Program Evaluation of a Value-Based Prescription Drug Insurance Design

by

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TABLE OF CONTENTS

ACKNOWLEDGEMENTS i

TABLE OF CONTENTS ii

LIST OF TABLES v

LIST OF FIGURES vii

LIST OF APPENDICES viii

ABSTRACT ix

I. INTRODUCTION 1

II. LITERATURE REVIEW 5

Medication adherence 5

Non-adherence to diabetes medications 7

Methods of assessing medication adherence 8

Value-Based Insurance Design 9

Definition and concept 9

Evidence for VBID 11

Gaps in Literature 15

III. OBJECTIVES, RESEARCH QUESTIONS, AND HYPOTHESES 18

Study Objectives 18

Research Questions and Hypotheses 19

Objective 1 19

Objective 2 20

Objective 3 21

IV. METHODS 22

Benefit Overview 22

Economic theory behind VBID 24

Theoretical Framework 26

Study Design 27

Data 28

Study Population 29

Variables 30

Analysis Plan and Statistical Methods 32

V. RESULTS 37

Description of Study Sample(s) 37

Results for Objective 1

Medication adherence 40

Drug expenditures 42

Results for Objective 2 46

Results for Objective 3 51

VI. DISCUSSION 55

Discussion of Results 56

Objective 1

Medication adherence 56

Drug expenditures 60

Objective 2 61

Objective 3 62

Implications..62

Limitations..64

Future Research 66

VII. CONCLUSIONS..70

REFERENCES 72

APPENDICES 80

LIST OF TABLES

1. Chronic medical conditions and medication classes targeted by the VBID benefit....24
2. Variables included in the claims database 28
3. Baseline (2012) characteristics of study sample....39
4. Overall medication use, 2012-2013....40
5. Mean adherence to VBID medications: difference-in-difference analysis....41
6. Prescription drug expenditures (all drugs)....42
7. Prescription drug expenditures (VBID drugs only)....43
8. Difference-in-difference model results: member drug expenditures....44
9. Difference-in-difference model results: payer drug expenditures 44
10. Difference-in-difference model results: total drug expenditures....45
11. Difference-in-difference model results: member drug expenditures per fill 45
12. Difference-in-difference model results: payer drug expenditures per fill 45
13. Difference-in-difference model results: total drug expenditures per fill 46
14. Difference-in-difference model results: proportion member out-of-pocket....46
15. Characteristics of study sample by baseline (2012) adherence category....47
16. Mean adherence to VBID medications: difference-in-difference-in-difference Analysis (reference category: medium)....49
17. Mean adherence to VBID medications: difference-in-difference-in-difference Analysis (reference category: low)....49
18. Baseline (2012) characteristics of sample with diabetes 52
19. Adherence to diabetes-specific medications, 2012-2013....53

20. Mean adherence to VBID oral diabetic medications:
difference-in-difference analysis 53
21. Mean adherence to VBID insulin medications:
difference-in-difference analysis 54
22. Mean adherence to VBID diabetic testing supplies:
difference-in-difference analysis 54

LIST OF FIGURES

1. Ganther's (1999) three stage decision model of prescription drug utilization.......27

2. Study inclusion criteria 38

3. Mean adherence to VBID medications between study groups, 2012-2013...........41

4. Pre-post adherence changes by baseline adherence category, 2012-2013.............50

LIST OF APPENDICES

A. Demographic characteristics of excluded members 81

B. Alternative pre-post VBID drug adherence analysis 82

C. Alternative pre-post VBID drug adherence analysis by baseline
adherence category...85

D. Mail order use analysis 90

ABSTRACT

Non-adherence to prescription drug therapy represents a major public health issue, and numerous studies show that poor adherence with prescribed medication regimens results in increased morbidity, mortality, hospitalizations, and healthcare costs, especially among patients with chronic diseases. Value-based insurance design (VBID) has been proposed as an approach to financing high quality, cost-effective care for the treatment of chronic diseases. The VBID concept was proposed to align patients' out-of-pocket costs with the clinical benefit or "value" of health services. The primary effect of VBID programs is to increase adherence rates by decreasing patient out-of-pocket spending. However, little empirical evidence exists to support VBID claims.

The present study evaluates the short-term effects of a VBID prescription drug benefit implemented by a small managed care organization located in the Midwestern United States in 2013. The goals of this study are to examine: (1) pre-post differences in medication adherence and expenditures between members enrolled in VBID plans and a comparison group enrolled in non-VBID plans for 2012 and 2013, (2) pre-post differences in medication adherence among VBID plan enrollees and comparison group enrollees with varying baseline adherence in 2012, and (3) pre-post changes in medication adherence among VBID plan enrollees with diabetes relative to comparison group enrollees.

A pre-post, non-equivalent comparison group, quasi-experimental study design using a population-level approach was used to address the study objectives. The pre-intervention period was defined as the 6 months before implementation of the VBID benefit (July 1 – December 31, 2012). The post-intervention period was defined as the first 6 months following VBID benefit implementation (January 1 – June 30, 2013). Members in the treatment (VBID) and comparison

groups were included if they met the following inclusion criteria: (1) age 18 years or older as of January 1, 2012; (2) continuous enrollment with the MCO from January 1, 2012 to June 30, 2013; and (3) at least one prescription fill in 2012 and 2013 for any medication(s) included in the value tier that was created by the VBID benefit.

Baseline adherence at the therapeutic class level was very high, at over 83% for both groups, and adherence to VBID drugs in 2013 remained essentially unchanged compared to 2012 in both study groups. The covariate adjusted difference-in-difference estimate was not significant, suggesting there was no difference in adherence trends between the VBID and comparison group members between 2012 and 2013. Although member out-of-pocket drug expenditures decreased in 2013 for all drugs (VBID and non-VBID), plan and total expenditures remained unchanged. In contrast, member, plan, and total drug expenditures significantly decreased in 2013 for VBID drugs only. Approximately 75% of members in both study groups were in the fully adherent category at baseline, and the results of the difference-in-difference-in-difference models showed no overall policy effect of the VBID benefit on changes in medication adherence between comparisons of the three baseline adherence categories. Baseline adherence to oral diabetic drugs, insulin, and testing supplies were high, with no statistically significant differences between the VBID and comparison groups in either year for any drug category.

Implementation of a VBID prescription drug benefit in a small managed care organization resulted in no short-term changes in medication adherence or expenditures after six months. Various factors may have impacted these findings, including characteristics of the member population, of the benefit structure, and the communication of benefit changes to the member population. The impact of a VBID benefit on such a member population was minimal, and raises questions on whether such a benefit was needed.

CHAPTER 1

INTRODUCTION

Former United States Surgeon General C. Everett Koop is famously quoted as saying "Drugs don't work in patients who don't take them." Non-adherence to prescription drug therapy represents a major public health issue, and can result in increased morbidity, mortality, hospitalizations, and healthcare costs, especially among patients with chronic diseases.[1-7] A World Health Organization (WHO) report on adherence to long-term therapies determined that poor adherence to treatment of chronic diseases is a "worldwide problem of striking magnitude," even in developed countries.[2] Medication adherence, or the extent to which patients take their medications as prescribed by their health care providers, is a major public health concern in the United States.[8-10]

Non-adherence to prescription drug therapy is common, and has major cost implications for the United States healthcare system. The WHO estimated medication adherence to long-term therapies in the general population to be approximately 50%, and much lower in developing countries.[2] Research has consistently found that 30% to 60% of patients are non-adherent.[8,11-12] The cost of medication non-adherence in the United States is estimated to be as high as $300 billion each year, or an average of $453 per adult in 2010.[8,13-15] Of all medication-related hospital admissions in the United States, 33% to 69% are due to poor medication adherence which results in costs of nearly $100 billion each year.[8]

Cost-related non-adherence has been documented as a significant problem, as it causes patients to forgo medication, skip doses, or ration medications by splitting tablets.[16-17] In response to the rising costs of healthcare, patients enrolled in prescription drug insurance plans have experienced an increasingly larger burden of their medication costs through higher deductibles and copayments.[3,18-22] Although increased patient cost sharing results in reduced drug spending for the employer, it is also associated with lower medication initiation rates, worse adherence among existing users, and more frequent discontinuation of therapy.[18-19,22-27] Studies show that when patient copayments are reduced or eliminated, significant increases are seen in patient adherence to recommended treatments.[28-34] Medication adherence in the treatment of diabetes is especially important, as research has shown a strong relationship between adherence and improved outcomes among patients with diabetes.[7] All-cause medical costs have been found to decrease as adherence with hypoglycemic drugs increased.[3] In 2010, the per capita cost of medication non-adherence in diabetes was estimated to be between $4,007 and $6,100.[15]

One concern when measuring medication adherence is that there is no “gold standard”.[10] The most commonly used measure of medication adherence is the medication possession ratio (MPR), which is determined based on the ratio of the total days’ supply of a medication to the number of days of study participation.[10,35] One frequently used method to assess medication adherence is using electronic pharmacy claims databases, which have long been considered a useful source of adherence information.[35-38]

Value-based insurance design (VBID) is a new and increasingly popular approach to financing high quality, cost-effective care for the treatment of chronic diseases. The VBID concept was proposed to align patients’ out-of-pocket costs with the clinical benefit or “value” of health services.[39-40] High-value services are those that provide substantial health benefit relative to the cost; low-value services are those that result in harm or are deemed too expensive for the health benefits produced.[41] VBID programs provide patient incentives by reducing barriers to high-value treatments (through lower patient cost sharing) and discouraging low-value treatments (through higher patient cost sharing).[39-40,42-43] These programs aim to align clinical and financial incentives while maximizing healthcare quality and efficiency, rather than to simply reduce drug spending.[41,44]

The primary effect of VBID programs is to increase adherence rates by decreasing patient out-of-pocket spending.[45-46] Research related to VBID plans and features (namely, reduced patient copayments) has consistently found a positive effect of VBID on medication adherence.[17,29,31,33,46-52] However, the impact of VBID on cost neutrality of the benefit has been mixed, with some studies finding decreased overall healthcare spending[51-54] and others finding no change[32,50] or even a slight increase[46,54] in overall costs in some instances. Additionally, the majority of studies on the effects of a VBID prescription drug benefit on medication adherence also require enrollment in an intensive disease state management program, which may positively bias the results. Experts claim that much of the support for VBID plan design is mainly theoretical in nature and suffers from weak study designs and a lack of evidence on payer costs, and that overall there is a lack of strong empirical evidence supporting the use of VBID.[27,45,55-57]

With explicit authorization of VBID in Section 2713(c) of the Patient Protection and Affordable Care Act, experimentation with this new approach to financing payment for prescription drugs is likely to increase.[83] Although fewer than 20% of large employers reported using VBID plans in 2007, up to 81% of employers with 10,000 or more beneficiaries were interested or very interested in implemented such plans within the next 5 years.[45] As of 2011, over one-third of employers utilized some sort of value-based plan design tool for their employees, with the most common strategy being reduced copayment incentives.[58] It is essential that these changes be informed with rigorous evidence; however, there is a lack of sound empirical evidence for VBID, especially in terms of the cost neutrality of this type of benefit to payers.

The present study evaluates the short-term effects of a VBID prescription drug benefit implemented by a small managed care organization located in the Midwestern United States in 2013. The VBID benefit to be evaluated in this study is more generous than others evaluated in the literature for two reasons. Not only does the current benefit reduce copayments for high value drugs to a flat $5 copayment for selected generic <u>and</u> brand name drugs, it does so without requiring enrollment in an intensive disease state management program. This study uses a rigorous difference-in-difference study design, utilizing prescription drug claims information pre- and post-VBID implementation and data on a comparison group of members that were unaffected by the VBID benefit to better identify the short-term effects of VBID adoption on medication adherence. This study also includes an evaluation of changes in payer drug costs to assess whether cost neutrality for a VBID benefit is attainable. This study provides empirical evidence on the short-term effects of VBID on medication adherence and expenditures shortly after benefit implementation to better guide health plans, employer groups, and policymakers in making decisions when designing, selecting, and administering prescription drug benefits.

CHAPTER 2

LITERATURE REVIEW

Medication adherence

Medication adherence generally refers to the extent to which patients take their medications as prescribed by their healthcare providers.[8-10] The World Health Organization (WHO) has described poor adherence as any deviation from the prescribed course of medical treatment, and includes a patient's failure to pick up or renew prescriptions, to take medications at the prescribed dosage level or interval, and failed persistence or the abandonment of a medication regimen altogether.[14] Numerous studies have shown that poor adherence and persistence with prescribed medication regimens result in increased hospitalizations,[2-4,6-8,22] morbidity,[1,2,8,22] mortality,[5,8] and healthcare costs,[2-3,7-8] particularly among patients with chronic diseases. In contrast, high levels of medication adherence have been associated with lower disease-related medical costs, such that increased medication costs are more than offset by medical cost reductions, producing a net reduction in overall healthcare costs.[3,4,59]

Non-adherence to prescription drug therapy is common, and has major cost implications for the United States healthcare system. The WHO estimated medication adherence to long-term therapies in the general population to be approximately 50%, and much lower in developing countries.[2] Medication adherence represents a major clinical practice issue, with 30% to 60% of patients being non-adherent.[8,11-12] Reported medication adherence rates are low even under more controlled conditions such as clinical trials, averaging 43% to 78% among patients receiving treatment for chronic conditions.[3] The cost of medication non-adherence in the United States is estimated to be as high as $300 billion each year, or an average of $453 per adult in 2010.[8,13-15]

Of all medication-related hospital admissions in the United States, 33% to 69% are due to poor medication adherence, which results in costs of nearly $100 billion each year.[8]

Medication adherence is a complex behavior influenced by many factors, and non-adherence occurs for a variety of reasons.[1,8,10] The World Health Organization has identified five dimensions of adherence: patient-related, condition-related, therapy-related, health system, and socioeconomic factors.[2] One particularly important multidimensional factor influencing medication adherence is cost. Cost-related non-adherence has been documented as a significant problem, as it causes patients to forgo medications, skip doses, or ration medications by splitting tablets.[16-17] Higher patient cost-sharing amounts significantly increase the risk of non-adherence.[4,60-61] Although prescription drug insurance provides some protection from cost-related non-adherence, this protection varies by the source, duration, and design features of a prescription drug insurance benefit.[18,61]

In response to the rising costs of healthcare, patients enrolled in prescription drug insurance plans have experienced an increasingly larger burden of their medication costs through higher deductibles and higher copayments.[3,18-22] Pharmacy benefit design creates barriers to adherence by limiting access to healthcare providers and pharmacies, restricting medication access through drug formularies, and having prohibitively high drug costs or copayments.[8,16,22] Although increased patient cost sharing results in reduced drug spending for the employer, it is also associated with lower patient medication initiation rates, worse adherence among existing users, and more frequent discontinuation of therapy.[18-19,22-27] There is also evidence that copayment increases lead to increased use of emergency department visits and hospital days for patients with chronic conditions.[16] Studies show that when patient copayments are reduced or eliminated, significant increases are seen in patient adherence to recommended treatments.[28-34]

Rising out-of-pocket costs are so important that the New England Healthcare Institute identified reducing medication cost barriers as one of the three most important factors for improving adherence.[14]

Non-adherence to diabetes medications

The World Health Organization has identified adherence to be a problem for patients with chronic illnesses including asthma, hypertension, diabetes, and HIV/AIDS.[2] Medication adherence in the treatment of diabetes is especially important, as research has shown a strong relationship between adherence and improved outcomes among patients with diabetes.[7] Additionally, poor adherence to diabetes treatment results in avoidable suffering for patients and excess healthcare costs.[2] All-cause medical costs have been found to decrease as adherence with hypoglycemic drugs increased.[3] Among patients with diabetes, the one-year risk of hospitalization was 13% for patients with high medication adherence and 30% for patients with low medication adherence; in contrast, total annual healthcare costs were $8,886 for patients with high adherence and were nearly twice as high among patients with low levels of adherence at $16,498.[3] In 2010, the per capita cost of medication non-adherence in diabetes was estimated to be between $4,007 and $6,100.[15]

Of particular concern is that adherence rates to medical recommendations are lower for patients with diabetes than for many other health conditions. A meta-analysis of patient adherence to medical recommendations (including adherence to medication regimens) found a mean adherence rate of 67.5%, resulting in an estimated 7.6 million medical visits ending in non-adherence.[62] Other studies have also found adherence to prescription medication recommendations to be low among patients with diabetes. Two studies found that 55% and 58%

of patients with diabetes adhered to their physicians' recommended drug treatments.[3,18] An additional study of anti-hyperglycemic therapy among patients with type 2 diabetes found adherence rates of 65% for monotherapy and 44% for polytherapy patients after one year; persistence with diabetes medications was even lower, with rates of 34% for monotherapy and 14% for polytherapy patients after one year.[63] Patients with diabetes have been found to be particularly sensitive to copayment changes, such that their use of medications decreased to a larger extent than for other disease specific medications in response to a doubling in copayments.[19]

Methods of assessing medication adherence

To complicate matters, there are many methods to collect adherence data and to calculate adherence rates.[8,35] Osterberg et al. (2005) identified three direct methods and eight indirect methods of measuring adherence.[8] Direct methods were directly observed therapy, measurement of the level of medicine or metabolite in blood, and measurement of the biologic marker in blood. Although these methods are more robust than indirect methods, they are expensive, burdensome to the healthcare provider, susceptible to distortion by the patient, and are not practical for routine clinical use.[8,10] Indirect methods were patient questionnaires or self-report, pill counts, rates of prescription refills, assessment of the patient's clinical response, electronic medication monitors, measurement of physiologic markers, patient diaries, and questioning caregivers.[8] Each of these methods has distinct advantages and disadvantages, and use of a specific method will depend on the clinical scenario and availability of the data.[8,10]

Using administrative data such as pharmacy claims databases can be useful for calculating medication adherence, as they provide accurate and readily available objective information that can be used to assess whether a patient is adhering to the regimen.[8,35] Additionally, claims-based measures of medication adherence have been found to be associated with clinical outcomes such as blood pressure, hemoglobin A_{1c}, and LDL cholesterol levels.[64] Electronic pharmacy claims databases are frequently used in assessing medication adherence,[10] and have long been considered a useful source of adherence information.[35-38]

However, no "gold standard" for measuring medication adherence exists.[10] One commonly used measure of medication adherence is the medication possession ratio (MPR) method.[10,35] The MPR is a ratio of the total days' supply of a medication to the number of days of study participation per participant.[65] The MPR can have a value greater than 1.0 to account for oversupplies, although it is commonly capped at 1.0 in many studies.[10,35]

Patients with medications available at least 80% of the time have commonly been categorized as adherent in previous research using pharmacy claims data.[10,66] However, this is an arbitrary cutoff, and additional benefits may be seen with adherence levels beyond 80%, especially for certain conditions such as human immunodeficiency virus or medications such as oral contraceptives,[10] where high levels of adherence are required for effectiveness. Therefore, the appropriate cutoff will depend on the specific medications and disease conditions studied. However, the commonly used cut-point of 80% has been found to have the best balance between sensitivity and specificity to define non-adherence.[67]

Value-Based Insurance Design

Definition and Concept

The concept of a value-based insurance design (VBID) was proposed to align patients' out-of-pocket costs with the clinical benefit or "value" of health services.[39-40] There are three primary components to VBID: (1) value equals the clinical benefit gained for the money spent, (2) value-based benefit packages adjust patient out-of-pocket costs based on the expected clinical benefits as determined by evidence-based medicine, and (3) the greater the expected clinical benefit, the lower the patient cost-sharing amount.[68-69] VBID programs target services known to be of high value or target patients with select diagnoses or medical conditions with a high potential benefit from therapy.[20,39,44] High-value services are those that provide substantial health benefit relative to the cost; low-value services are those that result in harm or are deemed too expensive for the health benefits produced.[41] VBID programs provide patient incentives by reducing barriers to high-value treatments (through lower patient cost sharing) and discouraging low-value treatments (through higher patient cost sharing).[39-40,42-43]

Cost savings due to VBID programs are realized through three potential avenues: (1) targeting those individuals who will benefit the most, (2) shifting costs to lower-value interventions, and (3) increasing productivity (e.g., gains in worker productivity or reduced absenteeism or disability).[69] Funding for VBID programs can be accomplished by offsetting the estimated increased employee costs associated with copay reductions with a broad, small copay increase for all remaining services, or by specifically targeting low-value health services.[20,41] These programs aim to align clinical and financial incentives while maximizing healthcare quality and efficiency, rather than to simply reduce drug spending.[41,44]

Four basic VBID formats have been proposed.[69] The first is “design by service”, which reduces or waives cost sharing for select drugs or services for all enrollees. The second is “design by condition”, which targets evidence-based interventions to treat patients with specific conditions. The third, “design by condition severity”, targets high-risk members found eligible to participate in disease management programs. The final format is “design by participation”, which extends the third approach to high risk-members who actively participate in disease management or similar incentive programs. Additional formats which blend these basic formats also exist for certain disease states.[69]

Evidence for VBID

The primary effect of VBID programs is to increase adherence rates by decreasing patient out-of-pocket spending.[45-46] Research related to VBID plans and features (namely, reduced patient copayments) has consistently found positive effects of a VBID benefit on medication adherence.[17,29,31,33,46-52]. VBID programs have also been associated with increased utilization of preventative services.[46] However, the impact of VBID on cost neutrality of the benefit has been mixed, with some studies finding decreased overall healthcare spending[51-54] and others finding no change[32,50] or even a slight increase[46,54] in overall costs in some instances.

One of the first and most well-known experiences with VBID comes from the large Fortune 500 company Pitney Bowes. In 2001, the company decreased copayments for diabetes, asthma, and hypertension drugs to a flat 10% coinsurance amount, resulting in 14% and 12% lower medical spending on diabetes and asthma, respectively.[47,53] Average prescription drug spending among patients with diabetes or asthma decreased 10% annually, compared with an 11% increase for the rest of the population.[53] Medication possession rates also significantly increased, while total pharmacy costs decreased 7% and emergency department visits decreased by 26%.[47] This resulted in over $1 million savings in 2004 alone, driven primarily by reduced emergency room visits, hospital admissions, and physician office visits.[53] In 2007, the company eliminated statin medication copayments for its beneficiaries with diabetes or vascular disease and lowered copayments on the clot-inhibiting drug clopidogrel for all patients.[48] This resulted in an immediate increase of 2.8% in adherence to statins, which was maintained for a year; adherence to clopidogrel was also 4% higher for the intervention group, which was also sustained for the entire year. However, although there was an immediate impact of the copayment policy on medication adherence, there was no difference between VBID and comparison group members in the subsequent rate of change in adherence, and adherence in both groups declined over time.

Other studies of VBID benefits have consistently found a positive effect on medication adherence. Antidiabetic medication adherence in three CVS Caremark clients that implemented a VBID program in 2007 found that VBID plan participants had higher overall treatment initiation rates, lower discontinuation rates, and significant increases in mean medication possession ratio.[31] Increased treatment initiation rates in this study were thought to be a result of patients previously avoiding treatment because of cost. The pharmaceutical manufacturer Novartis implemented a VBID program for all enrollees taking medications for asthma, diabetes, and cardiovascular disease, and found significantly improved medication adherence while remaining cost-neutral to the company.[50.70] A program implemented by a large regional health plan in Illinois reduced diabetes medication copayments by 36.1%, which reduced the number of non-adherent patients (n=71) by 30.0%.[49] In 2008, the health plan expanded this benefit by reducing copayments for certain brand name statin medications by half, and found medication adherence increased by 2.7 percentage point, decreasing non-adherence by 11.9%.[71]

An evaluation of a VBID program offered by Blue Cross Blue Shield of North Carolina that eliminated generic medication copayments and reduced copayments for brand name medications found improved adherence to medications for diabetes, hypertension, hyperlipidemia, and congestive heart failure.[33] A longer-term evaluation of this same program found a 1.4-3.2% improvement in medication adherence at 1 year following VBID adoption, which increased to 2.1-5.2% at 2 years.[17] This evaluation also examined whether changes in adherence due to VBID varied by level of baseline adherence, and found that previously non-adherent patients were most affected by VBID. It should be noted that approximately 15-20% of the sample was enrolled in disease management, although the highest rate was seen in the metformin group (31.4%).[17]

Some employers have elected to implement VBID benefits only in combination with disease management programs. An evaluation of a large employer's VBID initiative in combination with a telephonic disease management program found that medication adherence increased for 4 of 5 medication classes, reducing non-adherence by 7-14%.[29] A second study found that VBID improved medication adherence and reduced total healthcare costs when active counseling was provided to high utilizers of care.[52] A similar study for patients with diabetes found sustained improvements in the use of diabetes medications and adherence to medical guidelines while receiving an overall return on investment over three years of $1.33 for every dollar spent.[51] A related study found that decreased cost sharing increased use of generic oral antidiabetic medications by 4.77 percentage points over 3 years, use of brand oral antidiabetic medications by 5.11 percentage points, and insulin by 2.7 percentage points.[72] However, baseline adherence rates were very low for all three drug categories (insulin 10.0%; brand oral medications 19.6%; generic oral medications 28.2%).

A 2-year analysis of a program that reduced copays for all diabetic drugs and testing supplies with an optional DSM program found an increase in adherence of approximately 3.0% in year 1 and a drop in adherence in year 2.[73] Additionally, use of brand name medications increased approximately 5%, whereas generic use decreased in both years. However, decreases in emergency room visits and hospitalizations were seen in both years, and a decrease in health care expenditures was seen in year 2. A final study evaluating the impact of waived copayments and a mandatory education and support program for patients with diabetes found significantly greater adherence and improved quality of care, although total healthcare costs did not differ over one year.[46] Other notable programs that have utilized VBID concepts include the Asheville project,[74] the Diabetes Ten City Challenge,[75-76] the University of Michigan MHealthy: Focus on Diabetes program,[77] and Oregon's test of VBID in coverage for state workers.[78] These programs reduced or eliminated copayments for diabetes-related medications or supplies in addition to disease management programs, and have seen positive effects on adherence and clinical outcomes.[45,74,75-76]

Simulation studies estimating the effects of reduced or eliminated copayments have shown the potential benefits of implementing VBID on a larger scale, particularly among Medicare beneficiaries. A study eliminating cost sharing for angiotensin-converting enzyme inhibitors for Medicare beneficiaries with diabetes estimated the program would increase utilization rates, extend life, and reduce Medicare costs.[79] A second study eliminating cardiovascular medication cost sharing for Medicare beneficiaries after acute myocardial infarction also estimated the program would improve clinical outcomes and reduce costs.[80] Estimated savings to society were $1 billion for the approximately 400,000 Medicare beneficiaries who have an acute myocardial infarction each year. It has also been estimated that varying copayments for cholesterol lowering therapy by therapeutic need on a national level would result in more than $1 billion in projected savings annually due to reduced emergency department use and hospitalizations.[4] A more recent study of statin copayment reductions for Medicare beneficiaries with diabetes estimated that a VBID approach would result in modestly increased statin use and reduced medical spending.[54] However, this VBID simulation strategy met financial feasibility criteria only for higher-risk patients. Another recent recently published study proposed using copayments to increase the use of generic statins, estimating that every 10 percent increase in the use of generic, rather than brand-name, statins would reduce Medicare costs by about $1 billion annually.[81] However, as of 2012, no Medicare plans utilized a VBID benefit structure.

Gaps in literature

Value-based insurance design has received growing attention from the media, employer groups, and policymakers.[27,32,57] Although fewer than 20% of large employers reported using VBID plans in 2007, up to 81% of employers with 10,000 or more beneficiaries were interested or very interested in implementing such plans within the next 5 years.[45] As of 2012, over one-third of employers utilized some sort of value-based plan design tool for their employees, with the most common strategy being reduced copayment incentives.[58] A U.S. Senate Bill (S. 1040) entitled the “Seniors’ Medication Copayment Reduction Act of 2009” was introduced to establish a Medicare Part D demonstration program to test the impact of a VBID plan for Medicare Part D beneficiaries, with the intended goals of increasing drug adherence, improving outcomes, and reducing costs.[82] Although this bill was unsuccessful, the VBID approach to financing health care was authorized in Section 2713(c) of the Patient Protection and Affordable Care Act.[83] Therefore, experimentation with this new approach to financing payment for prescription drugs is likely to increase.

Despite receiving much attention and excitement, there are concerns about the quality of the empirical evidence that exists to support this approach to financing healthcare.[27,45,55-57]

Experts are still debating the merits of VBID and the strength of existing evidence, especially on its ability to reduce prescription drug and healthcare costs.[27,56-57,84-86] Indeed, VBID adoption has been slow in the fully insured market due to the inability to observe the cost offsets in health plans.[87]

Fairman & Curtis (2011) identified several research gaps that payers need addressed to make an informed decision about VBID.[57] They expressed concerns that much of the available evidence to support VBID is mainly theoretical and suffers from a lack of information about generic utilization and payer costs, problems in study design and/or reporting, and a lack of randomized trials. The present study aims to address several weaknesses with previous evaluations by utilizing a rigorous study design with clear and transparent reporting of the methods and results, and by including information on payer costs in order to better inform payers on designing and implementing VBID benefit designs.

The present study evaluates the short-term effects of a VBID prescription drug benefit implemented by a small managed care organization located in the Midwestern United States in 2013. The VBID benefit to be evaluated in this study is more generous than others evaluated in the literature for two reasons. Not only does the current benefit reduce copayments for high value drugs to a flat $5 copayment for selected generic and brand name drugs, it does so without requiring enrollment in an intensive disease state management program. The present study uses a rigorous difference-in-difference study design, utilizes prescription drug claims information pre- and post-VBID implementation, and includes data for a comparison group of members that were unaffected by the VBID benefit to better identify the effects of VBID adoption on medication adherence. Also, the present study includes an evaluation of changes in payer drug costs to assess whether cost neutrality for a VBID benefit is attainable. The present study provides empirical evidence on the short-term effects of VBID on medication adherence and expenditures shortly after benefit implementation to better guide health plans, employer groups, and policymakers in making decisions when designing, selecting, and administering prescription drug benefits.

CHAPTER 3

OBJECTIVES, RESEARCH QUESTIONS, AND HYPOTHESES

The present study evaluates the short-term effects of a VBID prescription drug benefit adopted by a small, privately owned managed care organization on January 1, 2013. The pre period was the last 6 months of 2012 (July 1 through December 31; before implementation) and the post period was the first 6 months of 2013 (January 1 through June 30; after implementation). The treatment group consisted of members enrolled in a VBID plan in 2013 who were enrolled in a non-VBID plan in 2012. The comparison group consists of members enrolled in a non-VBID plan for both 2012 and 2013. “Value tier” drugs included selected brand and generic medications used to treat chronic conditions that were determined by the managed care organization to be of high value, and were offered to members at a flat copayment of $5 per 30-day fill.

Study Objectives:

1. To examine pre-post differences in medication adherence and expenditures between members enrolled in VBID plans and a comparison group enrolled in non-VBID plans for 2012 and 2013.
2. To examine adherence changes among VBID plan enrollees with varying baseline adherence in 2012.
3. To examine changes in adherence to prescription drug therapy among VBID plan enrollees with diabetes.

Research Questions and Hypotheses:

Objective 1

1. Was there a significant difference in drug use in 2012 and 2013 between members enrolled in VBID plans and members enrolled in non-VBID plans?

   H1: There was no significant difference in total prescription fills in 2012 for members enrolled in VBID plans and members enrolled in non-VBID plans.

   H2: Total prescription fills in 2013 for members enrolled in VBID plans were significantly higher than for members enrolled in non-VBID plans.

   H3: There was no significant difference in 2012 in the proportion of prescription fills that were for value tier drugs for members enrolled in VBID plans and members enrolled in non-VBID.

   H4: The proportion of prescription fills that were for value tier drugs in 2013 for members enrolled in VBID plans were significantly higher than for members enrolled in non-VBID plans.

2. Was there a significant difference in adherence to VBID drugs in 2012 and 2013 between members enrolled in VBID plans and members enrolled in non-VBID plans?

   H5: There was no significant difference in adherence to VBID drugs in 2012 between members enrolled in VBID plans and members enrolled in non-VBID plans.

   H6: Adherence to VBID drugs in 2013 for members enrolled in VBID plans was significantly higher than for members enrolled in non-VBID plans.

3. Was the pre-post change in adherence to VBID drugs for members enrolled in VBID plans significantly different from the change in adherence for members enrolled in non-VBID plans?

H7: The pre-post change in adherence to VBID drugs for members enrolled in VBID plans was significantly higher than the change in adherence to VBID drugs for members enrolled in non-VBID plans.

4. Was there a significant difference in drug expenditures in 2012 and 2013 between members enrolled in VBID plans and members enrolled in non-VBID plans?

   H8: There was no significant difference in patient out-of-pocket expenditures in 2012 for members enrolled in VBID plans and members enrolled in non-VBID plans.

   H9: Patient out-of-pocket expenditures in 2013 for members enrolled in VBID plans was significantly lower than for members enrolled in non-VBID plans.

   H10: There was no significant difference in total drug expenditures in 2012 for members enrolled in VBID plans and members enrolled in non-VBID plans.

   H11: There was no significant difference in total drug expenditures in 2013 for members enrolled in VBID plans and members enrolled in non-VBID plans.

5. Was the pre-post change in drug expenditures for members enrolled in VBID plans significantly different from the change in expenditures for members enrolled in non-VBID plans?

   H12: There was no significant difference in the pre-post change in total drug expenditures for members enrolled in VBID plans and members enrolled in non-VBID plans.

Objective 2

1. What is the proportion of VBID plan enrollees that were non-adherent ($MPR \leq 0.50$), somewhat adherent ($0.5 < MPR < 0.80$), and fully adherent ($MPR \geq 0.80$) in 2012?

2. Did pre-post changes in adherence among VBID plan enrollees in 2012 and 2013 vary by baseline adherence in 2012?

Objective 3

1. For VBID plan enrollees with diabetes, was there a significant difference in adherence to oral diabetic medications between 2012 and 2013?

   H13: Adherence to oral diabetic medications among VBID plan enrollees with diabetes in 2013 was significantly higher than in 2012.

2. For VBID plan enrollees with diabetes, was there a significant difference in the use of insulin medications between 2012 and 2013?

   H14: Use of insulin medications among VBID plan enrollees with diabetes in 2013 was significantly higher than in 2012.

3. For VBID plan enrollees with diabetes, was there a significant difference in the use of diabetic testing supplies between 2012 and 2013?

   H15: Use of diabetic testing supplies among VBID plan enrollees with diabetes in 2013 was significantly higher than in 2012.

CHAPTER 4

METHODS

This section provides information about the methods used to accomplish the aims and objectives of this study. The first section describes the program being evaluated in this study. The next section describes the study design, the data files that were used, the study population and inclusion criteria, and the theoretical concepts that were used to guide the study. The last section outlines the analytical plan for the study.

Benefit Overview

In 2012 a small, privately owned managed care organization (MCO) located in the Midwestern United States began offering a VBID pharmacy benefit to its employer groups for implementation January 1, 2013. As of the January 1, 2013 renewal period, the VBID prescription drug benefit became the required benefit option for small employers (consisting of 50 or fewer employees) and the preferred renewal option for large employers. Self-selection into the VBID drug benefit among large employers was performed at the employer group level rather than at the individual employee level.

The overall goal of the benefit according to the MCO was to increase member medication adherence to high value medications used to treat chronic medical conditions while remaining cost-neutral to the MCO's employer groups. Under this benefit, selected high value preferred brand and generic medications used to treat chronic conditions were moved to a new "value tier" with a flat copayment of $5 per 30-day fill. Prior to implementation of the benefit, these drugs had $25 and $10 copayments per 30-day fill, respectively. Unlike other VBID programs that use copayment decreases as patient incentives to engage in disease management programs or for rewarding patient behaviors (such as obtaining wellness screenings or for engaging in healthy behaviors), the $5 copayment for value tier drugs was offered by the MCO to its members without any other requirements. Members also were able to receive additional savings by using a mail order pharmacy option, whereby members could receive a three month supply of a maintenance medication for two copayments (i.e., $10 for a three month supply of a value tier drug).

The mail order program allowed members to receive up to a 90-day supply of medications that are needed on a chronic basis and remain at a stable, unchanging dosage regimen. This program was provided by a small number of community pharmacies. Pharmacists at the pharmacies determine whether a medication meets the eligibility requirements, and then mail the medication(s) directly to the member. Unlike many other mail order pharmacy programs, the mail order program in the current study did not utilize an automatic refill service. Instead, members were called by pharmacy staff prior to each medication fill to ensure the refill was needed and to provide consultation. The mail order program does not have a standard time, prior to each medication fill, that pharmacy staff is required to call members.

Because the primary goal of the VBID benefit was to improve medication adherence, chronic conditions for which medication adherence is a documented problem or is vital to avoid adverse patient outcomes (e.g., asthma and HIV) were targeted by the VBID benefit. Medications included in the benefit were determined by the MCO's Pharmacy & Therapeutics Committee based upon available clinical evidence and treatment costs. Table 1 contains an overview of the medical indications and medication classes that were included in the value tier. It is important to note that not all approved drugs from each medication class were included in the value tier; each class contained only a subset of the approved drugs within the respective class.

Table 1: Chronic Medical Conditions and Medication Classes Targeted by the VBID Benefit

Cardiovascular angiotensin-converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), beta blockers, calcium channel blockers, diuretics, vasodilators/nitrates, antiplatelet/anticoagulant
Endocrine Agents diabetes (oral medications, insulins, and testing supplies), cholesterol (fibrates and statins), prenatal multivitamins
Infectious Disease antivirals (hepatitis and HIV)
Central Nervous System Agents smoking cessation, antidepressants
Respiratory Agents inhaled corticosteroids, oral respiratory agents, inhaler assistance devices/spacers

In order to remain cost neutral to the employer groups and to encourage member use of value tier medications, the MCO increased the copayments for all remaining tier 2 and tier 3 (brand name) medications by $10; tier 1 (generic) medication copayments were unchanged. The copayment increases resulted in cost neutrality for the benefit based on simulations performed by the MCO. It is important to note that these copayment increases were put into effect only for members whose employer decided to enroll in the VBID benefit; members whose employers enrolled in traditional insurance benefits were unaffected by this copayment increase.

Economic Theory behind VBID

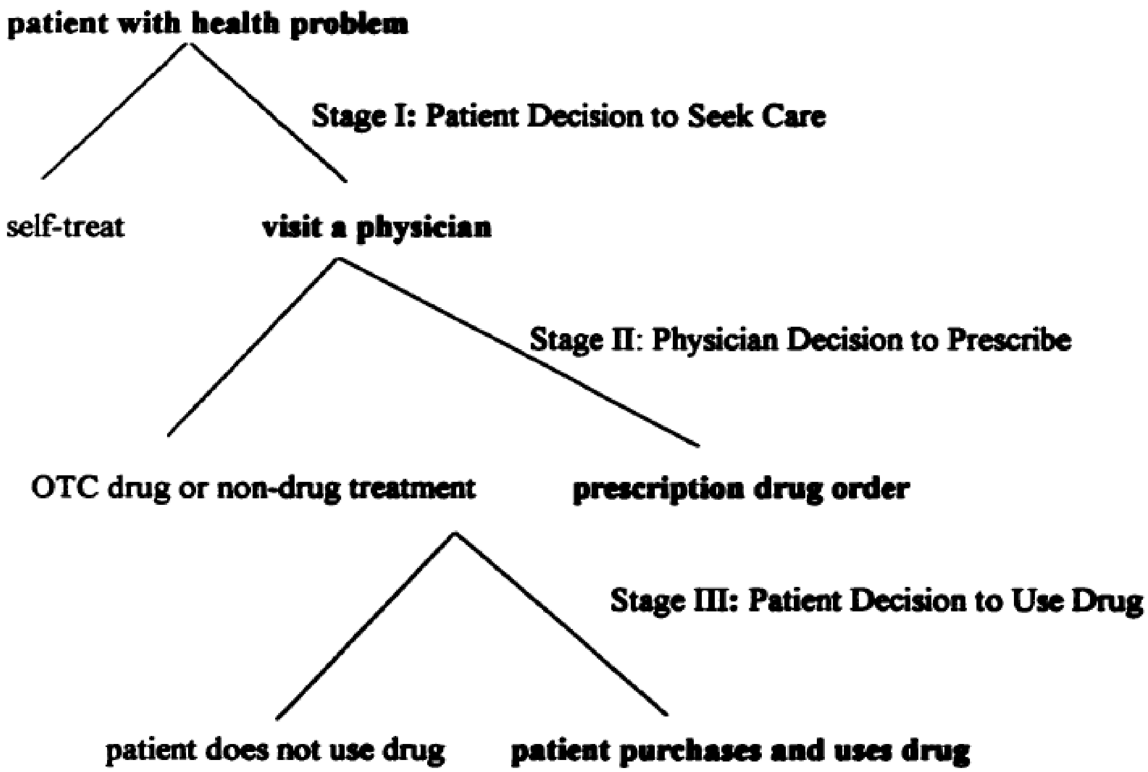
Economic theory suggests that the market for health insurance arises due to its ability to alleviate the financial risk and uncertainty associated with illness.[88] Insurance coverage also allows purchasers to access care that would otherwise be unaffordable.[89] Insurance also provides a societal benefit, as pooling medical risks on different individuals reduces the risk involved to the insurer to relatively small proportions.[88] Additionally, the collection of premiums is used to offset welfare losses, thus producing a net social gain. However, insured individuals will alter their desired use of and expenditures for medical care due to the presence of elasticity in the demand curve for medical care.[90] Rational economic behavior suggests that by lowering the marginal cost of care to the individual, increased usage may occur. This leads to excess or overconsumption and an associated welfare loss, which is termed "moral hazard". Deductibles, copayments, and coinsurance are several cost sharing methods to reduce the moral hazard associated with health insurance.[90] These cost sharing methods increase costs at the point of service, thus reducing demand for care, such that consumers will use only those services whose benefit exceeds the cost to them. Thus, the optimal amount of cost sharing reflects a tradeoff between moral hazard and risk avoidance.[91]

Conventional economic theory states that optimal coinsurance rates for health insurance with moral hazard should vary with the price responsiveness or price-elasticity of demand for different medical services.[92] However, patient demands do not always optimally balance costs and clinical value, such that valuable clinical services are underused even with modest copayments. For example, preventive health services such as immunizations or health screenings are often underutilized because patients do not recognize the value of these services.[93] Value-based cost sharing has been proposed as a superior method to improve patient decision making for medical care, and suggests that coinsurance should be lower for services with higher marginal benefits relative to costs.[92] As an example of this approach is a provision in the Patient Protection and Affordable Care Act that requires many health insurance plans to pay, in full, for preventive health services to increase access to these services, and subsequently increase use by patients.[83] Thus, targeted reductions in the level of cost sharing is hypothesized to increase value and efficiency by increasing the use of high value services and reducing the use of low value services.[92]

Theoretical Framework

A three stage decision model of prescription drug utilization developed by Ganther (1999) was used as a guiding theoretical framework for this study (Figure 1).[94] This model highlights three important stages for a prescription drug to be used: (1) the patient must visit a prescribing professional, (2) the patient must obtain a prescription order, and (3) the patient must choose to purchase and use the drug prescribed. Although the original focus of this model was to examine the effect of patient factors on prescription drug utilization, characteristics of the insurance benefit also can impact the likelihood of drug utilization. For example, at stage I, an open or restricted network may affect a patient's decision to seek care or may restrict the type of provider a patient may see. At stage II, characteristics of the insurance benefit structure such as the number of formulary tiers, the use of prior authorization, and other formulary restrictions may affect a physician's decision to prescribe at all, and/or the medications they may be able to prescribe. At stage III, a patient's likelihood of purchasing and/or using the prescribed drug may be affected by formulary tier placement, prior authorization requirements, and out-of-pocket spending amounts. A VBID benefit likely would have the largest impact at stage III, as its primary effect is to reduce patient out-of-pocket spending for high value drugs. It may also have an impact at stage II, as it could impact prescribers' selection of drugs for patients with this type of a benefit.

Figure 1: Ganther's (1999) Three Stage Decision Model of Prescription Drug Utilization



Study Design

A pre-post, non-equivalent comparison group, quasi-experimental study design was used to address the study objectives. A broad, population-level approach was used to examine short-term changes in drug adherence and expenditures from 2012 to 2013 due to enrollment in a VBID prescription drug benefit. The pre-intervention period was defined as the 6 months before implementation of the VBID benefit (July 1 – December 31, 2012). The post-intervention period was defined as the first 6 months following VBID benefit implementation (January 1 – June 30, 2013).

This study length was selected for two reasons. First, this would allow estimation of the programs effect shortly after implementation, providing evidence on the immediate effects of the program. The second reason was that the MCO planned to implement additional programs to improve member adherence in the second half of 2013. These programs would likely impact member behavior that would confound evaluation of the effects of the VBID benefit.

Data

The data for this study were extracted from the pharmacy claims and administrative enrollment databases from the MCO implementing the VBID program. The pharmacy claims database used in this study contained typical member, drug, and reimbursement variables (Table 2). Information about enrollment history was obtained from the administrative enrollment database to identify plan type (i.e., VBID or non-VBID plan), and to determine the start date for each plan. The study was granted exemption status by the University of Wisconsin-Madison Health Sciences Minimal Risk Institutional Review Board.

Table 2: Variables Included in the Claims Database

Member variables	Drug variables	Reimbursement variables
De-identified Unique ID	AHFS Classification System	Member Copay Amount
Age	Fill Date	Insurance Payment Amount
Sex	New/Refill Code	
	National Drug Code (NDC)	
	Drug Name/Strength	
	Route	
	Dosage Form	
	Generic Flag	
	Quantity	
	Days' Supply	

A list of the drugs included in the VBID value tier were obtained from the MCO and were merged with the claims database using the First DataBank 5-digit "GPID code. Drugs that did not include a GPID code were merged with the claims database using the National Drug Code (NDC).

The therapeutic category of each drug dispensed (required for objective 3) was coded within the prescription claims database using the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification System. Developed and maintained by the American Society of Health-System Pharmacists, the AHFS classification system is a hierarchical system for classifying drugs by pharmacologic and therapeutic activity, and is used by prescription drug plans to organize drug formularies and to facilitate utilization review of drugs by class. The AHFS third tier classification was used to determine the corresponding drug class for each drug in the database.

Study Population

Objectives 1 & 2

Members in the treatment (VBID) and comparison groups were included if they met the following inclusion criteria: (1) age 18 years or older as of January 1, 2012; (2) continuous enrollment with the MCO from January 1, 2012 to June 30, 2013; and (3) at least one prescription fill in 2012 and 2013 for any medication(s) included in the value tier that was created by the VBID benefit. The second criterion was selected to ensure members were not switching between different plans prior to January 1, 2013, as some employer groups adopted VBID benefits prior to this date. The age as of January 1, 2013 was also used because of this requirement. This final requirement enabled evaluation of adherence changes in individuals that already were using the medications that were affected by the VBID benefit.

Continuous member enrollment in an employer sponsored plan with the MCO over the entire study period was determined by the MCO's pharmacy director. The treatment group included MCO members who met the inclusion criteria and whose employer coverage transitioned from a traditional insurance benefit in 2012 to a VBID benefit beginning on January 1, 2013. The comparison group included MCO members who met the inclusion criteria and whose employer coverage remained in a traditional insurance benefit in both years (i.e., not enrolled in the VBID benefit).

Objective 3

To address the third aim of the study, the study population was screened by the researcher to identify members with diabetes. Members were included if they obtained one or more prescription fills for value tier medication(s) to treat diabetes in both 2012 and 2013. Medication categories that were included in the value tier were oral antidiabetic medications, insulins, and diabetic testing supplies.

Variables

Medication Adherence to VBID Drugs

Adherence to VBID drugs was determined separately in the pre- and post-periods using the medication possession ratio (MPR) at the therapeutic class level. The MPR was calculated as the ratio of total days supply of a medication class to the number of days of study participation per participant. Total days supply of medication in the pre-period and the post-period was determined by summing the days supply of the medication in the pre- and post-periods. The number of days of study participation in the pre-period and the post-period was defined as the length of time in days from the date of the first fill of a medication in 2012 until the end of the pre-period (December 31, 2012), and from the date of the first fill of a medication in 2013 until the end of the post-period (June 30, 2013). The therapeutic class level was selected as the level of aggregation to calculate MPR, as this accounts for switching between different agents within the same therapeutic class.

This level of aggregation is appropriate considering the goal of the MPR calculation was to determine adherence to the class of medication rather than an individual therapeutic agent. Although the MPR may exceed 1.0 due to oversupplies of medication, the MPR was capped at a maximum of 1.0 to be consistent with prior research. Medication supply was truncated at the end of each study period to prevent inflated adherence measurement due to medication oversupply. For example, if a member filled a 90 day supply of medication with only 30 days remaining in the study period, only 30 days of medication supply were applied towards the adherence calculation for that study period.

Prescription Drug Expenditures

Changes in member and MCO prescription drug expenditures were measured to assess whether cost-neutrality was achieved for the program. The claims database contained information on member out-of-pocket expenditures and payer drug expenditure amounts. Total prescription drug expenditures was calculated as the sum of payer drug expenditures and member out-of-pocket expenditures for each prescription in the claims database. Member, payer, and total drug expenditures were calculated for both study periods. The proportion of total drug expenditures paid by the member and mean expenditures per fill for the member, payer, and total was also calculated.

Covariates

Member sex and age at the beginning of the study period were abstracted from the administrative enrollment data for each member and included as control variables in the analyses. The number of unique drug categories used by each member was used as a proxy for comorbidity burden, and was calculated using the AHFS third tier classification. Member use of mail order to obtain prescriptions was determined using the days supply variable in the prescription claims database. The days supply for prescriptions dispensed not using the MCO's mail order option was restricted to 30 days; any days supply greater than 30 days was assumed to be dispensed using the mail order option. The percentage of members using the mail order option in each time period was determined for each study group. The proportion of medication fills for new prescriptions was determined using the new/refill code included in the claims database, and was calculated as the number of medication fills for new medications divided by the total number of medication fills for each year. The proportion of medication fills for brand name (single-source) prescriptions was determined using the generic flag included in the claims database, and was calculated as the number of medication fills for brand medications divided by the total number of medication fills for each year.

Analysis Plan and Statistical Methods

Descriptive statistics were calculated to describe the characteristics of the VBID and comparison groups. Chi-squared tests were used for evaluations of statistical differences between treatment and comparison groups for categorical variables, and t-tests were used for statistical comparisons between the groups for continuous variables.

To statistically test the VBID benefit effects on medication adherence to VBID medications and costs, a difference-in-difference approach was used. This is a powerful approach used to estimate program effects because it accounts for differences in outcomes among study groups (a group exposed to the program [treatment] and a group not exposed [comparison]) and differences in outcomes within study groups across time (a period before the program was in effect [pre-period] and a period while the program was in effect [post-period]). That is, a comparison group of individuals unaffected by the program change is used to establish what would have occurred in the absence of the program. Additionally, the difference-in-difference approach controls for all differences across the study groups that are invariant over time, even if these characteristics are not measured in the data.[95] This feature of difference-in-difference models makes it possible to control for individual-level characteristics that may confound the VBID program effect without actually measuring them. Examples of factors that are assumed to remain constant over the short study period include stable clinical factors, disease severity, and preferences to use medical care.

The difference-in-difference analysis can be described using the following equation:

Difference-in-difference = (outcome after program change in treatment group – outcome before program change in treatment group) – (outcome after program change in comparison group – outcome before program change in comparison group)

Letting μ_{ij} be the mean of the outcome in group i at time j, where i=0 for the comparison group and i=1 for the treatment group, and j=0 to be the pre-program period and j=1 to be the post-program period, then:

Difference-in-difference estimator = $(\mu_{11} - \mu_{10}) - (\mu_{01} - \mu_{00})$

Where:

μ_{11} = mean of the outcome in the treatment group in the post-program period

μ_{10} = mean of the outcome in the treatment group in the pre-program period

μ_{01} = mean of the outcome in the comparison group in the post-program period

μ_{00} = mean of the outcome in the comparison group in the pre-program period

The following linear regression model was used to evaluate the effect of the VBID benefit on the study outcomes:

$$Y_{ij} = B_0 + B_1\text{post} + B_2\text{VBID} + B_3\text{post x VBID} + B_4\text{age} + B_5\text{gender} + B_6\text{drugclasses} + B_7\text{mailorder} + e_{ij}.$$

Where:

Post is a dummy variable (0 = pre-program period, 1 = post-program period)

VBID is a dummy variable (0 = non-VBID comparison group, 1 = VBID treatment group)

B_3 is the difference-in-difference estimator (interaction coefficient)

In this model, the variable Y_{ij} represents the dependent variable of interest (e.g., medication adherence, member out-of-pocket expenditures, etc.) for person i in time period j, and B_3 represents the VBID program effect of interest. The value of B_3 represents the difference between the pre-post, within-subjects differences of the treatment and comparison groups. B_1 and B_2 are time and study group dummies, respectively, and $B_{4\text{-}7}$ are demographic control variables for age, gender, number of unique drug classes used, and an indicator variable for mail order pharmacy use, for person i in time period j, respectively.

In order to address the second study aim, members were stratified into 1 of 3 adherence categories based on their 2012 (pre-period) baseline adherence levels: non-adherent (MPR ≤ 0.50), somewhat adherent (0.5 < MPR < 0.80), and fully adherent (MPR ≥ 0.80). These adherence categories were selected based upon the only other VBID study to adopt this approach.[17] A difference-in-difference-in-difference modeling approach was used, as this method accounts for differences in outcomes between study groups, differences across time, and differences in baseline adherence levels. The following linear regression model was used for this portion of the analysis:

$$Y_{ijk} = B_0 + B_1\text{post} + B_2\text{VBID} + B_3\text{High} + B_4\text{Low} + B_5\text{post x VBID} + B_6\text{post x high} + B_7\text{post x low} + B_8\text{VBID x high} + B_9\text{VBID x low} + B_{10}\text{post x VBID x high} + B_{11}\text{post x VBID x low} + B_{12}\text{age} + B_{13}\text{gender} + B_{14}\text{drugclasses} + B_{15}\text{mailorder} + e_{ijk}.$$

The coefficients B_{10} and B_{11} were the coefficients of interest from this model, which show whether the VBID program effect was different between the high and moderate levels of pre-VBID adherence and the moderate and low levels of pre-VBID adherence, respectively. To determine whether the VBID program effect was different between the high and low levels of pre-VBID adherence, a similar model was estimated with the low level of pre-VBID adherence as the excluded group.

To address the third study aim, difference-in-difference models were estimated for the subgroup of members with diabetes to assess changes in adherence to oral hypoglycemic, insulins, and diabetic testing supplies. All difference-in-difference regression models were adjusted using clustered robust standard errors to adjust for correlations between repeated member observations. A conventional alpha of 0.05 was used to determine statistical significance. Statistical analyses were performed using Stata 12 (Stata Corp., College Station, TX).

CHAPTER 5

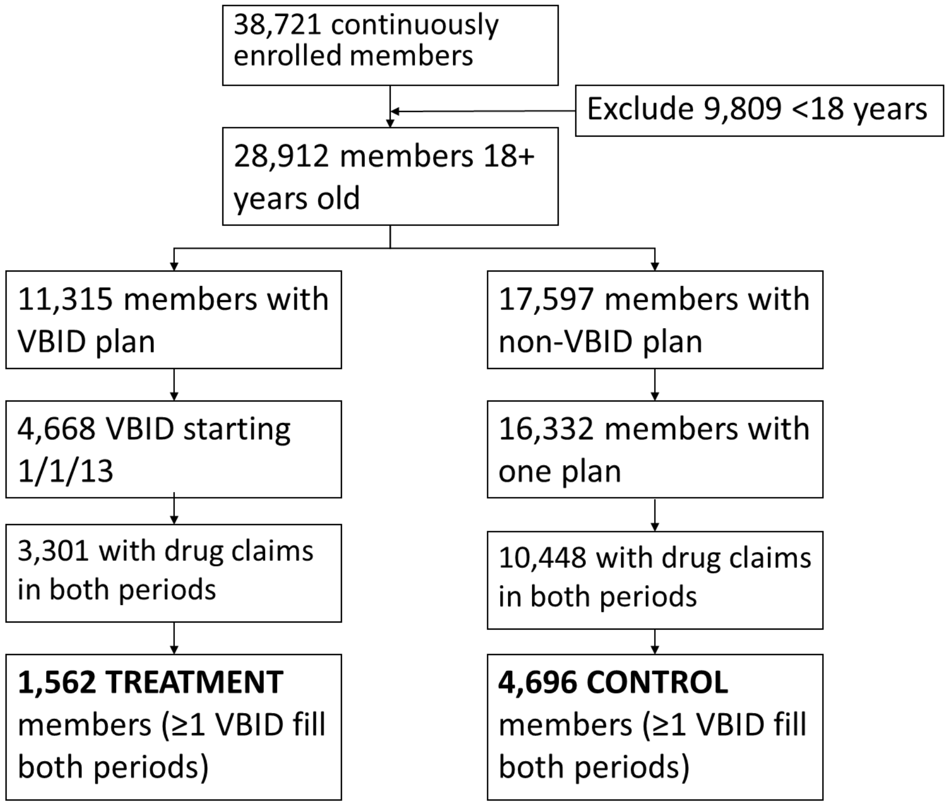
RESULTS

This section outlines the results of the study. A description of the study sample is presented first, followed by the findings for Objectives 1 and 2. Findings for the diabetic cohort (Objective 3) are presented in the last section.

Description of Study Sample

The data obtained from the MCO contained information for approximately 40,000 continuously enrolled members, of which approximately ¼ were children under 18 years of age (Figure 2). Of the remaining continuously enrolled members, just over 1/3 were enrolled in an employer-sponsored VBID prescription drug benefit; about 40% of these members had a benefit that became active on January 1, 2013. About 70% of members enrolled in a VBID plan had any drug claims during the study period (July 1, 2012 – June 30, 2013), while only 60% of members in non-VBID plans had any drug claims during the study period. Once the final inclusion criterion, a member having a fill for a VBID medication in both years, was applied, the sample size decreased by about half for both groups. The final sample size was such that the treatment group contained 1,560 members enrolled in VBID plans, and the comparison group contained 4,685 members enrolled in non-VBID plans.

Figure 2: Study Inclusion Criteria



Characteristics of the VBID and comparison group members in 2012 (baseline) are presented in Table 3. There were several significant differences between the VBID and comparison group members at baseline. Although member age was not different between the two groups, a higher percentage of the VBID group was female. Although the total number of drug fills did not differ between the two groups, the days supply of medications was significantly higher in the treatment group due to a nearly 16% higher rate of mail order use in the VBID group, which allows up to a 90-day supply with each medication fill. The VBID group also had significantly higher payer and total drug expenditures, though there was no difference in member out-of-pocket expenditures. Members in the VBID group were slightly sicker, as measured by the number of unique drug classes used. Although VBID members had a higher percentage of new prescriptions (as opposed to refills), brand name medication use did not differ between the two groups; however, over 86% of all prescriptions for both groups were for generic medications. Of particular interest, the comparison group used a significantly higher proportion of drugs included in the VBID value tier at baseline. Just under 2/3 of all drug fills obtained by members in both groups were for VBID medications.

Table 3: Baseline (2012) Characteristics of Study Sample

	VBID (SD)		Comparison (SD)	
Sample size (n)	1,562		4,696	
Age (years)	48.6	(11.6)	49.0	(11.4)
% Male	41.0[a]		49.0[a]	
Total drug fills	16.2	(13.5)	15.7	(12.6)
Total days supply	541[b]	(421)	485[b]	(378)
Members using mail order (%)	37.7[b]	(48.5)	22.3[b]	(41.6)
Member OOP expenditures	$166	($160)	$169	($163)
Payer expenditures	$998[b]	($2,704)	$790[b]	($2,237)
Total expenditures	$1,164[b]	($2,785)	$959[b]	($2,325)
# of unique drug classes	4.9[b]	(3.3)	4.5[b]	(3.1)
New prescription fills (%)	39.3[b]	(25.0)	37.0[b]	(25.3)
Brand drug fills (%)	13.9	(20.7)	13.6	(21.5)
VBID drug fills (%)	57.9[b]	(26.9)	61.6[b]	(27.6)

OOP: Out-of-pocket expenditures.
[a] $P < 0.05$; difference in mean between members in the VBID group and members in the comparison group, Chi-squared test.
[b] $P < 0.05$; difference in mean between members in the VBID group and members in the comparison group, *t*-test.

Characteristics of excluded members are presented in Appendix A. As may be expected based on the inclusion criterion requiring at least one VBID drug fill in both years, excluded members were significantly younger and healthier, and had significantly lower prescription drug use and expenditures than those included in the study sample.

Results for Objective 1 – Medication Adherence

The first study objective was to examine pre-post differences in medication adherence and prescription drug expenditures between the two study groups. Members in both groups obtained approximately 16 total fills in the six month pre-period and post-period, respectively, on average (Table 4). The total number of prescription drug fills and the number of fills for VBID drugs increased slightly in 2013, although there were no differences between the VBID group and comparison group in either year. Approximately 60% of all medication fills were for VBID medications, which is likely because these medications are primarily used for chronic conditions. Interestingly, the proportion of fills for VBID medications was significantly higher in the comparison group for both study years. Although the proportion of total fills that were for VBID medications decreased in 2013 for both groups, this finding was not statistically significant.

Table 4: Overall Medication Use, 2012-2013

	2012		2013	
	VBID Mean (SD)	Comparison Mean (SD)	VBID Mean (SD)	Comparison Mean (SD)
Total drug fills	16.2 (13.5)	15.7 (12.6)	16.3 (13.3)	16.1 (12.8)
Total VBID fills	8.4 (7.6)	8.6 (7.1)	8.4 (7.4)	8.7 (7.3)
% VBID fills	57.9[a] (26.9)	61.6[a] (27.6)	57.7[a] (26.8)	61.3[a] (27.1)

[a] $P < 0.05$; difference in mean between members in the VBID group and members in the comparison group, *t*-test.

Adherence to VBID drugs for the two study groups in 2012 and 2013 is shown in Figure 3. Baseline adherence at the therapeutic class level was very high, at over 83% for both groups. Although adherence in the VBID group was slightly higher at baseline, this difference was not statistically significant once covariates were controlled for. Adherence to VBID drugs in 2013 remained essentially unchanged compared to 2012, decreasing by 0.2 percentage points in both study groups. The covariate adjusted difference-in-difference estimate was not significant (Table 5), suggesting there was no difference in adherence trends between the VBID and comparison group members. These findings were robust to the time period selected, as a sensitivity analysis using the first 6 months of 2012 as the pre-period showed similar results (Appendix B).

Figure 3: Mean Adherence to VBID Medications between Study Groups, 2012-2013

Note: Adherence measured using the medication possession ratio at the therapeutic class level.

Table 5: Mean Adherence to VBID Medications: Difference-in-Difference Analysis

Variables	**Coefficient**	**(95% CI)**
Post (2013)	-0.006*	(-0.011, 0.000)
Treatment	0.005	(-0.006, 0.016)
Post*Treatment	0.000	(-0.010, 0.011)
Age	0.003*	(0.003, 0.004)
Male	0.010*	(0.002, 0.018)
Drug classes used	-0.004*	(-0.005, -0.003)
Mail order	0.068*	(0.060, 0.076)
Constant	0.673*	(0.653, 0.693)

* $p<0.05$

Results for Objective 1 – Drug Expenditures

Prescription drug expenditures for all drugs (VBID and non-VBID) used by VBID and comparison group members in both study years are shown in Table 6. There was a significant difference between the two groups in total drug expenditures in each study year. This difference was due to significantly higher plan expenditures in the VBID group, as total member out-of-pocket expenditures did not differ between the two groups in either year. For both study groups, member out-of-pocket expenditures decreased significantly in 2013 overall and on a per fill basis, although plan expenditures did not differ significantly between the two years. Although VBID members had slightly lower out-of-pocket expenditures and higher plan expenditures per fill in 2012, these gaps closed in 2013. Overall, for both groups, total drug expenditures per fill decreased significantly in 2013. Compared to the comparison group, members in the VBID group paid a significantly smaller proportion of total drug expenditures in both years (about 6%); however, the proportion of total drug expenditures paid by members increased significantly in 2013 for both groups.

Table 6: Prescription Drug Expenditures (All Drugs)

	2012				2013			
	VBID (SD)		Comparison (SD)		VBID (SD)		Comparison (SD)	
Member OOP+	$166	($160)	$169	($163)	$146	($152)	$147	($159)
Plan Expenditures	$998[a]	($2,704)	$790[a]	($2,237)	$962[a]	($2,940)	$799[a]	($2,344)
Total Expenditures	$1,164[a]	($2,785)	$959[a]	($2,325)	$1,107[a]	($3,011)	$946[a]	($2,437)
OOP Per Fill+	$10[a]	($5)	$11[a]	($6)	$9	($5)	$9	($6)
Plan Per Fill	$53[a]	($129)	$44[a]	($121)	$50	($135)	$43	($124)
Total Per Fill+	$63[a]	($131)	$55[a]	($123)	$59	($137)	$52	($127)
Proportion OOP+	42.6%[a]	(30.8)	48.7%[a]	(32.4)	43.8%[a]	(32.2)	49.1%[a]	(33.1)

OOP: Out-of-pocket expenditures.
[a] $P < 0.05$ between VBID and comparison groups.
\+ $P < 0.05$ between 2012 and 2013.

Prescription drug expenditures for VBID drugs only are shown in Table 7. VBID members had significantly lower out-of-pocket expenditures and higher plan expenditures compared to comparison group members in both years, although total drug expenditures were not significantly different between the two study groups in either year. Out-of-pocket expenditures per fill were significantly lower in the VBID group for both years; though plan and total expenditures per fill were slightly higher in the VBID group in both years, these differences were not significant. In both study groups, members paid nearly 20 percentage points more of the total expenditures for VBID drugs than for all drugs, which is likely because these agents are considerably cheaper on average. Out-of-pocket expenditures per fill for VBID drugs was about half that for all drugs in both study groups, while plan expenditures per fill for VBID drugs was about 1/3 of that for all drugs. Interestingly, mean out-of-pocket expenditures per fill in 2013 were less than the stated $5 copayment for VBID drugs. Although members in the VBID group paid a significantly smaller proportion of the total drug cost than did members in the comparison group in both years, the proportion of drug expenditures paid by members increased significantly in 2013 for both groups. All other cost measures for VBID drugs decreased significantly in 2013.

Table 7: Prescription Drug Expenditures (VBID Drugs Only)

	2012				2013			
	VBID (SD)		Comparison (SD)		VBID (SD)		Comparison (SD)	
Member OOP+	$62[a]	($68)	$76[a]	($77)	$41[a]	($36)	$56[a]	($65)
Plan Expenditures+	$290[a]	($930)	$230[a]	($725)	$270[a]	($927)	$218[a]	($763)
Total Expenditures+	$352	($971)	$306	($769)	$311	($943)	$274	($800)
OOP Per Fill+	$4[a]	($3)	$6[a]	($4)	$3[a]	($2)	$4[a]	($3)
Plan Per Fill+	$18	($47)	$16	($63)	$16	($49)	$15	($64)
Total Per Fill+	$22	($49)	$22	($65)	$19	($49)	$19	($65)
Proportion OOP+	57.1%[a]	(36.2)	66.2%[a]	(35.5)	59.5%[a]	(37.0)	67.8%[a]	(35.1)

OOP: Out-of-pocket expenditures.
[a] $P < 0.05$ between VBID and comparison groups.
+ $P < 0.05$ between 2012 and 2013.

Covariate adjusted difference-in-difference models were estimated for the various cost measures for all drugs and for VBID drugs only (Tables 8-14). Member out-of-pocket expenditures per fill was the only cost measure with a significant interaction coefficient, and was significant for both models estimated. The positive interaction coefficients suggest that the decreases in member out-of-pocket expenditures from 2012 to 2013 were significantly less for the VBID group than the comparison group. However, this result is likely due to VBID group members having significantly lower baseline out-of-pocket expenditures per fill than comparison group members (Table 7).

Table 8: Difference-in-Difference Model Results: Total Member Drug Expenditures

Variables	All Drugs		VBID Drugs Only	
	Coefficient	**(95% CI)**	**Coefficient**	**(95% CI)**
Post (2013)	-29.3*	(-31.8, -26.8)	-22.3*	(-23.7, -21.0)
Treatment	-15.1*	(-21.3, -8.9)	-14.9*	(-18.5, -11.4)
Post*Treatment	1.6	(-3.3, 6.4)	-0.4	(-3.2, 2.4)
Age	0.6*	(0.4, 0.8)	0.6*	(0.4, 0.7)
Male	10.4*	(5.3, 15.4)	12.0*	(9.2, 14.8)
Drug classes used	36.1*	(34.7, 37.5)	9.6*	(8.9, 10.3)
Mail order	-8.0*	(-13.8, -2.1)	-12.3*	(-15.3, -9.3)
Constant	-27.6*	(-38.1, -17.2)	2.5	(-3.5, 8.5)

* p<0.05

Table 9: Difference-in-Difference Model Results: Total Payer Drug Expenditures

Variables	All Drugs		VBID Drugs Only	
	Coefficient	**(95% CI)**	**Coefficient**	**(95% CI)**
Post (2013)	-33.9	(-68.5, 0.8)	-20.0*	(-27.5, -12.4)
Treatment	101.4	(-41.8, 244.5)	38.4	(-9.9, 86.7)
Post*Treatment	-50.2	(-107.9, 7.5)	-9.9	(-25.9, 6.1)
Age	-3.0	(-6.7, 0.8)	-2.0*	(-3.2, -0.9)
Male	263.4*	(149.3, 377.4)	120.8*	(79.2, 162.4)
Drug classes used	254.0*	(228.1, 279.9)	56.5*	(48.3, 64.7)
Mail order	168.2*	(36.1, 300.3)	56.0*	(9.2, 102.8)
Constant	-372.3*	(-591.4, -153.2)	3.7	(-66.0, 73.3)

* p<0.05

Table 10: Difference-in-Difference Model Results: Total Drug Expenditures

Variables	All Drugs		VBID Drugs Only	
	Coefficient	(95% CI)	Coefficient	(95% CI)
Post (2013)	-63.2*	(-98.9, -27.4)	-42.3*	(-50.4, -34.1)
Treatment	86.3	(-59.3, 231.8)	23.5	(-26.8, 73.8)
Post*Treatment	-48.6	(-108.4, 11.1)	-10.3	(-27.2, 6.6)
Age	-2.3	(-6.1, 1.5)	-1.5*	(-2.7, -0.2)
Male	273.8*	(157.4, 390.1)	132.8*	(89.7, 175.9)
Drug classes used	290.1*	(263.5, 316.7)	66.1*	(57.5, 74.7)
Mail order	160.3*	(25.3, 295.2)	43.7	(-4.8, 92.1)
Constant	-399.9*	(-623.5, -176.3)	6.2	(-67.0, 79.4)

* $p<0.05$

Table 11: Difference-in-Difference Model Results: Member Drug Expenditures Per Fill

Variables	All Drugs		VBID Drugs Only	
	Coefficient	(95% CI)	Coefficient	(95% CI)
Post (2013)	-2.12*	(-2.24, -2.00)	-1.68*	(-1.76, -1.59)
Treatment	-1.18*	(-1.47, -0.88)	-1.14*	(-1.33, -0.94)
Post*Treatment	0.38*	(0.13, 0.62)	0.31*	(0.15, 0.47)
Age	-0.01	(-0.02, 0.00)	0.01*	(0.00, 0.02)
Male	0.48*	(0.23, 0.73)	0.70*	(0.55, 0.86)
Drug classes used	0.20*	(0.16, 0.23)	-0.26*	(-0.28, -0.24)
Mail order	3.72*	(3.37, 4.06)	0.72*	(0.54, 0.90)
Constant	9.18*	(8.62, 9.74)	5.85*	(5.46, 6.23)

* $p<0.05$

Table 12: Difference-in-Difference Model Results: Payer Drug Expenditures Per Fill

Variables	All Drugs		VBID Drugs Only	
	Coefficient	(95% CI)	Coefficient	(95% CI)
Post (2013)	-1.77	(-3.57, 0.03)	-1.39*	(-2.05, -0.74)
Treatment	3.16	(-4.21, 10.53)	0.75	(-2.14, 3.65)
Post*Treatment	-1.68	(-4.93, 1.57)	0.34	(-0.96, 1.64)
Age	-0.50*	(-0.72, -0.27)	-0.35*	(-0.45, -0.26)
Male	14.82*	(8.80, 20.84)	8.94*	(5.83, 12.05)
Drug classes used	3.95*	(3.22, 4.68)	0.03	(-0.33, 0.38)
Mail order	29.88*	(22.11, 37.66)	6.71*	(3.46, 9.96)
Constant	36.91*	(24.62, 49.20)	27.75*	(22.10, 33.40)

* $p<0.05$

Table 13: Difference-in-Difference Model Results: Total Drug Expenditures Per Fill

Variables	All Drugs		VBID Drugs Only	
	Coefficient	(95% CI)	Coefficient	(95% CI)
Post (2013)	-3.89*	(-5.73, -2.05)	-3.07*	(-3.76, -2.39)
Treatment	1.98	(-5.49, 9.46)	-0.38	(-3.37, 2.61)
Post*Treatment	-1.31	(-4.62, 2.01)	0.65	(-0.69, 1.99)
Age	-0.50*	(-0.74, -0.27)	-0.34*	(-0.45, -0.24)
Male	15.30*	(9.16, 21.44)	9.65*	(6.46, 12.83)
Drug classes used	4.14*	(3.40, 4.89)	-0.23	(-0.60, 0.14)
Mail order	33.60*	(25.64, 41.56)	7.43*	(4.09, 10.76)
Constant	46.09*	(33.55, 58.63)	33.60*	(27.72, 39.48)

* p<0.05

Table 14: Difference-in-Difference Model Results: Proportion Member Out-of-Pocket

Variables	All Drugs		VBID Drugs Only	
	Coefficient	(95% CI)	Coefficient	(95% CI)
Post (2013)	0.009*	(0.003, 0.015)	0.018*	(0.012, 0.024)
Treatment	-0.034*	(-0.050, -0.017)	-0.078*	(-0.098, -0.058)
Post*Treatment	0.009	(-0.003, 0.021)	0.009	(-0.003, 0.022)
Age	0.003*	(0.003, 0.004)	0.003*	(0.002, 0.004)
Male	0.004	(-0.010, 0.018)	-0.016	(-0.032, 0.001)
Drug classes used	-0.042*	(-0.044, -0.040)	-0.031*	(-0.034, -0.029)
Mail order	-0.062*	(-0.077, -0.048)	-0.003	(-0.021, 0.015)
Constant	0.527*	(0.496, 0.558)	0.658*	(0.619, 0.697)

* p<0.05

Results for Objective 2

The second study objective was to examine changes between 2012 and 2013 in adherence to VBID medications among VBID plan enrollees and comparison group enrollees with varying baseline adherence in 2012. Members were stratified into the following three categories according to their baseline adherence in 2012: nonadherent (MPR ≤ 0.50), somewhat adherent (0.5 < MPR < 0.80), and fully adherent (MPR ≥ 0.80). Baseline characteristics of members in the VBID and comparison groups for each of the three baseline adherence categories are presented in Table 15. Baseline medication adherence was high, with approximately 75% of members in both study groups in the fully adherent category at baseline. Only 19% and 6% of members in both study groups were classified as being somewhat adherent and non-adherent at baseline, respectively. The proportion of members in each category was similar for the VBID and comparison groups (p=0.077).

Table 15: Characteristics of Study Sample by Baseline (2012) Adherence Category

	Non-Adherent (6%)		Somewhat Adherent (19%)		Fully Adherent (75%)	
	VBID	Comparison	VBID	Comparison	VBID	Comparison
Sample size (n)	95	307	273	933	1,194	3,456
Age (years)	40.5[a]	43.3[a]	45.5[a]	47.1[a]	49.9	50.0
% Male	41.1	45.0	40.3	46.5	41.2[b]	50.0[b]
Total drug fills	9.6[a]	7.6[a]	12.8	13.1	17.5	17.2
Total days supply	76	68	195	197	347[a]	324[a]
Members using mail order (%)	22.1[a]	12.7[a]	24.9[a]	16.5[a]	41.9[a]	24.7[a]
Member OOP expenditures	$22	$27	$49[a]	$62[a]	$68[a]	$85[a]
Payer expenditures	$131	$137	$230	$233	$317[a]	$237[a]
Total expenditures	$153	$163	$279	$295	$385[a]	$321[a]
# of unique drug classes	4.4[a]	3.7[a]	4.6	4.6	5.0[a]	4.5[a]
VBID drug fills (%)	42.9	49.6	55.6	58.4	59.6[a]	63.5[a]

OOP: Out-of-pocket expenditures. Baseline categories: non-adherent (MPR ≤ 0.50), somewhat adherent (0.5 < MPR < 0.80), and fully adherent (MPR ≥ 0.80).
[a] $P < 0.05$; difference in mean between members in the VBID group and members in the comparison group, *t*-test.
[b] $P < 0.05$; difference in mean between members in the VBID group and members in the comparison group, Chi-squared test.

In general, similar differences were seen between the VBID and comparison group members for all three adherence categories. Members in the VBID group were significantly younger for the non-adherent and somewhat adherent categories, and the VBID group had a higher percentage of females, although this finding was only significant for the fully adherent category. VBID members had significantly higher total drug fills in the non-adherent category than comparison group members, and significantly higher total days supply for the fully adherent category. Mail order pharmacy use was significantly higher for the VBID group for all three adherence categories. Out-of-pocket expenditures were significantly lower in the VBID group compared to comparison group members for the somewhat and fully adherent categories. Although payer and total drug expenditures were slightly higher in the VBID group compared to the comparison group, this finding was significant only in the fully adherent category. VBID members were slightly sicker than comparison group members, as measured by the number of unique drug classes used, although this difference was significant only in the non-adherent and fully adherent categories. Finally, comparison group members had a higher percentage of VBID fills, although this difference was also significant only in the fully adherent category.

The results of the difference-in-difference-in-difference models showed no overall policy effect of the VBID benefit on changes in medication adherence between comparisons of the three baseline adherence categories (Tables 16-17). Pre-post adherence changes by adherence category are shown visually in Figure 4. Although adherence changes from 2012 to 2013 were significantly different by baseline adherence category, these changes were nearly identical for the VBID and comparison groups for all three baseline adherence categories. Adherence among members in both study groups in the fully adherent category decreased by about 3 percentage points, but still remained at approximately 90% in both years. Members in both study groups in the somewhat adherent category at baseline had small adherence improvements in 2013, increasing by about 5 percentage points. The largest adherence improvements were seen among members in the non-adherent baseline category, where adherence significantly increased in the by about 20 percentage points.

Table 16: Mean Adherence to VBID Medications: Difference-in-Difference-in-Difference Analysis (Reference Adherence Category: Medium Adherence)

Variables	Coefficient	(95% CI)
Post (2013)	0.050*	(0.036, 0.064)
Treatment	-0.007	(-0.023, 0.009)
Low adherence	-0.295*	(-0.310, -0.280)
High adherence	0.252*	(0.243, 0.261)
Post*Treatment	0.003	(-0.026 ,0.033)
Post*Low adherence	0.189*	(0.155, 0.224)
Post*High adherence	-0.083*	(-0.099, -0.068)
Treatment*Low adherence	0.000	(-0.030, 0.031)
Treatment*High adherence	0.007	(-0.010, 0.025)
Post*Treatment*Low adherence	-0.036	(-0.102, 0.030)
Post*Treatment*High adherence	0.002	(-0.029, 0.033)
Age	0.001*	(0.001, 0.002)
Male	0.002	(-0.003, 0.008)
Drug classes used	-0.005*	(-0.006, -0.004)
Mail order	0.041*	(0.035, 0.047)
Constant	0.606*	(0.591, 0.621)

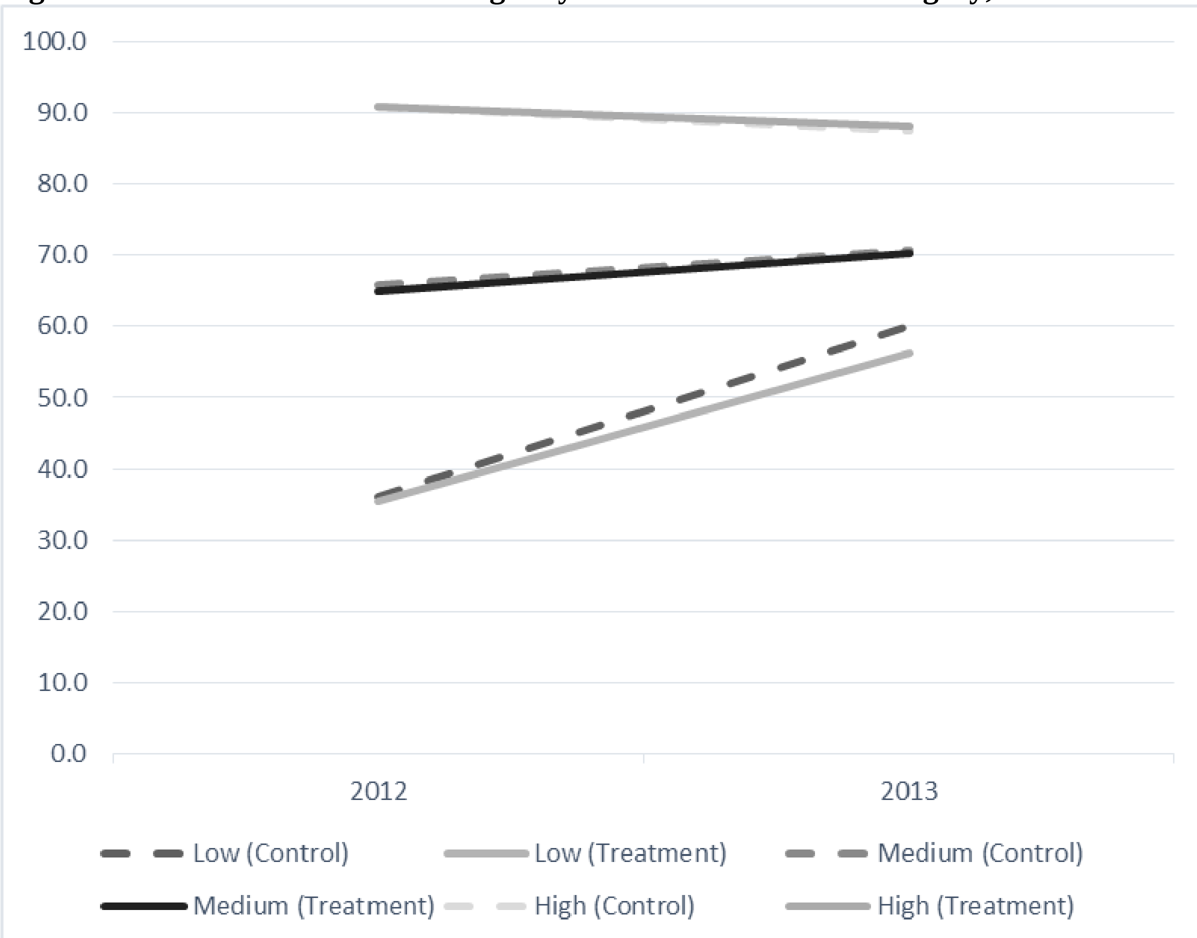
* $p<0.05$. Adherence categories determined using baseline (2012) adherence. Baseline categories: non-adherent (low), somewhat adherent (medium), fully adherent (high).

Table 17: Mean Adherence to VBID Medications: Difference-in-Difference-in-Difference Analysis (Reference Adherence Category: Low Adherence)

Variables	Coefficient	(95% CI)
Post (2013)	0.239*	(0.208, 0.270)
Treatment	-0.006	(-0.032, 0.020)
Medium adherence	0.295*	(0.280, 0.310)
High adherence	0.547*	(0.534, 0.560)
Post*Treatment	-0.033	(-0.092, 0.026)
Post*Medium adherence	-0.189*	(-0.224, -0.155)
Post*High adherence	-0.273*	(-0.304, -0.241)
Treatment*Medium adherence	0.000	(-0.031, 0.030)
Treatment*High adherence	0.007	(-0.020, 0.034)
2013*Treatment*Medium adherence	0.036	(-0.030, 0.102)
2013*Treatment*High adherence	0.038	(-0.022, 0.098)
Age	0.001*	(0.001, 0.002)
Male	0.002	(-0.003, 0.008)
Drug classes use	-0.005*	(-0.006, -0.004)
Mail order	0.041*	(0.035, 0.047)
Constant	0.311*	(0.294, 0.328)

* $p<0.05$. Adherence categories determined using baseline (2012) adherence. Baseline categories: non-adherent (low), somewhat adherent (medium), fully adherent (high).

Figure 4: Pre-Post Adherence Changes by Baseline Adherence Category, 2012-2013



Adherence measured using medication possession ratio (MPR). Adherence categories determined using baseline (2012) adherence. Baseline categories: non-adherent (MPR ≤ 0.50), somewhat adherent (0.5 < MPR < 0.80), and fully adherent (MPR ≥ 0.80). Predicted values adjusted using mean age, gender, # of unique drug classes, and mail order pharmacy use.

A sensitivity analysis using the first 6 months of 2012 as the pre-period showed similar results, although the change in adherence for the three categories were slightly larger (Appendix C). This variability in the non-adherent category is likely due in part to the very small sample sizes seen in both time periods. Because the adjusted difference-in-difference-in-difference coefficients were not significant, this supports the finding that the VBID benefit did not have a differential effect on adherence by baseline adherence category relative to the comparison group.

Results for Objective 3

The third study objective was to examine changes in adherence to VBID drug therapy among VBID plan enrollees and comparison group members with diabetes. Table 18 shows the baseline characteristics of the study sample with diabetes in 2012. The sample size for the diabetic cohort was very small, encompassing only 16% of members across both groups. Compared to the study sample overall, the diabetic cohort was slightly older and had a higher percentage of males. Diabetics had nearly twice as many drug fills and days supply of medication as the general member population, and member out-of-pocket, payer, and total drug expenditures were nearly twice as high relative to the study sample overall. Mail order use among the diabetic population was similar to the overall study population. Diabetic members used a higher number of unique drug classes, which is suggestive of a higher comorbid disease burden. Use of new and VBID drugs was similar to the entire study sample, although diabetics used a higher proportion of brand name drugs. This is likely because all insulins and diabetic testing supplies (i.e., test strips) included in the VBID group were considered brand name (single source) medications; in contrast, nearly all oral diabetes medications in the value tier were generic medications.

Table 18: Baseline (2012) Characteristics of Sample with Diabetes

	VBID (SD)		Comparison (SD)	
Sample size (n)	245		741	
Age (years)	52.1	(10.7)	51.3	(10.6)
% Male	50.2		54.5	
Total drug fills	27.2	(18.7)	25.1	(17.0)
Total days supply	942[a]	(587)	780[a]	(497)
Members using mail order (%)	41.2[a]	(49.3)	23.1[a]	(42.2)
Member OOP expenditures	$289	($216)	$287	($216)
Payer expenditures	$1,874[a]	($2,441)	$1,423[a]	($2,324)
Total expenditures	$2,163[a]	($2,589)	$1,710[a]	($2,455)
# of unique drug classes	7.7[a]	(4.0)	6.9[a]	(3.8)
New prescription fills (%)	36.2	(20.5)	34.9	(22.2)
Brand drug fills (%)	23.1	(21.4)	24.1	(25.8)
VBID drug fills (%)	60.4[a]	(24.3)	66.1[a]	(24.0)

OOP: Out-of-pocket expenditures.
[a] $P < 0.05$; difference in mean between members in the VBID group and members in the comparison group, *t*-test.

Differences in baseline characteristics between members in the VBID and comparison groups for the diabetic cohort were generally similar to those seen in the general member population, although there was no significant difference in gender or the percentage of new prescription fills between the two groups in the diabetic cohort. There was no difference in total drug fills, though the VBID group had a significantly larger days supply of medication, along with a corresponding significantly higher rate of mail order pharmacy use. There was no difference in member out-of-pocket drug expenditures; however, the VBID group had significantly higher payer and total drug expenditures. The VBID group used significantly more unique drug classes than the comparison group, although the comparison group used a significantly higher percentage of VBID drugs at baseline.

Adherence to oral diabetic medications, insulin, and testing supplies are shown in Table 19. Adherence to oral medications and insulin was very high in both groups, with baseline levels over 80%. Baseline adherence to testing supplies was much lower (approximately 60%).

Adherence to oral diabetic drugs and insulin increased slightly in 2013 for the VBID group, while adherence for these categories in the comparison group decreased slightly; in contrast, adherence to testing supplies decreased for both groups. However, none of these changes were statistically significant, and there were no significant differences between the VBID and comparison groups in either year for any drug category. Correspondingly, the covariate adjusted difference-in-difference results were not significant for oral diabetic drugs (Table 20), insulin (Table 21), or testing supplies (Table 22).

Table 19: Adherence to Diabetes-specific Medications, 2012-2013

	Oral Diabetic Drugs			Insulin			Testing Supplies		
	n	2012	2013	n	2012	2013	n	2012	2013
VBID	203	87.3%	88.8%	59	83.8%	85.6%	78	62.8%	59.9%
Comparison	600	86.6%	85.9%	174	85.7%	84.6%	235	60.0%	59.3%

Table 20: Mean Adherence to VBID Oral Diabetic Medications: Difference-in-Difference Analysis

Variables	Coefficient	(95% CI)
Post (2013)	-0.011	(-0.028, 0.005)
Treatment	0.000	(-0.030, 0.031)
Post*Treatment	0.020	(-0.007, 0.047)
Age	0.004*	(0.002, 0.005)
Male	0.012	(-0.012, 0.036)
Drug classes used	0.001	(-0.002, 0.004)
Mail order	0.053*	(0.031, 0.075)
Constant	0.652*	(0.572, 0.731)

* p<0.05

Table 21: Mean Adherence to VBID Insulin Medications: Difference-in-Difference Analysis

Variables	Coefficient	(95% CI)
Post (2013)	-0.016	(-0.043, 0.010)
Treatment	-0.045	(-0.113, 0.022)
Post*Treatment	0.025	(-0.019, 0.069)
Age	0.001	(-0.001, 0.003)
Male	0.063*	(0.012, 0.114)
Drug classes used	0.001	(-0.006, 0.007)
Mail order	0.096*	(0.048, 0.144)
Constant	0.746*	(0.643, 0.849)

* $p<0.05$

Table 22: Mean Adherence to VBID Diabetic Testing Supplies: Difference-in-Difference Analysis

Variables	Coefficient	(95% CI)
Post (2013)	-0.012	(-0.047, 0.023)
Treatment	0.006	(-0.063, 0.075)
Post*Treatment	-0.025	(-0.089, 0.039)
Age	0.002	(-0.001, 0.004)
Male	0.006	(-0.046, 0.058)
Drug classes used	0.002	(-0.005, 0.009)
Mail order	0.098*	(0.040, 0.157)
Constant	0.461*	(0.331, 0.591)

* $p<0.05$

CHAPTER 6

DISCUSSION

Although there is growing excitement about the VBID approach to financing health care, there exists little empirical evidence to support its widespread adoption. Additionally, although previous literature has shown positive effects on medication adherence, there exists little evidence on the cost implications for payers of adopting the VBID approach for prescription drugs. The current study was focused on evaluating the short-term effects of implementing a value-based prescription drug insurance design on member medication adherence and drug expenditures for both patients and payers, and had three primary objectives. The first objective was to examine pre-post differences in medication adherence and expenditures between members enrolled in VBID plans and a comparison group enrolled in non-VBID plans for 2012 and 2013. The second objective was to examine adherence changes among VBID plan enrollees with varying baseline adherence in 2012. The final objective was to examine changes in adherence to prescription drug therapy among VBID plan enrollees with diabetes.

The following section will discuss the results of the study as they pertain to the specific objectives, followed by a summary of the research and its implications for patients, payers, and policymakers. Finally, limitations of the study will be discussed along with areas for future research.

Discussion of Results

Objective 1 – Pre-post differences in medication adherence

Contrary to nearly all other studies of VBID prescription drug benefits, the benefit described in the current study had no effect on member medication adherence to VBID medications six months after implementation. Adherence to VBID medications remained essentially unchanged at very high levels in both the VBID and comparison groups. There are several potential explanations for why the VBID benefit studied had no effect on medication adherence.

First, baseline adherence to VBID medications was considerably higher in the present study compared to the majority of previous studies that have been published.[29,31,33,46,52,70,72-73] Many previous studies specifically targeted populations with pre-existing adherence problems or targeted individuals enrolled in disease management programs who likely were having adherence issues; therefore, increases in medication adherence may be more likely for these groups. For example, Gibson et al. (2013) evaluated a voluntary disease management program in combination with a value-based pharmacy program.[72] They found significant MPR increases of 5 percentage points for brand and generic oral diabetes medications, and 3 percentage points for insulin; however, baseline adherence to these three categories were only 20%, 28%, and 10%, respectively.

Baseline adherence to VBID medications in the current study was over 83% for both VBID and comparison group members. As such, there is less room for adherence improvements in such a population that is already highly adherent. Few studies of VBID benefits have had baseline adherence rates over 70%.[17,33,49] Cost-related non-adherence did not appear to be a significant problem for this member population at baseline; thus it is likely that the impact of a copayment change on medication adherence would be minimal.

Additionally, it is unclear what the impact of automatic refill programs was on member medication adherence. Although the mail order program in the current study did not utilize an automatic refill program, many community pharmacies offer some type of automatic refill service, including many of those in the MCO's pharmacy network. In such programs, members may automatically receive a new supply of medication or a notification that a new supply is ready to be picked up. Members using an automatic refill service may obtain a medication even if it is not yet needed; therefore, adherence may be overestimated. Because no information was provided on the dispensing pharmacy or whether a medication fill was obtained via an automatic refill program, it is unknown to what extent this type of program may have impacted the measurement of medication adherence.

A second reason for not seeing an impact of the VBID benefit on medication adherence involves the way in which the benefit changes were communicated to the member population. For the VBID benefit studied, information about the new benefit structure was communicated only to employer groups, with no information provided by the MCO directly to members via modalities such as direct mailings or newsletters. A list of the medications included in the new value tier was made available to members through the online formulary on the MCO's website. However, the formulary only shows what tier a medication is located in; it does not display information on member cost sharing amounts for these tiers (as member cost sharing varies across individual benefit plans). Thus, there was no indication on the MCO's website that medications in the value tier had reduced cost sharing amounts. Additionally, unless the employer groups informed their employees about the change in their prescription drug benefit, members would have no way of knowing they were enrolled in the VBID benefit or that they could take advantage of the reduced copayments for the value tier medications. It is unknown to what extent the employer groups shared this information with their employees, but it is likely that many members were unaware of the changes.

The only alternative way a member would know of a copayment decrease (or a copayment increase for a non-VBID brand name medication) would be when they go to pick up the medication at the pharmacy and notice a discrepancy from a previous fill of the medication. However, they would only know that a copayment change occurred, and not the reason for the change; members would have to contact the MCO to obtain additional information. Any change in copayment may have resulted in patients asking questions to the pharmacist about the change in copayment from the previous year. It is unknown whether a pharmacist could correctly inform the member about why the copayment amount changed. Additionally, not all members may have noticed a price difference, and members who had not previously obtained a fill of a particular medication would be unaware of these copayment changes.

The short study period (i.e., 12 months total) may be another important factor in not detecting a change in medication adherence, as two studies have found that the effects of a VBID program increased over time.[17,50] Gibson et al. (2011) suggested that a longer time period after the changed to a VBID is needed because patients and their providers may need time to respond to the program and to determine which high-value medication treatments are the best for their condition.[50] Further evaluation of the current benefit will be performed looking at 12 months after the VBID change to evaluate the longer-term effects of the benefit change.

Characteristics of the VBID benefit design may be a final important factor in the reason no effect was seen. The majority of previous research on VBID benefits has focused on medications for diabetes and/or cardiovascular conditions.[17,29,31,33,46-53,70-73] The benefit described in the present study included several medication classes not typically seen in other VBID benefits described in the literature (e.g., antivirals for hepatitis and HIV, antidepressants), and little is known of the effect of a VBID prescription drug benefit on medications for these conditions. In the present study, an analysis of a sub-population of diabetics showed no significant impact of the VBID benefit on medication adherence. However, baseline adherence for the diabetic population was much higher in the present study than in previous studies.

Another characteristic of the current VBID design compared to previous studies of VBID designs is the generosity of the VBID benefit resulting from changes in patient out-of-pocket expenditures for medications. Although the VBID benefit in the current study was generous for coverage of preferred brand name medications (copayments were reduced from $25 per fill to $5), coverage for generic medications was not as generous (reduced from $10 to $5). Many VBID studies have elected to completely waive copayments for generic drugs while reducing brand name copayments by varying amounts.[17,29,31-33,46,52] Somewhat surprisingly, the present study population had very high use of generic medications at baseline (>86%). Given the high medication adherence rates in the pre-VBID period, it appears that the $10 copayment per prescription for generic medications may not have been a cost-related barrier to medication adherence. One conclusion is that the $5 reduction in copayment for generic medications was insignificant from a patient perspective in terms of impacting medication refill behavior. Unfortunately, the sample size was too small to examine changes in medication adherence for brand name drug use alone.

Objective 1 – Pre-post differences in prescription drug expenditures

Prescription drug expenditures did not significantly change between the two 6-month study periods, suggesting that cost neutrality for the benefit was achieved in the short term. Small decreases were seen for nearly all cost metrics for both VBID and comparison group members. The largest decreases were seen in member out-of-pocket expenditures, which occurred despite increases in the proportion of total drug costs paid by members. Interestingly, member out-of-pocket expenditures were significantly lower at baseline in the VBID group compared to the comparison group, while plan and total expenditures were significantly higher. The reason for these differences between the two groups is unclear, as it may be related to characteristics of the benefits before the VBID implementation (e.g., more generous coverage), characteristics of the source of medications by members (e.g., higher mail order pharmacy use in the VBID group), or characteristics of the drugs used by the two groups (e.g., higher use of new prescriptions and lower use of value tier drugs in the VBID group).

Also of interest is the finding that member out-of-pocket spending per fill for value tier drugs in the post period was less than the stated $5 copayment amount for the value tier. This suggests that members may have paid the actual cost of the medication if it was less than the $5 copayment (or the “usual and customary” price). Many of the medications in the value tier are inexpensive, and are often included in $4 generic pharmacy discount programs. Total expenditures per fill for value tier drugs in the post period were about 1/3 of that for all drugs, suggesting these agents are considerably cheaper on average than non-VBID drugs. Additionally, the decreased member out-of-pocket per fill in the post period could reflect cost savings due to increased mail order pharmacy fills in 2013, which offered reduced copayment incentives (i.e., two copayments for a three month supply of a medication).

Objective 2 – Pre-post differences in medication adherence by baseline adherence category

There were no significant differences between the VBID group and the comparison group in terms of changes in medication adherence before and after the VBID program in groups of members based on baseline medication adherence level. The results of the difference-in-difference-in-difference analysis suggests that the VBID benefit did not have a differential effect on adherence by baseline adherence category relative to the comparison group. As before, adherence was very high, as 3/4 of all members were fully adherent (MPR ≥ 0.80) at baseline.

Although there were no significant differences between the two groups in either period, changes in medication adherence after the VBID program went into effect did significantly differ by baseline adherence category, which is consistent with prior research.[17] Previously non-adherent members (MPR ≤ 0.50) had the largest pre-post increase in medication adherence, somewhat adherent members ($0.5 < \text{MPR} < 0.8$) had small pre-post increases in adherence, and fully adherent members (MPR ≥ 0.80) actually decreased slightly. Previously non-adherent members may be more responsive to the copayment changes resulting from the VBID program; however, the small sample sizes in this group limited the ability to detect a significant difference in the present study. Additionally, the comparison group also saw an increase in adherence, so it is unclear how much of this increase is actually due to the VBID program. Medications with the lowest adherence rates were antidepressants and controller medications for asthma, which have documented adherence problems.[2] Use of these medication classes was highest among non-adherent members and lowest among fully adherent members. The finding that the changes resulting from a VBID benefit may have the biggest effect on low adherence populations is consistent with the only other study to adopt this approach.[17]

Objective 3 – Diabetic cohort

The findings for the diabetic cohort were limited by sample size issues. Similar to the overall study sample, adherence was very high for diabetic medications, with no significant differences between the two groups in either year. The small sample size and high adherence rates are likely a reflection of the relatively young, healthy member population. Baseline adherence to diabetic medications was higher than previous studies have found.[17,29,31,33,46, 51,70,73] To put these findings into perspective, the present study had a baseline adherence rate of approximately 85% for insulin; previous studies that reported baseline adherence rates using MPR ranged from 10% to 64%.[31,49,52,72-73] As such, the member population studied did not appear to be very representative of other diabetic populations included in previous research on this topics

Implications

Communication to members about benefit changes has been proposed as an important factor in changing member behavior.[46] In the present study, it is likely that many members were unaware of the changes resulting from the adoption of a VBID benefit design. Patient and provider education could potentially play a major role in changing prescribing behavior to help members take advantage of copayment reductions or to maximize medication adherence, especially in closed health care systems such as health maintenance organizations or managed care organizations. Additionally, educating the staff at local pharmacies could help them better explain the prescription drug insurance benefit changes to patients and the reasons for copayment changes. This could provide pharmacy staff with valuable information to help modify patient drug therapy to meet the patient's financial and medical needs, and reduce member confusion or anger with pharmacy staff over copayment changes.

Targeting of members who would benefit most from copayment reductions, such as patients with low medication adherence rates, is another important factor to consider when designing VBID benefits. The benefit described in the current study was made available to all members, and may have been more effective had efficient targeting been employed. In addition, much of the current evidence for VBID is from studies that employ a VBID benefit in combination with some type of targeted disease management program.[29,46,51-52,46,72-73] Although it is difficult to disentangle the effects of the VBID benefit from the effects of the disease management program, the combination of the two may be more effective than a VBID benefit alone. The MCO described in the present study planned to implement additional programs to impact member medication adherence, including a disease management program. However, these programs were put on hold indefinitely due to the need to reallocate resources to developing benefits for the federal health insurance exchanges.

Even with a benefit more generous than others described in the literature, cost neutrality both for members and for employers appears to be an attainable goal. This finding is consistent with two other studies that have evaluated payer costs associated with a VBID benefit.[32,50] A VBID benefit like the one described in this study appears to be at least no worse financially for the MCO and members, and may be a way to reorganize prescription drug benefits to improve health care quality and efficiency by encouraging the use of cheaper or higher value agents and to decrease the use of drugs with high costs or uncertain benefits. However, the current study population already had high generic utilization and adherence to VBID medications; this suggests that VBID benefits should be implemented by payers only after some analysis to determine whether such an approach would be beneficial in their member population. Additionally, there is still some debate about the cost neutrality of a VBID benefit, as some recent studies have found slightly increased costs due to VBID benefits.[46,54] Additionally, the impact of such a benefit on medical costs is unclear. Because the present study found no effect on medication adherence, it is likely medical utilization was similarly unaffected. However, further research is needed to establish a link between VBID prescription drug benefits and medical utilization and costs.

Limitations

It is important to acknowledge certain limitations of using a prescription drug claims database to calculate medication adherence. First and foremost, just because a patient obtains a medication does not necessarily mean the patient is actually taking the medication, or is taking the medication as prescribed. The current study evaluated medication adherence by examining prescription refill patterns, not actual medication taking behavior. Second, prescription fills may be omitted from a prescription drug claims database if a patient elects to obtain the medication without having it billed through their insurance; for example, electing to pay with cash to take advantage of discount drug programs offered by some pharmacy organizations (e.g., $4 generics). The extent to which refills were omitted from the prescription drug claims database is unknown. Third, adherence measures such as MPR may be over- or under-stated early in therapy due to dosage adjustments. Also, because days' supply is manually entered by pharmacy staff and may be entered incorrectly or require adjustment due to third party payer regulations, it may not reflect the true number of days' supply of the prescription. Finally, medication adherence to VBID medications was measured at the therapeutic class level until the end of the study period to account for possible switching between different drugs within the same therapeutic class. However, members that switch to a drug in a different therapeutic class would appear non-adherent to the first class and adherent to the second. Information from medical records, medication profiles, or longer claims history would allow for better identification of when to stop the study period for the discontinued drug.

Other unmeasured factors may have impacted medication adherence and prescription drug expenditures during the study period. Such factors may include changes in drug reimbursement rates (e.g., atorvastatin) or the introduction of several new generics for value tier medications (e.g., candesartan and montelukast) that would affect the MCO's entire member population. Such changes could result in reduced payer and/or member drug expenditures. For example, the introduction of a new generic for a value tier medication could result in cost savings for members in both study groups, although it is unclear whether such changes would have a differential effect for VBID and non-VBID members.

The member population studied was composed of young, healthy individuals with employer sponsored insurance coverage that had high baseline levels of adherence. The MCO draws their member population primarily from employer groups located in an area with potential employees that are primarily white, well-educated individuals, with low unemployment rates and a median household income of approximately $50,000. As such, the member population studied may not be very representative of other insured populations, and caution should be used when extrapolating the results to other populations.

Adherence in the present study was compared between members whose employer enrolled in a VBID prescription drug benefit and a non-equivalent comparison group of members whose employer remained in a traditional prescription drug benefit in both time periods. Due to small sample sizes and a lack of information on members, matching of individuals on variables that were associated with the outcomes of interest in the two groups was not performed. Although this study controlled for a limited number of covariates that were thought to influence medication adherence, unobservable confounders may have influenced the study results. Additionally, the study population was restricted to members previously using medications for chronic health conditions prior to the initiation of the policy and may not reflect changes in medication use by members initiating new treatments following VBID implementation.

Future Research

Based on the results and limitations, as well as the questions raised by this study, a few key areas of research have been identified for the future. Further evaluation of the current benefit is important to investigate longer-term changes in member behavior and drug expenditures due to the VBID benefit. Evaluating changes in health care use (e.g., urgent care or emergency room visits, outpatient provider visits, etc.) in response to the VBID benefit is also important to fully investigate the full impact of the benefit. The present study evaluated a VBID benefit implemented by a managed care organization and found that atypical baseline characteristics of the member population may have affected the impact of the benefit. Future research should explore whether the impact of VBID benefits differ between different insurance models. This would help provide a better understanding of the organizations and member populations that might benefit most from a VBID approach to prescription drug coverage.

The majority of previous research about VBID benefits focuses on the payer perspective, and little is known about patient experiences with VBID benefits. Future research should explore factors such as member perceptions and satisfaction with VBID benefits relative to traditional pharmacy benefits. Patient surveys could yield valuable information on plan characteristics or offerings that appeal most to patients, or plan characteristics and offerings that would have the highest likelihood of impacting member behavior. Differences may exist between members that voluntarily enroll in a VBID prescription drug benefit and those that are not given the option to enroll (e.g., their employer elects to adopt a VBID benefit, or enrollment is a required component of an employer-sponsored program such as a disease management program).

Gathering information from pharmacists and health care providers about VBID benefits could also help payers understand how changes in benefit design impact prescribing behavior and patient care. For example, how is information about changes in benefit design communicated between providers and patients? When insurance benefits change, how much do providers consider formulary changes when deciding which medications to prescribe? Because providers play an important role in deciding which drugs to prescribe for a patient, profiling providers to look at prescribing habits or evaluating changes in VBID drug prescribing before and after VBID benefit implementation may be useful to examine how provider behavior is impacted by VBID benefits. Additionally, pharmacists are medication experts that are uniquely qualified to be able to help their patients maximize the safety, quality, and effectiveness of drug therapy for chronic conditions while attempting to minimize costs. It is important to further understand the pharmacist’s role in modifying drug therapy in response to prescription drug benefit changes.

The majority of previous research has been performed using MPR as the assessed adherence measure. In the current study, the calculation of MPR for each study subject combined medications from different therapeutic classes into one adherence measure. Future research will evaluate whether adherence changes differed by therapeutic category and indication to determine whether the impact of the VBID benefit varied across therapeutic categories. Further investigation of member switching behavior (e.g., from non-VBID medications to VBID medications) is also warranted. The use of alternative adherence measures may be useful to look at other characteristics of medication adherence. For example, the use of a measure such as the Continuous Measure of Medication Gaps, or CMG, may be useful to evaluate the impact of a VBID benefit on gaps or lapses in drug therapy.[35] Additionally, little is known about how VBID benefits may impact patient medication persistence, or the duration of time from initiation to discontinuation of therapy.[9]

Several questions were raised during this study that merit further investigation. Mail order pharmacy use is common, and its role in VBID benefits and medication adherence is unclear. In the current study, mail order use did not have large effects on adherence due to high baseline adherence rates; however, this may not be true in other insured populations. Although the current study truncated medication supplies at the end of the study period to prevent medication supplies from being over-counted, member mail order use to obtain 90 day fills may positively bias adherence estimates. Additionally, although previous research has shown an improvement in medication possession resulting from a VBID benefit, there is little evidence that this actually correlates to improved medication taking behavior by patients and improved health outcomes.

Further understanding of the role of disease management programs and efficient targeting of VBID benefits is required. Much of the previous research that has shown positive effects of a VBID benefit did so in combination with a disease management program, and little is known about the impact of a standalone VBID benefit. The lack of an effect in the present study may have been due, in part, to inefficient targeting of the benefit to the populations that would benefit most from the copayment changes resulting from a VBID benefit. There was some evidence that the largest impact on adherence was seen among members that were non-adherent prior to benefit implementation; however, the reason for this effect is unclear.

The current study used a population approach and a non-equivalent comparison group observational study design to evaluate the impact of a VBID benefit on member medication adherence. Propensity score matching (PSM) is a strategy that can be used to reduce the nonequivalence of the treatment and comparison groups on observed covariates.[17] Such an approach was not used in this analysis due to the small sample size and lack of member information. However, PSM may be particularly important when stratifying members by baseline adherence category, as members may have been selected on extreme values in the pre-period. This could result in regression to the mean, which is a statistical phenomenon that can happen when unusually large or small measurements are followed by less extreme measurements that are closer to the subject's true mean.[96] This could account in part for the large apparent improvements in adherence in the post-period for the non-adherent baseline category. Future research will explore the impact of PSM on the results of this study.

Finally, stratifying members by baseline spending may be useful to see if differences were seen for members with the highest drug cost burden prior to benefit implementation. Further research using stratified approaches such as these may provide further evidence of the impact of VBID benefits.

CHAPTER 7

CONCLUSIONS

Implementation of a VBID prescription drug benefit in a small managed care organization resulted in no short-term changes in medication adherence or expenditures after six months. Various factors may have impacted these findings, including characteristics of the member population, of the benefit structure, and the communication of benefit changes to the member population. The study population was composed mainly of young, healthy individuals with low incidence of chronic disease and low baseline drug use. They also had high generic utilization rates, and higher baseline adherence than the majority of previous research, suggesting cost-related non-adherence was not a significant problem for this member population. The impact of a VBID benefit on such a member population was minimal, and raises questions on whether such a benefit was needed.

Several characteristics of the VBID benefit in the present study differed from those seen in the literature. The current benefit was more generous than other benefits studied for brand name drugs, but potentially less generous for generic drugs. Additionally, the impact of a VBID benefit has not been studied for several of the drug classes included in the benefit. Designing VBID benefits to target members who would benefit most from the copayment reductions is important to achieve program goals. The benefit in the current study was made available to all members, and may have been more effective had efficient targeting been employed. Much of the current evidence for VBID is from studies that also employ some type of disease management program; thus, it is difficult to disentangle the effects of the VBID benefit from the effects of the disease management program. Further research is needed to examine the benefit characteristics related to successful implementation of a VBID benefit.

Member education on benefit changes is an important aspect of impacting member behavior. For the current benefit studied, information about the VBID benefit structure was communicated only to employer groups, with no benefit information being provided directly to members by the MCO. It is unknown to what extent the employer groups shared this information with their employees, but it is likely many members were unaware of the copayment changes.

Finally, this study found that even with a benefit potentially more generous than others in the literature, cost neutrality both for members and for payers is a realistic goal. Additionally, medication adherence under the VBID benefit appeared to be similar than under a traditional benefit design. A VBID benefit like the one described appears to be at least no worse financially for members or payers, and may be a way to reorganize prescription drug benefits to encourage the use of high value, low cost agents for the treatment of chronic medical conditions, and to reduce the use of high cost agents with uncertain benefits.

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APPENDICES

APPENDIX A: Demographic Characteristics of Excluded Members

Shown below are demographic characteristics of the members excluded from the study compared to those members that were included in the study. Excluded members were significantly different from the study sample for all measured characteristics. Excluded members were 10 years younger on average, and had a higher proportion of females. They had considerably lower drug use as measured by the total number of drug fills and the total days supply of medication obtained in the year. Member, payer, and total drug expenditures for excluded members were less than half those of the study sample. Excluded members were significantly healthier, as they used half as many unique drug classes on average; they also used a higher proportion of new medications, had lower mail order pharmacy use, and used a much lower proportion of VBID drugs, which suggest lower rates of chronic medical conditions and higher use of acute medications.

Table A1: Baseline (2012) Characteristics of Excluded Members

	Excluded Members (SD)		Study Sample (SD)	
Sample Size (n)	7,491		6,258	
Age (years)	38.9[a]	(12.7)	48.9[a]	(11.5)
% Male	40.2[b]		47.0[b]	
Total drug fills	5.1[a]	(5.4)	15.9[a]	(12.8)
Total days supply	141[a]	(164)	499[a]	(390)
Members using mail order (%)	22.9[a]	(42.0)	26.1[a]	(43.9)
Member OOP expenditures	$66[a]	($83)	$169[a]	($162)
Payer expenditures	$381[a]	($1,807)	$842[a]	($2,363)
Total expenditures	$448[a]	($1,847)	$1,011[a]	($2,449)
Number of unique drug classes	2.4[a]	(1.8)	4.6[a]	(3.2)
New prescription fills (%)	66.3[a]	(35.6)	37.6[a]	(25.3)
Brand drug fills (%)	14.8[a]	(28.8)	13.7[a]	(21.3)
VBID drug fills (%)	3.9[a]	(15.8)	60.7[a]	(27.5)

OOP: Out-of-pocket expenditures.

[a] $P < 0.05$; difference in mean between members excluded from the study and members included in the study sample, *t*-test.

[b] $P < 0.05$; difference in mean between members excluded from the study and members included in the study sample, Chi-squared test.

APPENDIX B: Alternative Pre-Post VBID Drug Adherence Analysis

In order to test the robustness of the adherence calculations to the time period selected, a sensitivity analysis was performed using the first first 6 months of 2012 as the pre-period (January 1, 2012 to June 30, 2012), and the first 6 months of 2013 as the post-period. Because the same six months were used in both time periods, this would account for any seasonal impacts on adherence (e.g., seasonal changes in the use of antidepressants and asthma controller medications). Member identification was identical to the process described previously, with the only exception being the pre-period dates. Baseline characteristics of the alternative study sample are presented in Table B1, and were similar to the study sample for the main analyses.

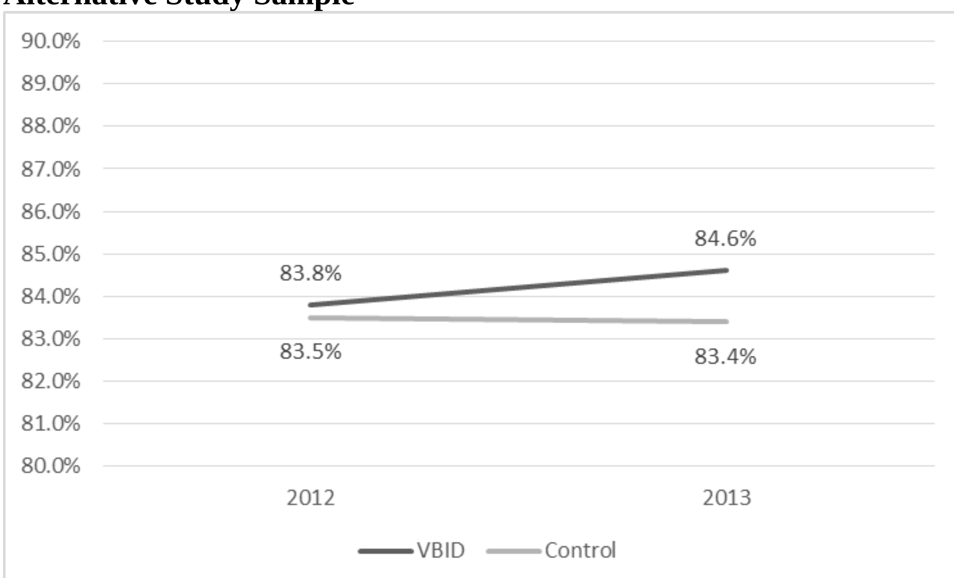
Table B1: Baseline (2012) Characteristics of Alternative Study Sample with Pre-period Defined as January 1, 2012 to June 30, 2012

	VBID (SD)		Comparison (SD)	
Sample size (n)	1,461		4,405	
Age (years)	49.0	(11.5)	49.3	(11.2)
% Male	40.8[a]		48.7[a]	
Total drug fills	16.7	(13.0)	15.9	(12.5)
Total days supply	548[b]	(415)	484[b]	(375)
% Mail order pharmacy use	34.9[b]	(47.7)	21.2[b]	(40.9)
Member OOP expenditures	$174	($167)	$175	($167)
Payer expenditures	$994[b]	($2,321)	$787[b]	($2,345)
Total expenditures	$1,168[b]	($2,414)	$962[b]	($2,432)
# of unique drug classes	5.1[b]	(3.3)	4.6[b]	(3.1)
% New prescriptions	41.3[b]	(23.5)	38.7[b]	(24.7)
% Brand drugs	16.3	(21.4)	15.1	(22.1)
% VBID drugs	56.5[b]	(26.5)	61.0[b]	(27.2)

OOP: Out-of-pocket expenditures. Pre-period for alternative study sample defined as January 1, 2012 to June 30, 2012.
[a] $P < 0.05$; difference in mean between members in the VBID group and members in the comparison group, Chi-squared test.
[b] $P < 0.05$; difference in mean between members in the VBID group and members in the comparison group, *t*-test.

Adherence changes to VBID drugs using the first 6 months of 2012 as the pre-period are presented in Figure B1. This sensitivity analysis had similar findings to the primary analysis, with adherence to VBID drugs remaining at a high level in both time periods. Adherence in the comparison group was slightly higher than in the primary analysis, although adherence did not significantly change in 2013. Adherence in the VBID group was slightly higher than the comparison group in both time periods and increased by 0.8 percentage points in 2013, although these findings were not significant. The covariate adjusted difference-in-difference estimate for the change in adherence by study group was not significant (Table B2), which confirms the finding from the primary analysis.

Figure B1: Adherence to VBID Medications between Study Groups, 2012-2013 Using Alternative Study Sample



Note: Adherence measured using the medication possession ratio at the therapeutic class level. Pre-period for alternative study sample defined as January 1, 2012 to June 30, 2012.

Table B2: Mean Adherence to VBID Medications: Difference-in-Difference Analysis Using Alternative Study Sample

Variables	**Coefficient**	**(95% CI)**
2013	-0.005	(-0.011, 0.000)
Treatment	-0.001	(-0.012, 0.010)
Post*Treatment	0.006	(-0.005, 0.018)
Age	0.003*	(0.003, 0.004)
Male	0.010*	(0.002, 0.018)
Drug classes	-0.005*	(-0.006, -0.004)
Mail order	0.069*	(0.061, 0.077)
Constant	0.677*	(0.657, 0.698)

* p<0.05. Pre-period for alternative study sample defined as January 1, 2012 to June 30, 2012.

APPENDIX C: Alternative Pre-Post VBID Drug Adherence Analysis by Baseline Adherence Category

In order to test the robustness of the adherence calculations to the time period selected, a sensitivity analysis was performed using the first 6 months of 2012 as the pre-period (as described in Appendix B). Baseline characteristics of the alternative study sample are presented in Table C1, with identical proportions of members falling into the fully adherent (75%), somewhat adherent (19%), and non-adherent (6%) categories. Baseline characteristics of the alternative study sample were similar to the study sample for the main analyses, with several minor differences. The differences seen in the non-adherent category for age, total drug fills, and members using mail order were not statistically significant, while there was a significant difference in member out-of-pocket expenditures. For the somewhat adherent category, the age difference was no longer significant, while there were significant differences in gender and the proportion of VBID drug fills. Finally, for the fully adherent category, the differences in total expenditures and number of unique drug classes were no longer significant.

Table C1: Characteristics of Alternative Study Sample by Baseline (2012) Adherence

	Non-Adherent (6%)		Somewhat Adherent (19%)		Fully Adherent (75%)	
	VBID	Comparison	VBID	Comparison	VBID	Comparison
Sample size (n)	80	284	285	860	1,096	3,261
Age (years)	44.9	42.9	46.0	47.3	50.1	50.5
% Male	41.3	41.9	37.9[a]	48.1[a]	41.5[a]	49.4[a]
Total drug fills	9.0	7.6	13.9	12.8	17.9	17.5
Total days supply	79	70	184	195	348[b]	324[b]
Members using mail order (%)	12.5	12.3	24.6[b]	15.7[b]	39.2[b]	23.5[b]
Member OOP expenditures	\$23[b]	\$31[b]	\$48[b]	\$63[b]	\$70[b]	\$89[b]
Payer expenditures	\$159	\$140	\$234	\$236	\$338[b]	\$262[b]
Total expenditures	\$182	\$170	\$282	\$299	\$408	\$351
# of unique drug classes	4.5[a]	3.6[a]	4.9	4.6	5.2	4.7
VBID drug fills (%)	43.7	47.3	53.8[b]	58.5[b]	58.2[b]	62.8[b]

OOP: Out-of-pocket spending. Baseline categories: non-adherent (MPR ≤ 0.50), somewhat adherent ($0.5 < \text{MPR} < 0.80$), and fully adherent (MPR ≥ 0.80). Pre-period for alternative study sample defined as January 1, 2012 to June 30, 2012.
[a] $P < 0.05$; difference in mean between members in the VBID group and members in the comparison group, Chi-squared test.
[b] $P < 0.05$; difference in mean between members in the VBID group and members in the comparison group, *t*-test.

As before, the results of the difference-in-difference-in-difference models using the alternative sample showed no overall policy effect of the VBID benefit across comparisons among the three levels of baseline adherence category (Tables C2-C3). Pre-post adherence changes by adherence category among the alternative sample are shown visually in Figure C1. Similar to the primary analysis, adherence changes from 2012 to 2013 were significantly different by baseline adherence category, though these changes were identical for the VBID and comparison groups for all three baseline adherence categories. The adherence changes seen were slightly larger than those in the primary analysis, with a 26 percentage point increase seen in the non-adherent group, a 7 percentage point increase in the somewhat adherent group, and a 3 percentage point decrease in the fully adherent group.

Table C3: Mean Adherence to VBID Medications: Difference-in-Difference-in-Difference Analysis Using Alternative Study Sample (Reference Category: Medium)

Variables	Coefficient	(95% CI)
2013	0.067*	(0.052, 0.081)
Treatment	-0.012	(-0.027, 0.002)
Low	-0.289*	(-0.304, -0.274)
High	0.252*	(0.243, 0.261)
2013*Treatment	0.014	(-0.017, 0.045)
2013*Low	0.189*	(0.153, 0.226)
2013*High	-0.103*	(-0.119, -0.087)
Treatment*Low	0.016	(-0.019, 0.052)
Treatment*High	0.009	(-0.007, 0.026)
2013*Treatment*Low	-0.015	(-0.088, 0.059)
2013*Treatment*High	-0.004	(-0.037, 0.029)
Age	0.001*	(0.001, 0.002)
Male	0.002	(-0.004, 0.007)
Drug classes	-0.006*	(-0.006, -0.005)
Mail order	0.043*	(0.037, 0.049)
Constant	0.602*	(0.586, 0.617)

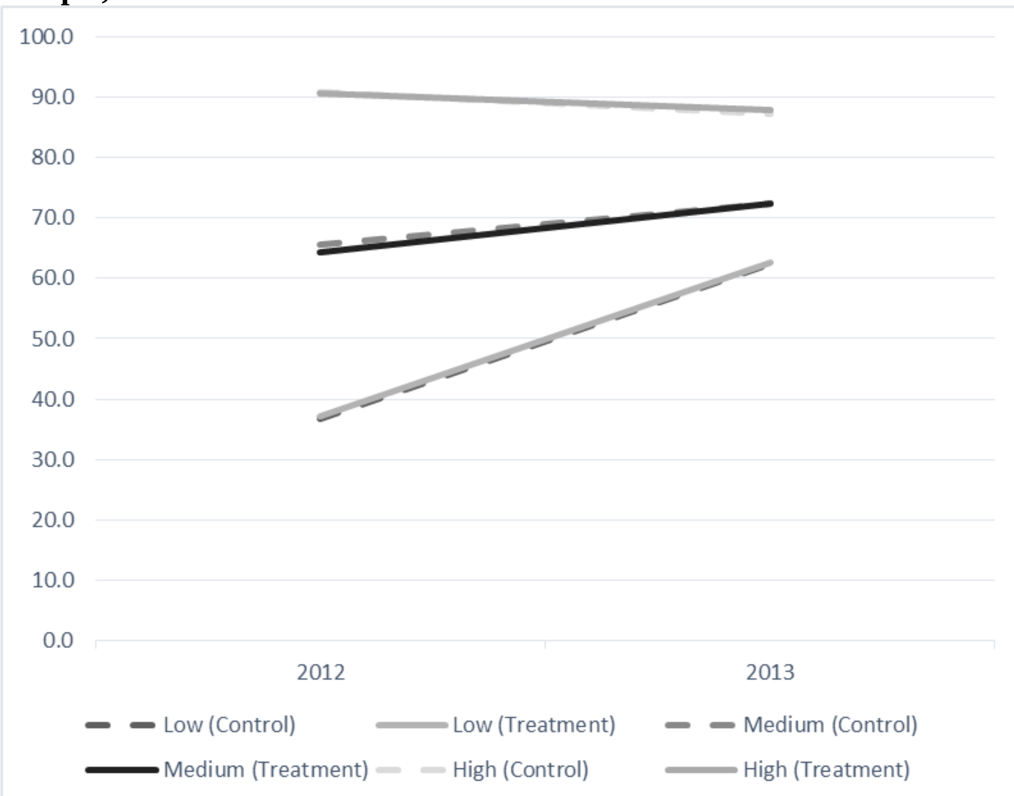
* $p<0.05$. Adherence categories determined using baseline (2012) adherence. Baseline categories: non-adherent (low), somewhat adherent (medium), fully adherent (high). Pre-period for alternative study sample defined as January 1, 2012 to June 30, 2012.

Table C4: Mean Adherence to VBID Medications: Difference-in-Difference-in-Difference Analysis Using Alternative Study Sample (Reference Category: Low)

Variables	**Coefficient**	**(95% CI)**
2013	0.256*	(0.223, 0.289)
Treatment	0.004	(-0.028, 0.036)
Medium	0.289*	(0.274, 0.304)
High	0.541*	(0.528, 0.555)
2013*Treatment	-0.001	(-0.068, 0.066)
2013*Medium	-0.189*	(-0.226, -0.153)
2013*High	-0.292*	(-0.326, -0.258)
Treatment*Medium	-0.016	(-0.052, 0.019)
Treatment*High	-0.007	(-0.040, 0.026)
2013*Treatment*Medium	0.015	(-0.059, 0.088)
2013*Treatment*High	0.010	(-0.057, 0.078)
Age	0.001*	(0.001, 0.002)
Male	0.002	(-0.004, 0.007)
Drug classes	-0.006*	(-0.006, -0.005)
Mail order	0.043*	(0.037, 0.049)
Constant	0.313*	(0.295, 0.330)

* $p<0.05$. Adherence categories determined using baseline (2012) adherence. Baseline categories: non-adherent (low), somewhat adherent (medium), fully adherent (high). Pre-period for alternative study sample defined as January 1, 2012 to June 30, 2012.

Figure C1: Pre-Post Adherence Changes by Adherence Category Using Alternative Study Sample, 2012-2013



Adherence measured using medication possession ratio (MPR). Adherence categories determined using baseline (2012) adherence. Baseline categories: non-adherent (MPR ≤ 0.50), somewhat adherent (0.5 < MPR < 0.80), and fully adherent (MPR ≥ 0.80). Predicted values adjusted using mean age, gender, # of unique drug classes, and mail order pharmacy use. Pre-period defined as January 1, 2012 to June 30, 2012.

APPENDIX D: Mail Order Use Analysis

As part of the benefit studied, members were able to utilize a mail order pharmacy option to obtain prescription fills for up to a 90 day supply of a chronic medication; in contrast, prescription fills at community pharmacies were restricted to a maximum of a 30 day supply. Due to the short time period in the pre- and post-period in the present study, it was believed that mail order pharmacy use might positively bias adherence measurement. This might occur because mail order users only need to obtain two prescription fills in each time period to be fully adherent; in contrast, members that did not use mail order needed to have at least 5 prescription fills in each period to be fully adherent. Therefore, several additional analyses were conducted to explore member mail order use and its impact on medication adherence.

Table D1 presents baseline characteristics of members in the VBID and comparison groups for mail order pharmacy users and those members that did not use mail order. Members were classified as mail order users if they obtained any medication fill for greater than a 30 day supply during either study period. About 2/3 of mail order users were female, compared to about ½ of non-users. Not surprisingly, the number of medication fills were significantly lower for mail users and the days supply was greater. Although mail order users had higher out-of-pocket, plan, and total drug expenditures, these findings were significant only in the comparison group. Mail order users used significantly more unique drug classes, suggesting these members may have higher rates of chronic conditions. Also not surprisingly, due to the fewer number of drug fills obtained, the proportion of new prescriptions were higher and the proportion of VBID prescriptions were lower in the mail order group. The proportion of drug fills for brand name medications was higher amongst mail order users, although this finding was significant only for the comparison group.

Table D1: Baseline (2012) Characteristics of All Mail Order Users and Non-Mail Order Users by Study Group

	VBID		Comparison	
	Mail Users	Non-Users	Mail Users	Non-Users
Sample size (n)	589	973	1,045	3,651
Age (years)	48.8	48.5	49.2	48.9
% Male	30.2[a]	47.6[a]	38.2[a]	52.0[a]
Total drug fills	14.3[b]	17.4[b]	14.5[b]	16.1[b]
Total days supply	648[b]	477[b]	634[b]	442[b]
Member OOP expenditures	$175	$161	$192[b]	$163[b]
Payer expenditures	$1,142	$911	$1,120[b]	$695[b]
Total expenditures	$1,317	$1,072	$1,313[b]	$858[b]
# of unique drug classes	5.5[b]	4.5[b]	5.2[b]	4.3[b]
New prescription fills (%)	46.4[b]	35.0[b]	43.4[b]	35.1[b]
Brand drug fills (%)	15.2	13.2	15.2[b]	13.1[b]
VBID drug fills (%)	51.3[b]	61.9[b]	51.9[b]	64.4[b]

OOP: Out-of-pocket spending. Members were classified as mail order users if they obtained any medication fill for greater than a 30 day supply during either study period.
[a] $P < 0.05$; difference in mean between members in the VBID group and members in the comparison group, Chi-squared test.
[b] $P < 0.05$; difference in mean between members in the VBID group and members in the comparison group, *t*-test.

Characteristics of mail order use amongst mail order users is presented in Table D2. Of members that used mail order, 93% of VBID group members and 91% of comparison group members used mail order in both study periods. Although the number of total and VBID drug fills obtained by mail order users did not significantly differ between VBID and comparison group members, the mean number of fills obtained via mail order was significantly higher in the VBID group in both years. Accordingly, the percentage of total fills obtained via mail order was also significantly higher in the VBID group. This difference may be a reflection of the VBID group having a higher chronic disease burden.

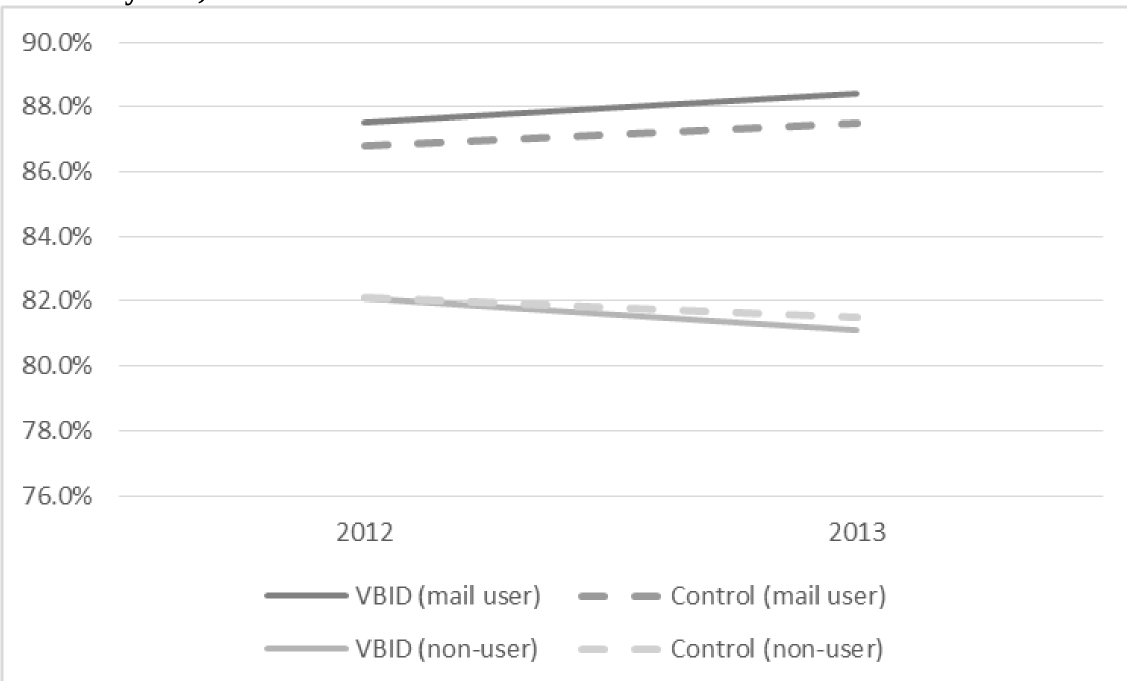
Table D2: Characteristics of Mail Order Use amongst Mail Order Users, 2012-2013

	2012				2013			
	VBID Mean (SD)		Comparison Mean (SD)		VBID Mean (SD)		Comparison Mean (SD)	
Sample size (n)	589		1,045		627		1,154	
Total drug fills	14.3	(12.8)	14.5	(11.6)	14.5	(13.0)	14.5	(11.9)
VBID drug fills	6.5	(6.4)	6.6	(5.8)	6.5	(6.6)	6.6	(5.8)
# Fills via mail order+	4.5[a]	(3.8)	4.1[a]	(3.7)	4.8[a]	(4.1)	4.2[a]	(3.8)
% Fills via mail order+	46.0[a]	(32.2)	42.3[a]	(33.1)	48.7[a]	(33.3)	43.2[a]	(33.2)

Members were classified as mail order users in a study period if they obtained any medication fill for greater than a 30 day supply during the corresponding study period.
[a] $P < 0.05$; difference in mean between members in the VBID group and members in the comparison group, *t*-test.

In order to test the robustness of the adherence findings to the use of mail order pharmacy, the adherence calculations were performed for members in both study groups that did and did not utilize mail order during the study period (Figure D1). Adherence was significantly higher among mail order users compared to non-users in both study groups and in both years; however, adherence rates remained over 80% for both groups in both study periods. Interestingly, adherence rates among mail order users in both groups increased slightly in 2013, possibly due to an increase in the number of fills obtained via mail order. In contrast, adherence rates actually decreased slightly among members in both study groups that did not use mail order. However, these differences were not statistically significant. Mail order pharmacy use appears to have had minimal impact on the results related to pre-post changes in adherence rates each found in the primary analysis, likely due to the high baseline rates of medication adherence among both mail order users and non-users.

Figure D1: Mean Adherence to VBID Medications between Study Groups by Mail Order Pharmacy Use, 2012-2013



Note: Adherence measured using the medication possession ratio at the therapeutic class level. Members were classified as mail order users if they obtained any medication fill for greater than a 30 day supply during either study period.