



## **Therapeutic Equivalency Pilot Program Legislative Report**

Report to:  
Senate Appropriations Committee  
Senate Health and Welfare Committee  
House Appropriations Committee  
House Health Care Committee  
House Human Services Committee

Agency of Human Services  
Office of Vermont Health Access  
Pharmacy Unit  
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## INTRODUCTION

The Vermont Therapeutic Equivalency Pilot Program requires, for designated drug classes, that VPharm Members use over-the-counter (OTC) or generic drugs to receive coverage for the Medicare Part D cost share, including the deductible, coinsurance and coverage gap. The designated pilot classes are the statins (or HMG-CoA reductase inhibitors), a class of anti-hyperlipidemic drugs used to lower cholesterol levels in patients at risk for cardiovascular disease, and proton pump inhibitors (PPIs) which are used to reduce gastric acid production and treat peptic ulcer disease, GERD, Zollinger-Ellison syndrome, and dyspepsia.

Pursuant to 2009 Special Section Act 1 Sec. E. 309.9 (d): "The Office of Vermont Health Access, in collaboration with the DUR board, shall evaluate the pilot program and provide a report no later than January 15, 2010. The evaluation and report shall include an estimate of the savings from the increased use of over-the-counter (OTC) and generic drugs, negative impacts on consumer choice and other positive or negative outcomes of the pilot program."

## HISTORY and RATIONALE

Last year, the General Assembly of the State of Vermont voted, as part of 2009 SS Act 1, 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. In addition, 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.

On June 9, 2009, the Drug Utilization Review (DUR) Board of the Office of Vermont Health Access (OVHA) determined the list of over-the-counter (OTC) and generic drugs that would be available for coverage in each class and the preferred choices are listed in the following tables.

### VPharm Preferred Proton Pump Inhibitors

Brand-Name	Active Ingredient	Preferred Strengths/Forms
Prilosec OTC®	omeprazole	20 mg tablet
omeprazole (generic)	same	10 mg and 20 mg capsules (NOT 40 mg)

### VPharm Preferred Statins

Brand-Name	Active Ingredient	Preferred Strengths/Forms
<b>High Potency</b> simvastatin (generic)	same	5 mg, 10 mg, 20 mg, 40 mg and 80 mg tablets
<b>Lower Potency</b> lovastatin (generic)	same	10 mg, 20 mg and 40 mg tablets
pravastatin (generic)	same	10 mg, 20 mg, 40 mg and 80 mg tablets

Some generically available medications and/or certain strengths were not included as covered drugs in the VPharm pilot. These include omeprazole 40 mg capsules and pantoprazole. This exclusion was necessary because the legislature required that the pilot include only those drugs available on the formularies of 90 percent of the Medicare Part D prescription drug plans available in Vermont. Additionally, lansoprazole became available generically in late November 2009, well after the implementation of this program and therefore was not included as a preferred product. While not all generics were available under VPharm, of those options that were preferred, approximately 50% of prescriptions for VPharm patients were already being written for preferred products and did not need to be changed. Although this program was titled a "Therapeutic Equivalency Pilot Program" in the legislature, no automatic therapeutic substitution can occur in Vermont according to Vermont pharmacy law, therefore a new prescription was needed for the preferred products.

Prescribers were contacted by mail with a list of their patients who were receiving prescriptions for medications that would be considered non-preferred. They were asked to convert patients to a preferred alternative if clinically appropriate to ensure the patient received the VPharm wrap benefit. Instructions for requesting exceptions were also included. Additionally, patients who received a prior authorization from their Part D plan prior to July 1, 2009 for a medication that would no longer be covered by VPharm were allowed to continue to receive coverage under VPharm for that drug.

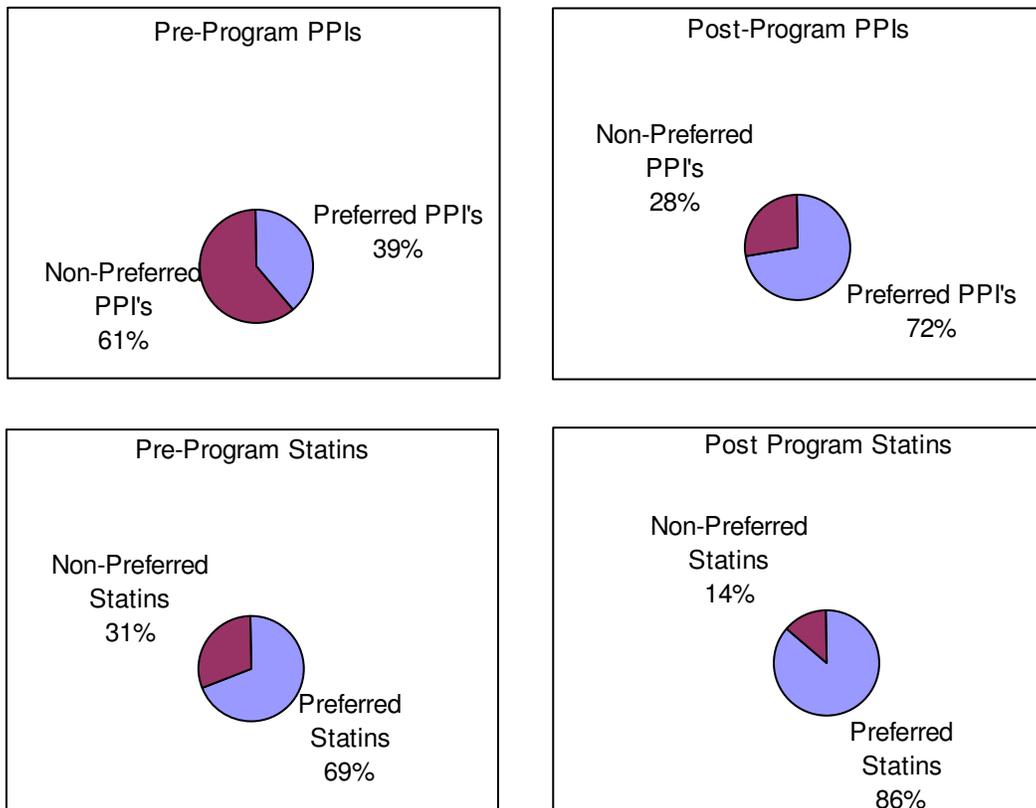
The Vermont Therapeutic Equivalency Pilot Program was implemented on August 3, 2009, after which time drug claims submitted by pharmacies for VPharm patients who were not using a preferred product were rejected if no exception had been requested. Although the patient may have had a portion of the claim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

## ANALYSES

### ANALYSIS OF OVERALL PROGRAM SAVINGS

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.

The charts below represent the shift in pre-program vs. post-program prescriptions for preferred PPI and statin products. As you will notice, 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. Please refer to the table below.

<b>PPI / Statin Drug Costs and Program Savings</b>					
				<b>3 MONTHS</b>	<b>PROJECTED ANNUALIZED</b>
<b>PRE-PROGRAM PPI PROGRAM COSTS</b>		<b>POST-PROGRAM PPI COSTS</b>		<b>INCREASE / (DECREASE)</b>	<b>INCREASE / (DECREASE)</b>
PREFERRED PPI's	\$ 32,344.21	PREFERRED PPI's	\$ 58,429.40	\$ 26,085.19	\$ 104,340.76
NON-PREFERRED PPI's	\$ 179,137.29	NON-PREFERRED PPI's	\$ 94,647.22	\$ (84,490.07)	\$ (337,960.28)
	<b>\$ 211,481.50</b>		<b>\$ 153,076.62</b>	<b>\$ (58,404.88)</b>	<b>\$ (233,619.52)</b>
<b>PRE- PROGRAM STATIN COSTS</b>		<b>POST-PROGRAM STATIN COSTS</b>		<b>INCREASE / (DECREASE)</b>	<b>INCREASE / (DECREASE)</b>
PREFERRED STATINS	\$ 40,287.46	PREFERRED STATINS	\$ 52,713.66	\$ 12,426.20	\$ 49,704.80
NON-PREFERRED STATINS	\$ 133,946.33	NON-PREFERRED STATINS	\$ 41,774.15	\$ (92,172.18)	\$ (368,688.72)
	<b>\$ 174,233.79</b>		<b>\$ 94,487.81</b>	<b>\$ (79,745.98)</b>	<b>\$ (318,983.92)</b>
<b>TOTAL PRE-PROGRAM COSTS</b>		<b>TOTAL POST-PROGRAM COSTS</b>		<b>INCREASE / (DECREASE)</b>	<b>INCREASE / (DECREASE)</b>
	<b>\$ 385,715.29</b>		<b>\$ 247,564.43</b>	<b>\$ (138,150.86)</b>	<b>\$ (552,603.44)</b>

## ANALYSIS OF THE REDUCTION IN COST PER UNIT AND DAY

To more closely examine the effective cost decreases of this program, claims for members who filled a claim in both the pre- and post-program evaluation periods were examined. Only those members who had claims in both periods where OVHA was paying the cost sharing were included. Members were excluded from the analysis if, in either period, OVHA was paying the entire cost of the claim because the member was in the coverage gap. This was done to remove the variability of the cost of member's medications in the coverage gap and provide a more accurate cost comparison. In addition, the cost per unit (e.g. cost per tablet or capsule) and the cost per day of therapy was used as the outcome measurement to eliminate any variation in days supply per prescription. Lastly, we removed from the overall gross analysis members who may have changed eligibility and therefore appear only in the pre-program period, and new starts on PPI / statin therapy who would appear only in the post-program period.

This analysis demonstrated a 30% reduction in cost per unit for Proton Pump Inhibitors (PPI's) and a 52% reduction in cost per unit for statin therapy. In addition, there was a 26% reduction in cost per day of the PPI's, and a 52% reduction in cost per day for statins. Please refer to the tables and graphs below.

### Program Savings – Same Members\*

#### ***COST PER UNIT***

COST PER UNIT	PRE PROGRAM	POST PROGRAM	PERCENTAGE DIFFERENCE
COMBINED PPI'S	\$ 0.33	\$ 0.23	-30%
COMBINED STATINS	\$ 0.25	\$ 0.12	-52%

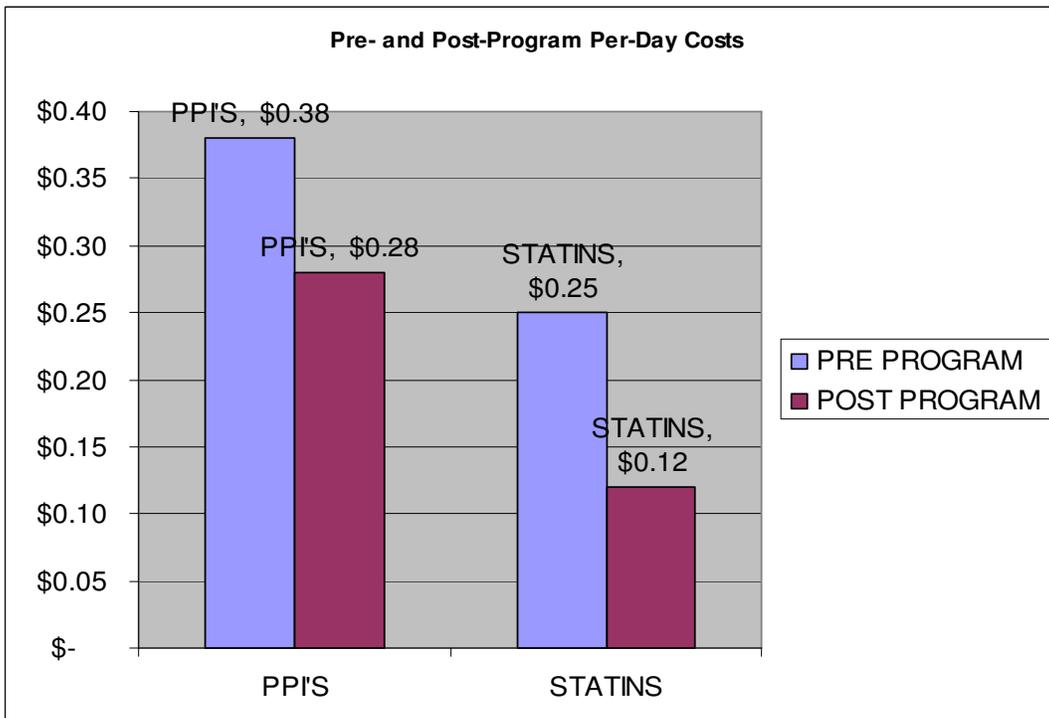
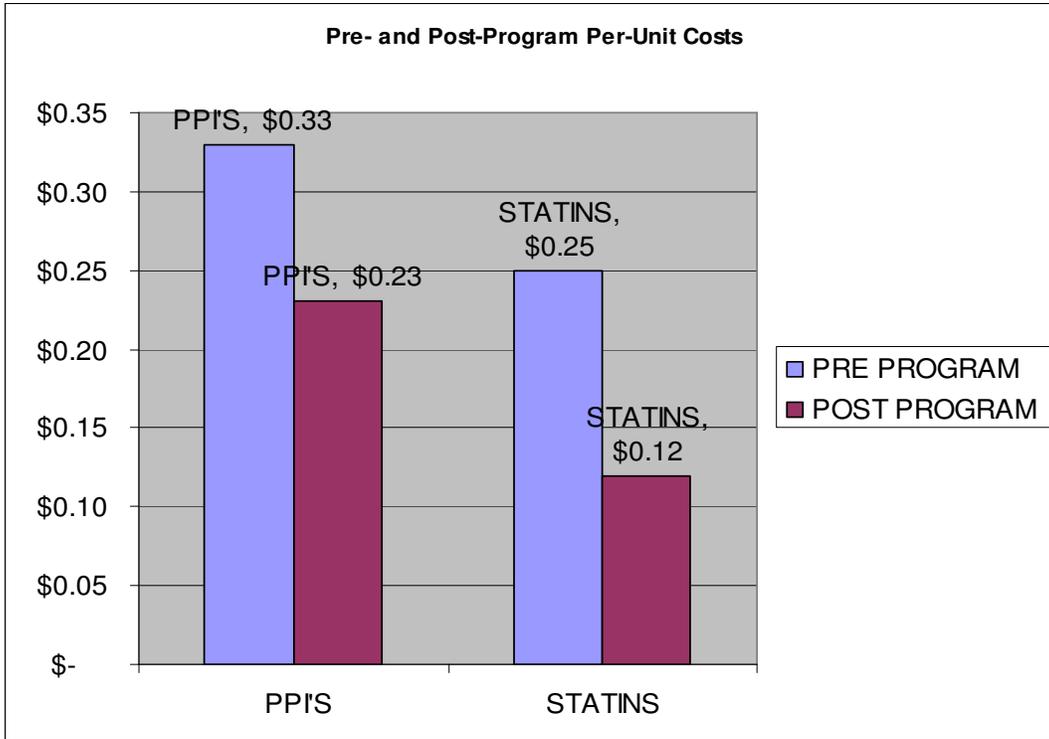
#### ***COST PER DAY***

COST PER DAY	PRE PROGRAM	POST PROGRAM	PERCENTAGE DIFFERENCE
COMBINED PPI'S	\$ 0.38	\$ 0.28	-26%
COMBINED STATINS	\$ 0.25	\$ 0.12	-52%

\*Members with a claim filled both in 04/01/09 through 06/30/09 and also 08/01/09 through 10/31/09

# PROGRAM COSTS

## PER UNIT AND PER DAY SAME MEMBERS



## ANALYSIS OF MEMBER ACCESS

A third analysis of claims was performed to evaluate whether there was any demonstrable access issue for members. This analysis examined the percentage of members who either had a paid claim in the post period, a rejected claim in the post period (e.g. it is assumed they chose to pay the co-insurance themselves) or who had no submitted claims in the post period. For this analysis, the post period was August 1, 2009, through December 31, 2009, which allowed us to capture the greatest number of claims associated with members who had pre-program and post-program statin and PPI claims. Please refer to the table below.

	<u>PPI'S</u>	<u>STATINS</u>
Members With Paid Claims Pre Program	3,315	4,958
Members Who Changed or Lost Eligibility	(250)	(283)
Potential Members Post Program	3,065	4,675
	<u>PPI'S</u>	<u>STATINS</u>
Members With Paid Claims Post Program	2,048	3,865
Members With Rejected Claims Post Program	697	487
	2,745	4,352
 <b>Members With Post-Program Claims as a Percentage of Potential Members Post Program</b>	 <b>90%</b>	 <b>93%</b>

Over 90% of members with a PPI prescription pre-program who continued to be eligible post program, filled a PPI prescription and received the wrap benefit or had a claim submitted for a non-preferred that was rejected. The conditions treated with a PPI are not necessarily chronic, therefore their therapy may not have been continued. Also, a recent major drug interaction has been identified with some PPIs and we would anticipate that some members may have changed therapy to another class of gastric acid reducers such as H2 Receptor Antagonists.

Additionally, 93% of members with a pre-program statin who continued to be eligible post program filled a statin prescription and received the wrap benefit or had a claim submitted for a non-preferred statin that was rejected. Statin therapy would be expected to continue as it is generally a maintenance medication, although therapy is sometimes discontinued by the prescriber due to unfavorable side effects. We must also consider that while the statin drug class is the most commonly prescribed lipid lowering drug class, there are other lipid lowering drug classes from which prescribers may choose. Claims were not evaluated to determine whether members may have been switched to an alternative drug class.

There are several explanations for why some members had no paid prescriptions or rejected claims during the post period. These reasons include:

- It is possible that the pharmacy did not submit the claim because they knew the cost share would not be paid by OVHA;
- The prescriber switched the member to a product with no cost share (e.g. simvastatin is a zero co-pay drug in some plans)
- Therapy was discontinued
- Therapy was changed to another class of lipid lowering or GI drugs
- The prescriber provided drug samples
- The member was non-compliant or chose not to fill the prescription

Research has demonstrated that as many as 50% of patients are non-compliant or non-adherent with their cholesterol and other chronic medications. Since OVHA is a secondary payer, it is very difficult to determine all the reasons. There have been no reports relayed to OVHA of members experiencing difficulty in continuing needed therapy either by prescribers or pharmacies, nor by Maximus or the Ombudsmen office. In addition, OVHA's exception policy allows prescribers to easily request exceptions if medically justified.

## SUMMARY OF FINDINGS

Even though the Vermont Therapeutic Equivalency Pilot Program has only been in effect for three months, cost savings have already been realized and a significant shift in prescribing to preferred products has been demonstrated. The savings for the three-month post period were \$138,000, with a projected annualized savings of \$552,600. Further, 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 analysis is complicated by certain factors including; a) the short period of time the program has been in place, b) the nature of the VPharm program as a secondary payer creates a lot of variability in the amount of the wrap payment due to deductibles, coinsurance and coverage gap periods, and c) the number of members whose eligibility changes during the course of the year.

A full year of data before and after the benefit change would be most valuable as it would contain claims data for the Part D population that includes the entire cycle of the part D benefit year, so members would have, to a great extent, cycled through deductible, coinsurance and coverage gap periods. Despite these measurement limitations however, the program has been highly successful and resulted in significant savings without negatively impacting members.