The following criteria were proposed for Abilify[®] and Zyprexa[®] in MDD: The patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization) OR if the indication for use is Major Depressive Disorder (MDD) the patient has had a documented side effect, allergy or treatment failure with one preferred product being used as adjunctive therapy.

Public Comment: No public comment.

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

- Cimzia[®] (certolizumab) Injection for Rheumatoid Arthritis: Cimzia[®] gained approval for use in Rheumatoid Arthritis after its initial approval for Crohn's approval. It was recommended that Cimzia[®] be a non-preferred agent after clinical criteria are met. The criteria for approval being the patient has a diagnosis of RA and has already been stabilized on Cimzia[®] 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 DMARD (other DMARDs include leflunomide, sulfasalazine, gold, antimalarials, minocycline, D-penicillamine, azathioprine, cyclophosphamide and cyclosporine) AND the prescriber must provide a clinically valid reason why either Humira[®] or Enbrel[®] cannot be used.

Public Comment: No public comment.

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

11. Updated New-to-Market Drug 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.

12. FDA Safety Alerts:

- Avandia[®] (rosiglitazone): Ongoing Review of Cardiovascular Safety: FDA notified healthcare professional and patients that it is reviewing the primary data from a large, long-term clinical study, RECORD, on possible cardiovascular risks with the diabetes drug, Avandia (rosiglitazone).
- Erythropoiesis-Stimulating Agents (ESAs): Procrit[®], Epogen[®] and Aranesp[®]: Drug Safety Communication: FDA and Amgen notified healthcare professionals and patients that all ESAs must be used under a REMS risk management program. As part of the risk management program, a Medication Guide explaining the risks and benefits of ESAs must be provided to all patients receiving an ESA. Under the ESA APPRISE Oncology program, Amgen will ensure that only those hospitals and healthcare professionals who have enrolled and completed training in the program will prescribe and dispense ESAs to patients with cancer.

- Long-Acting Beta-Agonists (LABAs): New Safe Use Requirements: FDA notified healthcare professionals and consumers that, due to safety concerns, FDA is requiring a risk management strategy (REMS) and class-labeling changes for all LABAs. The REMS will require a revised Medication Guide written specifically for patients, and a plan to educate healthcare professionals about the appropriate use of LABAs. These changes are based on FDA's analyses of studies showing an increased risk of severe exacerbation of asthma symptoms, leading to hospitalizations in pediatric and adult patients as well as death in some patients using LABAs for the treatment of asthma.
- Oral Bisphosphonates: Ongoing Safety Review of Atypical Subtrochanteric Femur Fractures: FDA notified healthcare professionals and patients that at this point, the data that FDA has reviewed have not shown a clear connection between bisphosphonate use and a risk of atypical subtrochanteric femur fractures
- Plavix[®] (clopidogrel): Reduced effectiveness in patients who are poor metabolizers of the drug: FDA notified healthcare professionals and patients that a Boxed Warning has been added to the prescribing information for Plavix[®], an anti-blood clotting medication. The Boxed Warning in the drug label will include information to warn about reduced effectiveness in patients who are poor metabolizers of Plavix[®]. Poor metabolizers do not effectively convert Plavix[®] to its active form in the body.
- Stalevo[®] (entacapone/carbidopa/levodopa): Ongoing Safety Review: FDA notified healthcare professionals and patients that it is evaluating data from a long-term clinical trial called Stalevo[®] Reduction in Dyskinesia Evaluation - Parkinson's Disease (STRIDE-PD), that may suggest that patients taking Stalevo[®] may be at an increased risk for developing prostate cancer.
- Tysabri[®] (natalizumab): Update of Healthcare Professional Information: FDA notified healthcare professionals and patients that the risk of developing progressive multifocal leukoencephalopathy (PML) increases with the number of Tysabri[®] infusions received. This new safety information, based on reports of 31 confirmed cases of PML received by the FDA as of January 21, 2010, will now be included in the Tysabri[®] drug label and patient *Medication Guide*.
- Zocor[®] (simvastatin): increased risk of muscle injury with high doses: FDA notified healthcare professionals and patients that, based on review of data from a large clinical trial and other sources, there is an increased risk of muscle injury in patients taking the highest approved dose of the cholesterol-lowering medication, Zocor[®] (simvastatin) 80 mg, compared to patients taking lower doses of simvastatin and possibly other drugs in the "statin" class.

Public Comment: No public comment.

Board Decision: The Board approved no coding changes and recommended posting the alerts on the web site.

13. Adjourn: Meeting adjourned at 8:59 p.m.

Next DUR Board Meeting

Tuesday, June 29, 2010 ****PLEASE NOTE DATE****

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.



Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 06/29/2010

Board Members:

Michael Scovner, M.D., Chair
Virginia Flood, M.D.

Norman Ward, M.D.
Stuart Graves, M.D.

Lynne Vezina, R.Ph.

Staff:

Nancy Hogue, Pharm.D., OVHA
Diane Neal, R.Ph., (MHP)
Michael Farber, M.D. OVHA

Nancy Miner, (MHP)
Stacey Baker, OVHA

Robin Farnsworth, OVHA
Jennifer Mullikin, OVHA

Guests:

Rick Angeli, Merck
Alan Blau, Forest
Thomas Currier, Purdue
Kevin Danielson, Pfizer
Dana Evans, Genentech
Amy Finn, Merck

Mark Kaplan, Abbott
James Kokoszyna, Allergan
Andrew Kuehn, Forest
Craig Lemley, Amylin
Ed MacMillan, Abbott Diabetes

John Mastrianni, Genentech
Christy Owens, Novartis
Carl Pepe, GSK
Natalie Prairie, Forest
Angelo Valeri, Novartis

Michael Scovner, M.D. Chair, called the meeting to order at 7:00 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 May 2010 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: Nancy Hogue, Pharm.D. - Pharmacy Director, OVHA

- Health Care Reform: Impact on Preferred Drug Selection: The Federal Government will be capturing larger amounts of rebate from drugs used in the Medicaid program. Certain "line extension drugs" will become much more unfavorably priced as even greater amounts of the federal rebate will go back to the federal government rather than staying with the State Medicaid program. This change in rebate program structure will need to be considered when reviewing new medications and as the PDI status of some older medications is re-evaluated.

4. Medical Director Update: Michael Farber, M. D. - OVHA

- Clinical Programs Update: Norman Ward, MD., will be leaving the DUR Board and will become a member of the new CURB. Dr. Ward was thanked for over a decade of membership on the DUR

Board. Several recommendations for new DUR Board members have been forwarded to the Governor for approval.

- Prescriber Comments: No comments were received.

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

- Suboxone®/Subutex® (buprenorphine): Work continues on determining implementation steps to the changes voted on last month in prior authorization criteria and changes to the PA form. There are a large number of prescribers and patients who will be impacted by these changes.

Public Comment: No public comment.

Board Decision: None needed.

6. RetroDur/Prior Authorization Quality Assurance Analysis: Diane Neal, R.Ph. (MHIP)
(Public comment prior to Board action)

- Topical Immunomodulators (Protopic® and Elidel®) – duplicate therapy: There was concern raised by the Clinical Call Center around patients who may be receiving duplicate therapy as a way to get around quantity limits that are in place. During the review period (March 1, 2008 to February 28, 2010) of the quality assurance for the topical immunomodulators, there were a total of 304 prior authorizations and 789 claims for 374 unique utilizers. Of these, there was only one member with claims and prior authorizations for duplicate therapy with topical immunomodulators. The prior authorizations for this member were appropriately approved and did not exceed the quantity limits. Therefore, based on a review of utilization and prior authorization requests for Protopic® and Elidel®, no changes to the current OVHA prior authorization approval criteria are recommended.

Public Comment: No public comment.

Board Decision: None needed

- Duplicate Therapy with Long-Acting Narcotics: Currently the Office of Vermont Health Access (OVHA) does not have restrictions on duplicate long-acting narcotic therapy. Preferred long-acting narcotics are available without a prior authorization and non-preferred LA narcotics pay after PA criteria and quantity limit criteria are met. There is no process in place to prevent the use of multiple LA narcotic products. A retrospective evaluation of LA narcotic utilization was performed to identify current utilization trends and to assess the need for coding implementation that would prevent duplicate LA narcotic claims from paying at the point of sale. A review of utilization data from April 1, 2009 to March 31, 2010 has identified 38 members receiving at least two long-acting narcotics concurrently for at least two consecutive months. A review of utilization data within the same time period has also identified 10 members receiving a long-acting narcotic concurrently with Suboxone® for at least two consecutive months. Of these members, 13 and 1 were receiving duplicate LA narcotic therapy and concomitant LA narcotic/Suboxone® claims, respectively, at the time of QA preparation. Furthermore, 7 members had claims for two or more LA narcotics from different prescribers. Suboxone® was prescribed concurrently with a LA narcotic by different prescribers for 6 members identified in the report. Of the identified members, 29 received duplicate LA narcotic therapy and 5 received Suboxone® in combination with a LA narcotic agent for longer than two consecutive months. The other 14 members identified by the review had duplicate LA narcotics or concomitant LA narcotic/Suboxone® claims for 2 consecutive months only. Members switching from

one form of therapy to another were excluded from the analysis. A regimen consisting of an oral LA narcotic and a transdermal product was the most common (55%) duplicate LA narcotic combination therapy. Fentanyl in combination with morphine sulfate extended-release was the most frequently encountered example of such therapy. Moreover, 20% of the identified duplicate LA narcotic claims were for Suboxone[®] used in combination with a LA narcotic. The following changes are recommended as criteria for approval of duplicate long acting narcotic therapy:

Duplicate Long-Acting Narcotic Therapy

The patient has a diagnosis or condition that requires a continuous, around-the-clock analgesic AND the prescriber has queried the VPMS (Vermont Prescription Monitoring System) to review patient's Schedule II-IV medication history AND the prescriber provides a clinically compelling rationale for duplicate therapy (not maximizing monotherapy).

Duplicate Buprenorphine/Long-Acting Narcotic Therapy

The patient has a diagnosis or condition that requires a continuous, around-the-clock analgesic AND the prescriber has queried the VPMS (Vermont Prescription Monitoring System) to review patient's Schedule II-IV medication history AND the prescriber provides a clinically compelling rationale for duplicate buprenorphine/long-acting narcotic therapy.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above but requested that the language concerning the VPMS be changed from required to recommended. These changes in clinical criteria will be implemented only after clarification has been obtained from OVHA's legal staff concerning the information the Clinical Call Center may give to prescribers concerning the duplicate therapy.

- RetroDUR/Educational Activities Currently in Process:
- Congestive Heart Failure: The Chronic Care Initiative has been looking at patients identified as having congestive heart failure and who are not on the recommended preferred beta-blocker and/or ACEI/ARB. The data set is being cleaned up as patients without a clear diagnosis are excluded. Further information will be presented at a later meeting.

Public Comment: No public comment

Board Decision: None needed

**7. Clinical Update: Drug Reviews: Diane Neal, R.Ph, (MIIP)
(Public comment prior to Board action)**

- Actemra[®] (tocilizumab) Intravenous Infusion: It is recommended that tocilizumab be added to the PDL as Prior-Authorization required with the criteria for approval being the patient age ≥ 18 years AND the patient has a diagnosis of rheumatoid arthritis AND the patient has documentation of an inadequate response, adverse reaction or allergic response to methotrexate, or if methotrexate is contraindicated, at least 1 DMARD AND the patient has documentation of an inadequate response to at least one preferred TNF antagonist agent (i.e. adalimumab (Humira[®]) or etanercept (Enbrel[®])). Initial approval duration should be 3 months with a quantity limit of 3 vials (80 mg or 200 mg vials) / 28 days and 2 vials (400 mg vials) / 28 days.

Public Comment: Dana Evans, MD., Genentech, commented on the various clinical trials submitted to the FDA for approval. It was recommended that a quantity limit be 4 vials of the 80 mg vials be allowed which is cost effective for a 80 kg patient receiving the 4 mg/kg dose.

Board Decision: The Board unanimously approved the MHP recommendations noted above with the revised quantity limit.

- Berinert[®] (C1 esterase inhibitor) Intravenous Infusion: It is recommended that Berinert[®] (C1 Esterase Inhibitor [Human]) be added to the PDL as Prior-Authorization required with the criteria for approval being the diagnosis or indication is **treatment** of an acute Hereditary Angioedema (HAE) attack. (Approval may be granted so that patient may keep a dose on hand). If Berinert[®] is approved, the proposed length of authorization is 6 months initially and 1 year upon recertification.

Public Comment: No public comment.

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

- Cayston[®] (aztreonam) Inhalation Solution: It is recommended that Cayston[®] be added to the Preferred Drug List as Prior-Authorization required with the criteria for approval being the patient has a diagnosis of Cystic Fibrosis. Approval duration should be 1 year with a quantity limit of 84 vials / 56 days (3 vials per day for 28 days followed by 28 days off). The new managed category will be Cystic Fibrosis Inhalation medications. It was also recommended that Pulmozyme require Prior Authorization as OVHA has discovered utilization outside of the FDA approved Cystic Fibrosis indication.

Public Comment: No public comment.

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

- Kalbitor[®] (ecallantide) Subcutaneous Injection: It is recommended that Kalbitor[®] (ecallantide) be added to the PDL as Prior Authorization required with the criteria for approval being the diagnosis or indication is **treatment** of an acute Hereditary Angioedema (HAE) attack. A quantity limit of 6 vials (2 packs) per fill is recommended.

Public Comment: No public comment.

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

8. Therapeutic Drug Classes-Periodic Review:
(Public comment prior to Board action)

- Otic Anti-Infectives
Deferred until a future meeting.
- Anesthetics: Topical: No changes are recommended in the medications managed or the clinical criteria

Public Comment: No public comment.

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

- Dermatological Agents: Antibacterials: Topical: The category is divided into single agent and combination products. More specific criteria were developed for particular agents.

Public Comment: No public comment.

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

- Dermatological Agents: Antifungals: Topical: This is a new category to cover all antifungals (not just onychomycosis) as are covered now. Generics are preferred and branded products are non-preferred.

Public Comment: No public comment.

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

- Dermatological Agents: Antivirals: Topical: This is a new managed category. These products have been shown to have minimal clinical effect compared to oral agents.

Public Comment: No public comment.

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

- Immunomodulators: Topical: As discussed earlier in the RetroDUR above, the medication is being used appropriately. It was recommended that that the step through a corticosteroid be through a moderate or high potency topical corticosteroid rather than just any corticosteroid.

Public Comment: No public comment.

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

9. New Managed Therapeutic Drug Classes:

(Public comment prior to Board action)

- Two new drug classes detailed above.

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

Diane Neal, R.Ph, (MHP)

- Alzheimer's Medications: Cholinesterase Inhibitors/NMDA Receptor Antagonists (proposed preferred drug changes): It was recommended that Aricept ODT move from preferred to PA required. Criteria for approval would be the diagnosis or indication for the requested medication is Alzheimer's disease AND the patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization.) OR medical necessity for a specialty dosage form has been provided.

Public Comment: No public comment.

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

- Anti-Hyperkinesia and Anti-Narcolepsy/Cataplexy (proposed preferred drug changes): It was recommended that Adderall XR[®] move from preferred to PA required for new users. Criteria for approval would be the patient has a diagnosis of ADD, ADHD or narcolepsy AND 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 on Vyvanse[®] AND if the request is for the generic product, the patient must have a documented intolerance to the brand name Adderall XR[®]. This change will be implemented January 1, 2011.

Public Comment: No public comment.

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

- Anti-Migraine: Triptans (proposed preferred drug changes): It was recommended that this category become a generic first category with sumatriptan as the preferred oral triptan. All brands would become PA required. Additionally, for Maxalt MLT[®], the patient would require a medical necessity for a specialty dosage form. A mailing will be sent to prescribers to ask them to consider moving patients on Maxalt MLT[®] to sumatriptan or, if not an option, to Maxalt[®]. The timing of this change will be such as an appropriate length of time will be provided to prescribers to move patients.

Public Comment: No public comment.

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

- Gastrointestinals: Proton Pump Inhibitors (proposed preferred drug changes): It was recommended that Prilosec OTC[®] move to PA required and omeprazole 20 mg and 40 mg generic would become preferred. This change will be implemented in a way to allow time for prescribers to transition patients.

Public Comment: No public comment.

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

- Urinary Antispasmodics (proposed preferred drug changes): It was recommended that Sanctura XR[®] move to PA required.

Public Comment: No public comment.

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

11. Brand to Generic Changes: *Diane Neal, R.Ph, (MHP)*

It was recommended that the following brands move to PA required and their generics would be preferred: Risperal[®] Oral Solution, Depakote ER[®], Topamax Sprinkle[®] and Tegretol XR[®]. Pharmacies will be notified in plenty of time to adjust their inventory.

Public Comment: No public comment.

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

12. Updated New-to-Market Monitoring Log (Consent agenda topic): *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.

13. General Announcements: *Diane Neal, R.Ph, (MHIP)*

FDA Safety Alerts

- **Benicar[®] (olmesartan) – Ongoing Safety Review:** FDA is evaluating data from two clinical trials in which patients with type 2 diabetes taking the blood pressure medication, Benicar (olmesartan), an angiotensin II receptor blocker, had a higher rate of death from a cardiovascular cause compared to patients taking a placebo. FDA's review is ongoing and the Agency has not concluded that Benicar increases the risk of death. FDA currently believes that the benefits of Benicar in patients with high blood pressure continue to outweigh its potential risks.
- **Proton Pump Inhibitors – Class Labeling Change:** FDA notified healthcare professionals and patients of revisions to the prescription and over-the-counter [OTC] labels for proton pump inhibitors, which work by reducing the amount of acid in the stomach, to include new safety information about a possible increased risk of fractures of the hip, wrist, and spine with the use of these medications. The new safety information is based on FDA's review of several epidemiological studies that found those at greatest risk for these fractures received high doses of proton pump inhibitors or used them for one year or more.
- **Tramadol – Label Change:** Ortho-McNeil-Janssen and FDA notified healthcare professionals of changes to the Warnings section of the prescribing information for tramadol, a centrally acting synthetic opioid analgesic indicated for the management of moderate to moderately severe chronic pain. The strengthened Warnings information emphasizes the risk of suicide for patients who are addiction-prone, taking tranquilizers or antidepressant drugs and also warns of the risk of overdose. Tramadol-related deaths have occurred in patients with previous histories of emotional disturbances or suicidal ideation or attempts, as well as histories of misuse of tranquilizers, alcohol, and other CNS-active drugs. Tramadol may be expected to have additive effects when used in conjunction with alcohol, other opioids or illicit drugs that cause central nervous system depression. Serious potential consequences of overdose with tramadol are central nervous system depression, respiratory depression and death. Tramadol has mu-opioid agonist activity, can be abused and may be subject to criminal diversion. A RetroDUR of tramadol utilization will be prepared and presented at a later meeting.

Public Comment: No public comment.

Board Decision: The Board approved no coding changes and recommended posting the alerts on the web site.

14. Adjourn: Meeting adjourned at 8:55 p.m.

Next DUR Board Meeting

Tuesday, September 14, 2010

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.



Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 09/14/10

Board Members:

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

Cheryl Gibson, M.D.
Virginia Hood, M.D.

Sommer Zarbock, Pharm. D.
Jeanne Greenblatt, M.D. (Executive
Session only)

Staff:

Nancy Hogue, Pharm.D., DVHA
Diane Neal, R.Ph., (MHP)
Robin Farnsworth, DVHA

Nancy Miner, (MHP)
Michael Farber, M.D., DVHA

Jennifer Egelhof, DVHA
Stacey Baker, DVHA

Guests:

Susan Alford, NovoNordisk
Tracy Cravaack, NovoNordisk
Christine Dube, MedImmune
Amy Finn, Merck
Rod Francisco, Forest

Craig Gill, Pfizer
Renee Hagerty, Takeda
Doug Kenyon, MedImmune
James Kokoszyna, Allergan
Jonathon Mast, AstraZeneca

John Mastrianni, Genentech
Keith Osburn, Sepracor
Carl Possidente, Pfizer
Ralph Quintana, Abbott
Tony Tommasello, Reckitt Benckiser
Joe Winalski, Biogen Idec

Michael Scovner, M.D. Chair, called the meeting to order at 7:05 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 June 2010 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. DVHA Pharmacy Administration Updates: Nancy Hogue, Pharm.D. - Pharmacy Director, DVHA

- Member Unique Identification Numbers: DVHA will no longer be using Social Security Numbers as identification numbers beginning October 1, 2010. New ID cards have been issued to all members.

4. Medical Director Update: Michael Farber, M. D. - DVHA

- Clinical Programs Update:
Opiate Addiction Conference at Statehouse: Several DVHA members attended this conference which discussed the issue of prescription drug addiction in the State of Vermont. Buprenorphine was intermittently discussed.

Resignations from DUR Board: Norman Ward, MD., has resigned from the DUR Board to serve on the CURB. Kathy Boland, Pharm.D., has also resigned.

New Appointments to DUR Board: Jeanne Greenblatt, MD., a Pediatric Psychiatrist will be joining the Board. Sommer Zarbock, Pharm.D, a member of the faculty of the Albany College of Pharmacy, Colchester, VT campus is also joining the Board.

- Prescriber Comments: No comments were received.

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

- Suboxone[®]/Subutex[®] (buprenorphine): A letter to prescribers describing the changes voted upon at the May meeting will be sent out shortly. A discussion surrounding the Suboxone[®] sublingual film was held.

Public Comment: Tony Tommasello, Reckitt Benckiser - Introduced the Suboxone[®] sublingual film dosage form that has just recently been released. He described the differences between the sublingual film and the already available sublingual tablet.

Board Decision: None needed. The formulary status of the sublingual film dosage form will be determined at a later meeting.

6. RetroDUR/Prior Authorization Quality Assurance Analysis: *Diane Neal, R.Ph., (MHIP)*

(Public comment prior to Board action)

- Synagis[®] :
In September 2009, the Department of Vermont Health Access (DVHA) had updated the Synagis[®] approval criteria for the upcoming 2009-2010 RSV season in response to the changes in the American Academy of Pediatrics guideline recommendations on RSV prophylaxis with palivizumab (Synagis[®]), published in the Red Book in July 2009. A retrospective drug utilization analysis of Synagis[®] from the 2009-2010 RSV season was performed to review utilization and evaluate the appropriateness of the current prior authorization approval criteria. As expected, Synagis[®] utilization decreased after the revision of the prior-authorization criteria in the fall of 2009. Following the implementation of the updated Synagis[®] approval criteria, there was a 42% reduction in the total number of unique utilizers, corresponding with a 46.4% reduction in paid Synagis[®] claims. The reduction in paid claims is consistent with a decrease in the submission of prior authorization requests (from 132 to 102 requests), as well as an increase in the overall denial rate (from 16% to 31%). There were no paid claims outside of the official RSV season (November 1-March 31) and no one received more than 5 Synagis[®] doses per season. By contrast, the vast majority of unique utilizers during the 2008-2009 RSV season received a total of 6 doses. Moreover, at the time of the previous Synagis[®] QA analysis in the fall of 2009, it was estimated that the revision of the approval criteria, in response to the 2009 AAP update, would lead to a cost savings of approximately \$300,577 per each RSV season. This prediction was based on the estimated cost savings associated with the elimination of the 6th dose, ending the official RSV season in March, implementation of a 3 months age cut off in providing RSV prophylaxis to infants born between 32 and 35 weeks of gestation, and allowing a maximum of 3 doses for this age group. An analysis of utilization from the 2009-2010 RSV season indicates that the total cost savings to DVHA had exceeded this prediction. The implementation of the revised approval criteria had led to a cost savings of \$428,518, translating into a 40.4% reduction in total spending on Synagis[®] per each RSV season. No changes to current criteria are recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously agreed to retain the current criteria.

- Actiq®/Fentora® Prior Authorization Requests: It was noticed on a quarterly drug report that there were several claims for Fentora (which is unusual) so PA requests for short acting fentanyl products for the period 1/1/2010 – 6/25/2010 were reviewed. There were 4 PA requests for 2 patients. The request for one patient was denied as it was requested for severe headache which is not considered an appropriate indication. The other requests were appropriate. There were no recommendations.

Public Comment: No public comment

Board Decision: None needed

- RetroDUR/Educational Activities Currently in Process
 - Congestive Heart Failure: An outreach letter to prescribers has been finalized and will be sent out. The letter reminds prescribers of the recommended medication therapy in CHIF therapy to reduce morbidity and mortality for patients without contraindications.

Public Comment: No public comment

Board Decision: None needed

7. Clinical Update: Drug Reviews *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.
(Public comment prior to Board action)

Abbreviated Drug Reviews

- Mirapex ER® (pramipexole) Extended Release Tablet: It was recommended that Mirapex ER® be added to the PDL as Prior-Authorization required with the criteria for approval being the diagnosis or indication is Parkinson's disease AND the patient has had an inadequate response (i.e., wearing off effect or "off" time) with the generic pramipexole or Mirapex® IR OR the patient has not been able to be adherent with a three times daily dosing schedule of pramipexole/Mirapex® IR resulting in a significant clinical impact. In addition, it was recommended to have the following quantity limits: 1 table/day for all strengths.

Public Comment: No public comment

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

- Revatio® (sildenafil) Intravenous Bolus Injection: Due to its limited FDA-approved indication and cost considerations, Revatio IV® is recommended to be added to the PDL as prior-authorization required with the criteria for approval being the patient has a clinical diagnosis of pulmonary hypertension AND there is no concomitant use of organic nitrate-containing products AND the patient has a requirement for an injectable dosage form AND arrangements have been made for IV bolus administration outside of an inpatient hospital setting. Approvals would be issued for the date of service only. Quantity limit is recommended to be 3 vials per day.

Public Comment: No public comment.

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

- Vpriv[®] (velaglucerase alfa) IV Infusion: Due to its limited FDA-approved indication and cost considerations, it is recommended that Vpriv[®] be added to the PDL as prior-authorization required with the criteria for approval being the diagnosis is Gaucher disease, confirmed by molecular or enzymatic testing. This approval criteria would also be applicable to Cerezyme[®]. The same criteria should apply in both the Pharmacy and Medical Benefit.

Public Comment: No public comment.

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

Full Drug Reviews

- Zyprexa[®] Relprevv (olanzapine pamoate monohydrate) Long Acting Injection
Deferred until next meeting.

8. Therapeutic Drug Classes – Periodic Review

(Public comment prior to Board action)

- Anti-Diabetics: Peptide Hormones: Incretin Mimetics (includes new drug review of Victoza[®] (liraglutide))
Deferred until next meeting.
- Ophthalmics:
 - Anti-Allergy: Antihistamines and Mast Cell Stabilizers: No changes were recommended to the antihistamine class. In the mast cell stabilizer class it was recommended that Alamast move to PA required and the sole preferred product would be generic cromolyn sodium.

Public Comment: No public comment.

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

- Antibiotics (expansion of class as previously only quinolones): This category would be expanded to include the previously listed quinolones (no changes) and also the marcolides where generic erythromycin would be the preferred product, the aminoglycosides where generic gentamicin and tobramycin would be preferred as single agents and generic tobramycin/dexamethasone would be the preferred combination product as well as a generic preferred miscellaneous category.

Public Comment: No public comment.

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

- Corticosteroids: Topical: No changes recommended.

Public Comment: No public comment.

Board Decision: The Board approved no changes to this category.

- Glaucoma Agents/Miotics
 - Beta-Blockers – No changes recommended.
 - Carbonic Anhydrase Inhibitors – Divided into single agent and combination products
 - Glaucoma Combinations – No changes recommended.
 - Prostaglandin Inhibitors – Recommended change to criteria to only require a trial of a preferred beta-blocker to be in line with clinical guidelines.

Public Comment: No public comment.

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

- Nonsteroidal Anti-inflammatory Drugs – No changes recommended.

Public Comment: No public comment.

Board Decision: The Board approved no changes to this category.

9. Newly Managed Therapeutic Drug Classes: Diane Neal, R.Ph., (MHP)

- Ophthalmics: Immunomodulators: It was recommended that Restasis be added to the PDL as prior-authorization required with the criteria for approval being the patient has a diagnosis of moderate to severe keratoconjunctivitis sicca (KCS)(dry eyes) AND the patient has had a documented treatment failure, adverse event, or contraindication to an artificial tear product. Additionally, a quantity limit of 60 vials per 30 days is also recommended.

Public Comment: No public comment.

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

10. Review of Newly-Developed/Revised

Clinical Coverage Criteria and/or Preferred Products Diane Neal, R.Ph., (MHP)

- No new/revised criteria this month

11. Updated New-to-Market Drug Monitoring Log

- Now on DVHA website

12. Selected FDA Safety Alerts

- Angiotensin Receptor Blockers (ARBs): Ongoing Safety Review for Cancer Risk: A recently published study - a meta-analysis combining cancer-related findings from several clinical trials - suggested use of ARBs may be associated with a small increased risk of cancer. FDA has not concluded that ARBs increase the risk of cancer. The Agency is reviewing information related to this safety concern and will update the public when additional information is available. FDA believes the benefits of ARBs continue to outweigh their potential risks.
- Lamictal (lamotrigine): Label Change – Risk of Aseptic Meningitis: FDA notified healthcare professionals and patients that Lamictal (lamotrigine), a medication commonly used for seizures in children two years and older, and bipolar disorder in adults, can cause aseptic meningitis.

Symptoms of meningitis may include headache, fever, stiff neck, nausea, vomiting, rash, and sensitivity to light. In cases of meningitis, it is important to rapidly diagnose the underlying cause so that treatment can be promptly initiated.

- Midodrine hydrochloride: FDA Proposes Withdrawal of Low Blood Pressure Drug: FDA recently notified Shire and the generic manufacturers of the agency's proposal to withdraw product approval for midodrine. The FDA's proposed action was based on the lack of required post-marketing data confirming the clinical benefit of the drug. FDA intends to work with Shire, the generic manufacturers, and other organizations to discuss the data that are necessary to establish the efficacy of midodrine. Midodrine remains approved and available in the marketplace. To reassure patients and their doctors, FDA has stated clearly that as the regulatory process moves forward, continued patient access to midodrine is a key agency priority.
- FDA Opioid Recommendations: It was expected that recommendations would be forthcoming from the FDA this past summer. The FDA now reports that the new opioid recommendations will be unveiled early next year as the advisory committee felt that the initial proposal was not strong enough.

13. Adjourn Meeting adjourned at 8:13 p.m. (Early adjournment due to loss of quorum).

Next DUR Board Meeting

Tuesday, October 26, 2010

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

FDS Building, DVHA 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.

Vermont is a "mandatory generic" state as outlined in the Vermont statutes below: Pharmacies must dispense generics unless the prescriber expressly requires the brand.

The Vermont Statutes

Title 18: Health

Chapter 91: PRESCRIPTION DRUG COST CONTAINMENT

18 V.S.A. § 4605. Alternative drug selection

§ 4605. Alternative drug selection

(a) When a pharmacist receives a prescription for a drug which is listed either by generic name or brand name in the most recent edition of the U.S. Department of Health and Human Services' publication Approved Drug Products With Therapeutic Equivalence (the "Orange Book") of approved drug products, the pharmacist shall select the lowest priced drug from the list which is equivalent as defined by the "Orange Book", unless otherwise instructed by the prescriber, or by the purchaser if the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, otherwise to pay the full cost for the higher priced drug.

(b) The purchaser shall be informed by the pharmacist or his representative that an alternative selection as provided under subsection (a) of this section will be made unless the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, otherwise to pay the full cost for the higher priced drug.

(c) When refilling a prescription, pharmacists shall receive the consent of the prescriber to dispense a drug different from that originally dispensed, and shall inform the purchaser that a generic substitution shall be made unless the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, otherwise to pay the full cost for the higher priced drug.

(d) Any pharmacist substituting a generically equivalent drug shall charge no more than the usual and customary retail price for that selected drug. This charge shall not exceed the usual and customary retail price for the prescribed brand. (Added 1977, No. 127 (Adj. Sess.), § 1; amended 2001, No. 63, § 124; 2005, No. 71, § 306, eff. June 21, 2005; 2009, No. 35, § 3.)

VT Medicaid PDL Management of Generic Drugs

PDL Categories: Preferred Drugs

Whenever possible, preferred drugs in a category will be generic. Clinical criteria for branded products will generally include a step through a generic product when available ("generic first"). The DUR Board heavily promotes the use of generics in general and directly through identified classes in the PDL by means of automated step therapies and/or prior authorizations in the following categories:

- Acne
- Analgesics: NSAID, Short Acting Narcotics, Long Acting Narcotics
- Anti-anxiety: Anxiolytics
- Anticonvulsants
- Antidepressants: Miscellaneous, SSRIs and Tricyclics
- Anti-diabetics: Biguanides and second generation sulfonylureas
- Anti-emetics: 5-HT₃ Receptor Antagonists
- Antihypertensives: ACE Inhibitors/Combinations, Beta-Blockers, Calcium Channel Blockers
- Anti-Infectives: Antibiotics: Cephalosporins: First and Second Generation, Macrolides and Penicillins
- Anti-infectives: Antifungals: Azoles
- Antipsychotics: Typicals
- BPH: Alpha Blockers
- Constipation: Chronic or IBS-C
- Coronary vasodilators / antianginals
- Corticosteroids: Oral
- Cough and cold medications
- Dermatological Agents: Corticosteroids, Scabicides and Pediculicides
- Gastrointestinals: H-2 blockers
- Lipotropics: Bile Acid Sequestrants, Fibric Acid derivatives, Statins
- Mood Stabilizers
- Musculoskeletal agents/Anti-spasticity agents
- Ophthalmics: Antihistamines and Corticosteroids(Topical)
- Parkinson's medications
- Pulmonary: Antihistamines: 1st generation and 2nd generation
- Sedative hypnotics (benzodiazepines)
- Sedative Hypnotics: Non-benzodiazepine, Non-barbiturate
- Skeletal Muscle Relaxants
- Vaginal Anti-infectives
- Vitamins: Prenatal Multivitamins

Additional drug classes reviewed and approved by the DUR board in FFY 2010 as generic preferred classes are:

- Dermatological Agents: Antibiotics: Topical and Antifungals: Topical
- Gastrointestinal: Prokinetic Agents
- Gout Agents: Xanthine Oxidase Inhibitors
- Ophthalmics: Antibiotics and Mast Cell Stabilizers

New generic entries:

When a new generic product becomes available within a PDL-managed therapeutic category, DVHA manages the addition of such generic product to the PDL without formal evaluation by the DUR Board, once the pricing of that product warrants PDL inclusion. Movement of such generic products to preferred status would be limited to AB-rated (bioequivalent) drug products where there exists no significant evidence of increased safety risk or diminished efficacy as compared to alternative PDL options.

Additionally, per positive vote of the OVHA DUR Board on May 9, 2006, OVHA reserves the right to restrict coverage of a new generic entity if the net pricing of its branded alternative remains lower to the State. Such coverage restrictions will remain in place until the time when generic pricing falls to a level representative of greater cost savings to the State versus the branded alternative.

Vermont Pharmacy Benefit Management Access Program Costs FFY 2010:

In FFY 2010 the Vermont State Medicaid program covered a monthly average of 127,819 eligible beneficiaries (117,258 FFY 2009), with a FFY 2010 total of 1,484,171 prescription claims with a net cost of \$123 million. This is a 5.9% decrease in Rx claim volume and a 2.1% increase in overall Rx cost versus FFY 2009.

DUR initiatives specifically resulting in annualized cost savings and/or cost avoidance in FFY 2010:

Initiative	\$ Savings
On-line POS/ProDUR	\$ 30,076,434.18
Lunesta	\$ 224,154.43
Restasis	\$5,764.92
Topical Antivirals	\$ 40,981.62
Specialty Pharmacy	\$ 613,454.00
Synagis	\$ 428,518.00
TOTAL	\$ 31,389,305.00

FFY 2010 Top 10 Therapeutic Classes by Cost

Drug Group	Rx Claims	\$ Spend	% of Total \$	\$/Claim
Analgesics - Opioid	194,845	\$14,191,780.07	11.54%	\$72.84
Antipsychotics/Antimanic Agents	52,411	\$13,213,790.17	10.75%	\$252.12
Antiasthmatic And Bronchodilator Agents	77,833	\$12,116,283.78	9.85%	\$155.67
Adhd/Anti-Narcolepsy/Anti-Obesity/Anorex	76,081	\$11,408,003.88	9.28%	\$149.95
Antidepressants	161,649	\$9,592,376.55	7.80%	\$59.34
Ulcer Drugs	49,826	\$6,887,820.03	5.60%	\$138.24
Anticonvulsants	83,516	\$5,414,636.69	4.40%	\$64.83
Antivirals	13,250	\$5,307,336.27	4.32%	\$400.55
Antidiabetics	29,600	\$5,091,958.67	4.14%	\$172.03
Contraceptives	31,249	\$3,001,376.04	2.44%	\$96.05
FFY 2010 TOTAL for TOP 10 CLASSES	770,260	\$86,225,362.15	70.12%	\$111.94
FFY 2010 TOTAL for ALL CLASSES	1,484,171	\$122,966,418.32	100.00%	\$82.85
FFY 2009	1,576,778	\$120,379,297.96		\$76.35
FFY 2008	1,507,622	\$104,769,077.93		\$69.49
FFY 2007	1,492,835	\$98,505,572.12		\$65.99
FFY 2006	1,929,013	\$128,547,761.00		\$66.64

FFY 2009	Rx Claims	\$ All Classes	\$/Claims
CY Q4 '08	385,641	\$28,234,462	\$73.21
CY Q1 '09	398,637	\$29,978,606	\$75.20
CY Q2 '09	407,111	\$30,271,424	\$74.36
CY Q3 '09	385,389	\$31,894,806	\$82.76

FFY 2010	Rx Claims	\$ All Classes	\$/Claims
CY Q4 '09	373,316	\$29,956,114	\$80.24
CY Q1 '10	375,435	\$31,189,995	\$83.08
CY Q2 '10	372,976	\$31,327,326	\$83.99
CY Q3 '10	362,444	\$30,492,984	\$84.13

- % Prescriptions Processed by ECM System in FFY 2010 – 99.90%

Please refer to (1) Attachment 1 – ProDur for On-line POS/ProDUR cost avoidance.

(2) Attachment 3 – Retrospective DUR Screening and Interventions for cost savings analysis for Lunesta, Specialty Pharmacy and Synagis.

(3) Topical Antivirals and Restasis cost savings analysis below.

Cost Savings Associated with Managing New Medication Categories

Restasis 6 month savings = \$ 2,882.46

Annualized Savings = \$ 5,764.92

Pre - Implementation (4/12/10 - 10/11/10)				
	Rx's	Total Amt Due	Amt Due/Rx	Amt Due PMPM
Brand	124	\$34,724.70	\$280.04	\$0.04

Post - Implementation (10/12/10 - 4/11/11)				
	Rx's	Total Amt Due	Amt Due/Rx	Amt Due PMPM
Brand	115	\$31,842.24	\$276.89	\$0.04

Antivirals: Topical 6 month savings = \$ 20,490.81 Annualized Savings = \$ 40,981.62

Pre - Implementation (2/17/10 - 8/16/10)				
	Rx's	Total Amt Due	Amt Due/Rx	Amt Due PMPM
Brand	379	\$39,811.59	\$105.04	\$0.05

Post - Implementation (8/17/10 - 2/16/11)				
	Rx's	Total Amt Due	Amt Due/Rx	Amt Due PMPM
Brand	233	\$19,320.78	\$82.92	\$0.02

Vermont Prescription Monitoring System

The Department of Health launched the Vermont Prescription Monitoring System ("VPMS") in 2009, as established under Act 205.

When a Schedule II, III, or IV controlled substance is dispensed to an outpatient, a standard set of information about the patient, the prescriber, and the drug will be collected by the VPMS and maintained for six years on a secure, central database.

Information from the System will be available to providers and pharmacists to help in their work to effectively manage their patients' treatment.

By maintaining complete and up-to-date information, providers will have access to a full history of their patient's prescriptions for controlled substances. Further, the system can alert a provider to possible abuse of - or addiction to - controlled substances.

Patients can request a report of their own records, but do not have direct access to the system. A patient for whom a prescription for a controlled substance is written may request information from the VPMS database relating to himself or herself. The request must be in writing, and the person must appear in-person, and produce a valid government-issued photographic proof of identify to receive the VPMS report.

Licensing Boards may request records, but do not have direct access to the VPMS database. A representative of a professional board that is responsible for the licensure, regulation or discipline of health care providers or dispensers, may request information from the database relating to a licensee, pursuant to a bona fide specific investigation of that licensee.

DVHA (VT Medicaid) does not have access to the VPMS and the system does not track source of payment. The VPMS only allows access for prescribers and dispensers that are treating their bonafide active patients. The reason for this is that the VPMS was established as a health oriented system. The data item of payment is obsolete to a provider when treating a patient. While it may lead to more questions about the patients reasoning for seeking medications, the VPMS is not in the business of "catching" people but improving health by identifying someone who may be abusing or addicted to controlled substances. In addition to insurers, law enforcement has no access to this system.

Currently, conversations about what kind of changes will be proposed to the present VPMS statute this legislative season are ongoing.



State of Vermont
Department of Vermont Health Access
312 Hurricane Lane, Suite 201
Williston, VT 05495-2807
<http://dvha.vermont.gov>

Agency of Human Services

Effective October 25th, 2010
Important Changes to Suboxone[®]/Subutex[®] (Buprenorphine) Program

September 22nd, 2010

Dear Colleague:

The Department of Vermont Health Access (DVHA) remains committed to providing medication-assisted opioid-dependence treatment in an office-based setting for appropriately selected beneficiaries. The Drug Utilization Review (DUR) Board of the DVHA made significant changes to the prior authorization requirements for Suboxone[®] and Subutex[®] that became effective in December 2007 with further changes in August 2008. After a thorough review of our claims data and prior authorization requests, and meeting with the Department of Corrections regarding reports of diversion and abuse (of both Subutex[®] and Suboxone[®]), the DUR Board voted May 18, 2010 to implement further changes to ensure access while limiting the risk of diversion.

Diagnosis: Suboxone[®] and Subutex[®] have received FDA approval only for the treatment of opioid addiction. Vermont Medicaid policy is consistent with these approved indications. DVHA will continue to grant prior authorization only for patients who have a diagnosis of opioid dependency. Prior authorization will not be granted for buprenorphine prescribed for pain control.

Who May Prescribe: The Drug Addiction Treatment Act of 2000 (DATA 2000) enables *qualifying physicians* to receive a *waiver* from the special registration requirements in the Controlled Substances Act for the provision of medication-assisted opioid addiction therapy. Physician assistants and nurse practitioners may not prescribe buprenorphine for opioid addiction treatment as these practitioners are not included in the definition of "*qualifying physicians*". Prior authorization will only be granted to patients whose requesting prescriber has a DATA 2000 waiver ID number.

Subutex[®]: Due to reports of Subutex[®] (buprenorphine "mono" tablet) diversion and abuse by injection or intranasal use (to a greater extent than Suboxone[®]), prior authorization will only be granted for Subutex[®] for pregnant women and women breastfeeding methadone dependent babies. The buprenorphine prescriber must provide documentation from the OB provider or pediatrician/neonatologist with the prior authorization request. All other requests for Subutex[®] must be discussed on a case-by-case basis with the DVHA Medical Director.

Prior Authorization Submission: To process your prior authorization request in the most expeditious manner, all PA requests must be submitted via fax to ensure that requests are not delayed for incomplete information. DVHA requests additional information on the revised PA form (copy attached). All requests will be processed within 24 hours.

Dosing: Correct dosing contributes to the success of your patients' treatment. Due to the "ceiling effect" of buprenorphine (see below), higher dosing offers little extra benefit and increases the potential for diversion, while low dosing may result in cravings and withdrawal symptoms causing the patient to drop out of treatment.¹ As the average buprenorphine dose prescribed to DVHA beneficiaries has increased, the following review is being provided.

¹ Medical Advisory & Best-Practices Update, Reckitt Benckiser Pharmaceuticals Inc. 11/06

Mechanism of Action

Buprenorphine binds tightly to the mu-opioid receptor and is not easily displaced by other opioid agonists and, therefore, it blocks the effects of subsequently administered opioids in a dose-dependent manner. There is considerable evidence that the generally effective daily Suboxone[®] dose is approximately 16 mg/day¹. At 16 mg/day, mu-opioid receptor availability is decreased by 85% to 92%. While the mean mu-opiate receptor binding potential values for 32 mg/day doses are higher than 16 mg/day, they do not significantly differ². This degree of blockade (at 16 mg/day) appears to minimize withdrawal symptoms, promotes attendance at counseling sessions, and prevents euphoria from other ingested opioids.

Maintenance Dosages

Following successful induction, a clinically effective maintenance dose should be established. The dosage should be progressively adjusted in increments/decrements of 2 mg or 4 mg to a level that maintains the patient in treatment and suppresses opioid withdrawal effects. While the target dose is 16 mg/day, expected doses can range from 4 mg – 16 mg/day and should be effective for at least 24 hours. The provider should assess other psychosocial and medical/psychiatric co-morbidity issues that may contribute to a patient's perception that the current dose is not adequate.¹

Dosing Instructions

The provider must educate their patients on the proper administration of buprenorphine (i.e., sublingual, not oral, administration).¹ Buprenorphine has low oral bioavailability relative to sublingual bioavailability. Sublingual buprenorphine takes at least 5 minutes and up to 12 minutes for a dose to adequately dissolve and completely absorb sublingually. Not allowing time for complete absorption may result in the perception that the dose is not sufficient. A patient instruction sheet with helpful tips to photocopy and to provide to your patients is included below.

The FDA has recently approved a new dosage formulation of Suboxone[®] (a sublingual film). The DUR Board will evaluate both the clinical and cost implications of this new dosage form in the coming months and determine the Medicaid policy for this product.

DHVA Dosing Limits

Patient buprenorphine needs are unique and a small number of patients may require up to 24 mg/day doses. The possibility for diversion of part or all of a dose must always be considered. **For either drug, caution should be used when prescribing doses higher than 16 mg per day.** Effective 10/25/2010, an absolute dose limit of 16 mg/day will be adopted for Subutex[®] and 24 mg/day for Suboxone[®]. Patient specific information is attached to this letter for all your patients who currently have claims exceeding these limits. Authorization for continuation of dosing at levels above these limits will require that additional clinical information justifying this need be provided. To prevent any disruption in medication therapy, please call DVHA at 879-5955 to discuss the patients prior to 10/15/2010.

Pharmacy Home: In order to assist patients in their recovery from opiate addiction, DVHA will be requiring all beneficiaries prescribed buprenorphine to identify a "pharmacy home" where *all* of their prescriptions will be filled. Please discuss this requirement with the patient and document their pharmacy choice on the PA form. Prescriptions may not be filled at other pharmacies and prior authorization requests for buprenorphine for patients without a pharmacy home will be returned as incomplete. In an urgent situation when a beneficiary cannot obtain a prescription at their chosen Pharmacy Home, DVHA may be contacted to arrange approval to obtain it at a different pharmacy.

Prescription Days Supply: In some circumstances, excess medication may tempt an individual to divert some of their medication to provide income or to share medication with others.¹ Beginning October 25, 2010, the maximum allowable days supply will be 14 days. This will limit quantities on hand in the community and also reduce medication waste from patients who do not tolerate or choose to discontinue therapy.

² Greenwald MK, Johanson CE, Moody DE, Woods JH, Kilbourn MR, Koeppe RA *et al* (2003). Effects of buprenorphine maintenance dose on mu-opioid receptor availability, plasma concentrations, and antagonist blockade in heroin-dependent volunteers. *Neuropsychopharmacology* 28: 2000–2009.

Vermont Prescription Monitoring Program (VPMS): As a provider of opioid addiction treatment, DVHA strongly recommends that all prescribers register for and use the VPMS. The VPMS was established to provide prescribers with as much information as possible about their patients' prescription medication history. This is particularly important if you are not the primary care physician for a patient obtaining Schedule II – IV medications from other prescribers in addition to buprenorphine. Please query the VPMS to review the patient's scheduled II-IV medication history before requesting prior authorization for buprenorphine and at regular intervals after that time and if there is a change in patient status.

Registration and designation instructions and forms may be found at <http://healthvermont.gov/adap/VPMS.aspx#HealthCareProvider> or you may contact Meika Zilberberg MS, Program Coordinator, at (802) 652-4147.

Diversion and Non-Compliance: DVHA is committed to providing the correct medication in the correct dose for appropriately selected patients. Some behaviors that may suggest non-adherence with treatment include offers to pay "out of pocket" for the mono-product or repeated requests for increased dosing. For patients discharged from your practice due to non-adherence with your medication-assisted opioid-dependence program, please contact the Clinical Call Center at 1-800-918-7549 to inactivate the prior authorization requested by you on file for that patient.

Drug Interactions/Safety Concerns: Buprenorphine exhibits a "ceiling effect" with regard to respiratory depression, making a lethal overdose unlikely. This ceiling effect and its potential safety margin are eliminated when combining buprenorphine with alcohol or other sedative drugs, including benzodiazepines (particularly when administered intravenously). Although the combination of buprenorphine and benzodiazepines is not absolutely contraindicated, buprenorphine should be prescribed with caution to patients taking benzodiazepines or other sedative drugs including tramadol. Additionally, the administration of opiates to patients receiving buprenorphine is discouraged since their effect may be blocked by buprenorphine and either the buprenorphine or the opiate may be subject to diversion.

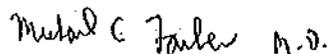
There have been reports of disastrous consequences when small children are exposed even briefly to buprenorphine as the "ceiling effect" does not appear to hold for this population. Please educate your patients about the need for safe storage of buprenorphine along with all other medications³.

Methadone vs Buprenorphine: Some patients may be better candidates for treatment with methadone in a clinic setting rather than with buprenorphine in an office based setting. The buprenorphine prior authorization form now includes a question asking if you would have referred your opioid dependent patient to a methadone clinic if this option was conveniently located and available. Please indicate your optimal choice each time you submit a buprenorphine prior authorization form.

Vermont Buprenorphine Practice Guidelines: Pharmacotherapy is only one aspect of opiate addiction treatment. The *Vermont Buprenorphine Practice Guidelines* provide Vermont practitioners with a consolidated set of recommendations and best practices for the management of opioid dependence in an office-based setting. Our full guidelines may be accessed at <http://dvha.vermont.gov/for-providers>.

If you have questions related to this change in benefit coverage, please feel free to contact our on-site MedMetrics' Clinical Account Manager, Diane Neal, R.Ph, at 1-802-879-5605. Thank you for your continued support of the State of Vermont's clinical pharmacy programs.

Sincerely,



Michael Farber, M.D.
Medical Director

³ Boyer EW, McCance-Katz E, Marcus, S, Methadone and Buprenorphine Toxicity in Children *The American Journal on Addictions*, 19: 89-95, 2009

THE VERMONT ACADEMIC DETAILING PROGRAM is a university-based prescriber education and support program that operates out of AHEC (Area Health Education Programs). The Program is offered by the University of Vermont's Office of Primary Care with funding from public and private sources, including the State of Vermont. There is no pharmaceutical company sponsorship associated with the Vermont Academic Detailing Program nor do the program faculty have any ties to the pharmaceutical industry. The faculty objectively review clinical topics, covering the latest evidence for lifestyle changes and generic medications in addition to the latest in medication releases. This information is shared with prescribers across Vermont.

DVHA provides medication utilization data to help in the development and evaluation of their academic detailing programs and works collaboratively with AHEC to identify medication topics of mutual interest. During FFY2010, AHEC choose to target antipsychotic medication use and prescribing as one of their next projects.

The goal of the Vermont Academic Detailing Program is to promote high quality, evidence-based, patient-centered, and cost-effective treatment decisions by healthcare professionals.

The program consists of one-hour, case-based interactive visits between one or more prescribers and a pharmacist or physician academic detailer. Academic detailing visits are typically delivered in the convenience of the prescribers' offices. The program presents an objective overview of evidence from studies about the various medications used to treat a specific medical condition. Patient resources and handouts often accompany the prescriber information.

To achieve these goals, AHEC relies on the guidance and broad opinions of multiple stakeholders. AHEC has formalized these stakeholders as Vermont Academic Detailing Program Advisors, including a representative from DVHA. The role of the Program Advisor is to provide opinions and practical advice regarding the approach, direction, and operation of the Vermont Academic Detailing Program.

e-Prescribing Activity Summary

At the time of the last update to the Vermont State HIT Plan in October 2010, it was reported that 93% of pharmacies in Vermont are accepting electronic prescribing and refill requests (e-Rx). However, the percentage of prescriptions being submitted electronically was then estimated to be 12%. A program, *ePrescribe Vermont*, offered through the Vermont Information Technology Leaders, Inc. (VITL, the State's HIE), provides a statewide license for prescribers without EHRs to use a free-standing e-prescribing application. It also provides incentives to providers with EHRs to implement e-prescribing functionality along with support to independent pharmacies in the state to accept and transmit electronic prescriptions.

Subsequently, the Department of Vermont Health Access has worked with its prescription management partner, MedMetrics Health Partners, to provide activity reports and assist the state in analyzing the e-prescribing landscape in Vermont. The direct health benefits of e-Rx are well documented, but include medication safety advantages, increased system efficiency and reduction in routine problem orders which allows the pharmacist to focus on more clinically significant medication interventions, and patient satisfaction associated with turnaround time on orders. e-Rx is a key aspect of Meaningful Use and this initiative in Vermont is consistent with our HIT roadmap goals of fully realizing the benefits of Meaningful Use for improved health outcomes, with lower costs.

During the period of this report, pharmacies reported that 10.18 % of prescriptions were received electronically. As this claim field is not mandatory for pharmacies, the origin of the prescription was not specified in 31.06 % of all claims.

DVHA - Net Paid Claims by Origination Code

Service Period: 10/01/09 - 09/30/10 (Based on Date Submitted)

Carrier ID	Account ID	Origination Code	Origination Code Description	Total Rx's	% of Rx's
MPSOVHA	99MPSOVHA	0	Not Specified	461,041	31.06%
MPSOVHA	99MPSOVHA	1	Written Prescription	430,576	29.01%
MPSOVHA	99MPSOVHA	2	Telephone Prescription	200,013	13.48%
MPSOVHA	99MPSOVHA	3	Electronic Prescription	151,104	10.18%
MPSOVHA	99MPSOVHA	4	Facimile Prescription	241,437	16.27%
		Total		1,484,171	100.00%