COMPARISON OF WASHINGTON STATE 2010 MEDICARE PRESCRIPTION DRUG PLAN COVERAGE OF PHARMACOTHERAPIES FOR OPIOID AND ALCOHOL DEPENDENCE

BY

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To the Faculty of Washington State University:

The members of the Committee appointed to examine the thesis of AARON DIPZINSKI find it satisfactory and recommend that it be accepted.

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Abstract

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Study Objectives

The objective of this study is to assess the current cost and availability of antiaddiction medications in Medicare drug plans in Washington State.

Specific Aims

The specific aims of the study are: 1) to determine the proportion of Medicare drug plans that cover opioid and alcohol dependence medications; 2) to compare coverage rates and formulary restrictions placed on older generic medications and newer patent protected medications; 3) to contrast coverage of antiaddiction medications in Medicare Advantage Plans (MAPs) and in Medicare Prescription Drug Plans (PDPs); and 4) to assess variation in MAPs coverage of antiaddiction medications in rural and urban communities.

Method:

This study examines MAPs and PDPs coverage of seven different opioid and alcohol dependence medications; Buprenorphine (Suboxone®), Methadone (Methadose®), Naltrexone

(ReVia®, Vivitrol®, and the generic formulation) Disulfiram (Antabuse®), and Acamprosate (Campral®).

The data for this study was obtained for the Center of Medicare and Medicaid Services (CMS) website (www.medicare.gov) via the Medicare Prescription Drug Plan Finder section. This data was gathered in February, 2010.

Results:

The results indicate that both PDP and MAP coverage of substance dependence medications varies by patent protection status. Two thirds of PDPs and almost half of MAPs exclude Vivitrol. ReVia faces formulary exclusion from 80% of PDPs and almost 50% of MAPs. Suboxone is placed in the most expensive cost-sharing tiers in 60% of Medicare plans. Campral is also generally placed in tiers 3 or 4; while ReVia and Vivitrol (with the exception of three MAPs) are exclusively placed in the highest cost-sharing tiers. Coverage and cost structure of dependence medications did not significantly differ between MAPs and PDPs. No significant difference exists between MAPs coverage of dependence medication for beneficiaries living in rural as compared to urban localities.

Conclusion:

Antiaddiction medications are usually covered, but the out-of-pocket costs may restrict access for some enrollees. Both MAPs and PDPs place patent protected medications on higher cost-sharing tiers which discourages beneficiaries' utilization of these medications. This is of particular importance for Suboxone, Campral, and Vivitrol as generic substitutes for these medications are not currently available.

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I Love You Mom

Thank you for all your support

CHAPTER ONE

INTRODUCTION

This study examines the availability and cost of opioid and alcohol dependence pharmacotherapies within the Medicare program in Washington State. There are two programs that provide prescription drug coverage in Medicare; Medicare Part C managed care plans, or Medicare Advantage Plans (MAPs), and Medicare Part D Prescription Drug Plans (PDPs). MAPs serve specific markets within the state, and are less likely to serve rural than urban areas. The study contrasts antiaddiction medication coverage and costs in PDPs and MAPs, and contrasts rural and urban country coverage among available MAPs. This chapter introduces the research problem, describes the study objectives and specific aims, and lists three distinct sets of hypotheses.

Introduction

Addiction is a serious problem in the United States (Manchikanti, 2006). Recognizing the need to address the growing problem of both heroin and prescription drug abuse, Congress passed the Drug Addiction Treatment Act or DATA 2000 (Congressional Record, 2000). The proposed legislation promoted buprenorphine as an alternative to methadone maintenance treatment. Buprenorphine offers an office based treatment of opioid dependence and abuse. The legislation was intended to create access for opioid dependency treatment in areas where methadone clinics rarely exist. However, almost a decade after the approval of buprenorphine, it is unclear whether the legislative objective has been accomplished (Thomas, Refi, Haq, Wallack, Hoyt, Ritter, 2008).

Fewer than 20% of opioid dependent individuals are enrolled in substance abuse treatment programs (Cunningham, Giovanniello, Sacajiu, Whitley, Mund, Beil, Sohler, 2008). Despite buprenorphine's demonstrated effectiveness, methadone maintenance therapy is still the most common treatment in the U.S. (Boothby & Doering, 2007). One obvious reason is the disparity in medication costs: methadone is a fraction of the cost of patent-protected buprenorphine.

In general, substance dependence medications are a relatively new phenomenon, particularly for alcoholism. Until 1994, disulfiram (Antabuse) was the only Food and Drug Administration (FDA) approved medication used to treat alcoholism (Mark, Kassed, Vandivort-Warren, Levit, Kranzler, 2008). Like buprenorphine, several pharmacotherapies aimed at treating alcohol dependence have recently entered the market. Also parallel to buprenorphine, these treatment options are much more costly than their predecessors. However, these new medications may provide patients with new treatment options in the primary care setting.

Purpose of Proposed Research

The purpose of the research is to examine the current availability and cost of Suboxone, Methadose, Naltrexone, ReVia, Vivitrol, Campral, and Antabuse among MAPs and PDPs to assess whether variations exist within drug type, plan type and/or locality. The findings of this study will guide policy recommendations and future research.

The Centers for Medicare and Medicaid Services requires Part D formularies to include "all or substantially all" antidepressant and antipsychotic medications. However, they do not require coverage of medications to treat one of the most common DSM –IV psychiatric diagnoses: alcohol and drug addiction.

Research Problem

Opioid and alcohol dependence is an epidemic in the United States. In 2005, 1.5 million individuals met the DSM-IV criteria for dependence on prescription pain relieving drugs (Gunderson & Fiellin, 2008). The trend continued in 2006, with an estimated 5.2 million individuals reporting abuse of prescription opioids (Sigmon, Dunn, Badger, Heil, Higgins, 2008). Dependence or abuse of prescription opioids is now more common than all other drugs except marijuana (Manchikanti, 2006). Older Medicare beneficiaries are at relatively high risk of opioid addiction, because of high prescribing rates in this group (Carrie, Grymonpre, Blandford, 2006). The abuse of prescription drugs is a significant concern in rural and suburban areas (Cicero, Inciardi, Alvaro, Muñoz, 2005). Currently, the demand for opioid dependency treatment is estimated at 800,000 treatment spaces, far out numbering the treatment positions available (McCance-Katz, 2004).

The prevalence of alcohol addiction is even more staggering. Approximately 8 million individuals in the United States currently satisfy the diagnostic criteria for alcohol dependence (Anton, O'Malley, Ciraulo, 2003). The economic cost of alcohol abuse was estimated at more than $184 billion over a decade ago (Williams, 2005) and is a leading preventable cause of morbidity and mortality (Hollingworth, Ebel, McCarty, 2006).

Alcohol abuse is also a growing concern for older adults (Kirchner, Zubritsky, Cody, 2007). In the primary care setting, the prevalence of alcohol use disorders varies from 20% to 36%, but most patients are never treated for their addiction (Anton et al., 2003). Similar to opioid dependence, primary care physicians can play a significant role in addressing alcohol abuse (Anton et al., 2003).

Study Objectives, Specific Aims, and Research Hypotheses

Study Objectives

The objective of this study is to assess the current availability and cost of antiaddiction medications in Medicare drug plans in Washington State.

Specific Aims

The specific aims of the study are: 1) to determine the proportion of Medicare drug plans that cover specific opioid and alcohol dependence medications; 2) to compare coverage rates and formulary restrictions placed on older generic medications and newer patent-protected medications; 3) to contrast coverage of antiaddiction medications in Medicare Advantage Drug Plans (MAPs) and in Medicare Prescription Drug Plans (PDPs); and 4) to assess variation in MAP coverage of antiaddiction medications in rural and urban communities.

Research Hypotheses

H_1: PDP and MAP coverage of opioid and alcohol dependence medications will vary by patent protection status - plans will be more likely to cover generic medications due to lower cost and longer clinical history. (Hillman, Pauley, Escarce, Ripley, Gaynor, Clouse, Ross, 1999).

H_2: Coverage of opioid and alcohol dependence medications will vary by plan type – MAPs, because they are responsible for total health care costs, will be more likely than PDPs to cover antiaddiction medications and offer at least partial coverage during the gap (aka doughnut hole). (Guterman, Davis, Schoenbaum, Shih, 2009) (Gerson, Boex, Hua, Liebelt, Zumbar, Bush, Givens, 2001).

H_3: Access to MAPs will be restricted in smaller markets, leading to fewer coverage options for patients with opioid or alcohol dependence in rural areas than in urban areas (Kemper, McBride, Mueller, 2009).

Significance of the Study

The availability and cost of opioid and alcohol dependency pharmacotherapies in Medicare C and Medicare Part D is unknown. It is important to examine the availability of coverage, the cost sharing structure, and the utilization management tools currently employed by these plans to determine whether lack of coverage or utilization management restrictions may limit access. It is also crucial to determine if a variance exists in these plans between populations in urban and rural localities to assess access and cost issues.

Current research does not examine the differences between MAPs and PDPs in regards to coverage of Suboxone verses Methadone, nor that of Campral and Vivitrol to their predecessors, Naltrexone, and Antabuse. Current research fails to examine the difference in coverage of these plans in rural and urban areas in regards to opioid and alcohol dependency treatment. This research will contribute to the current body of literature by providing an analysis of how MAPs and PDPs in Washington State provide coverage of antiaddiction medications.

CHAPTER TWO

THEORETICAL BASIS/LITERATURE REVIEW

This chapter presents a comprehensive literature review encompassing the current body of knowledge and gaps in the literature. The methodology section describes the techniques employed to complete this literature review.

Literature Review Methodology

This literature review was conducted utilizing several computer databases; including LexisNexis and PubMed. The review was limited to English-language articles published in peer-reviewed journals, congressional hearing records, state government reports, and interviews with local healthcare providers.

To locate relevant articles on opioid addiction treatment and medications, research terms such as "buprenorphine treatment efficacy", "opioid addiction treatment", "access to buprenorphine treatment", "regulation of buprenorphine treatment," "methadone maintenance therapy," "substitution therapy," "dependency medications," "Medicare prescription drug plan," were utilized. To search databases for alcohol dependency treatments relevant search terms used included; "alcoholism medication," "alcohol dependence," "barriers to alcohol medication," and the drug names of each medication. Medicare information was searched through the same databases as drug information and on the CMS website.

This literature review includes 74 different references. Articles regarding access to buprenorphine prior to 2002 were excluded from the literature review, as the prescribing of this medication was prohibited in the United States prior to FDA approval of Suboxone and Subutex in October of 2002. Articles solely describing the chemical formulations of these medications,

and articles focused on 12 step programs or other psychosocial treatment methods were also excluded from this literature review.

Literature Review

Opioid Dependence: A Growing Problem

Opioid dependence is an epidemic in the United States (McCance-Katz, 2004). Americans consume 80% of the global opioid supply and 99% of the global hydrocodone supply (Manchikanita, 2006). Prescription narcotics are the most commonly misused opioids (Barry, Irwin, Jones, Becker, Tetrault, Sullivan, et al., 2008). Incidence of abuse of prescription opioids such as, Oxycotin, hydrocodone, and hydromorphone, ballooned by more than 400% from 1990 to 2000 (Sigmon et al., 2008). This represents an increase of abuse from 628,000 to 2.4 million Americans (Compton & Volkow, 2006). Emergency department visits involving prescription opioid abuse increased by 45% from 2000 to 2002, with admissions to treatment for primary abuse of prescription opioids increasing by 186% from 1997 to 2002 (Rosenblum, Marsch, Joseph, Portenoy, 2008). In 2005, 1.5 million individuals met the DSM-IV criteria for drug abuse or dependence on prescription pain relieving drugs (Gunderson & Fiellin, 2008). The trend continued in 2006, with an estimated 5.2 million individuals reporting abuse of prescription opioids (Sigmon et al., 2008). Abuse of prescription opioids is now more common than all other drugs except marijuana (Manchikanti, 2006).

Prescription drug abuse in rural America is an alarming problem (Cicero et al., 2005, Levine & Coupey, 2009). Suggested reasons for drug abuse in rural areas are: 1) prescription drugs are relatively easy to obtain compared to illicit drugs; 2) the purchase of illicit drugs, such as heroin, is closely monitored by law enforcement and arrests are far more likely; 3) the use and

abuse of prescription drugs is more socially acceptable; and 4) the purity and the dosage of prescription medications is highly predictable and consequently these medications are perceived as much safer than illicit drugs (Cicero et al., 2005).

Opioid abuse regularly leads to addiction with physical dependence, manifest by tolerance and withdrawal (Collins & McAllister, 2007). Opioid dependence is a chronic, relapsing, medical disorder (Gordon, Trafton, Saxton, et. al., 2007). The use of heroin and other opioids is linked with higher societal costs and burdens associated with increased morbidity and mortality, and increased risk of social dysfunction, including lengthy unemployment, criminal activity, homelessness, and incarceration (Netherland, Botsko, Egan, Saxon, Cunningham, Finkelstein, Gourevitch, et al., 2009).

The estimated cost of untreated opiate dependence is about $20 billion per year (Wallack, Thomas, Martin, Chilingerian, Reif, 2008). Drug treatment expenses account for 5.7% of the total costs (Jones, Moore, Sindelar, O'Connor, Schottenfeld, Fiellen, 2009). The largest portion of these costs are derived from drug treatment and complications such as AIDS (23%), lost of productivity (52.6%), and crime (23.9%) (Jones et al., 2009). Annually, costs for prescription drug abuse accounts for $4.6 billion in the workplace, $2.6 billion in healthcare, and $1.4 billion in criminal justice system (Jones et al., 2009). Treatment of addiction provides 1.3 to 23 times its medical costs in savings to society in terms of lost productivity, lower medical expenditures, and cost of criminal activity (Wallack et al., 2008).

The increase in opiate dependence creates a higher demand for addiction treatment (Sigmon et al., 2008). However, access remains extremely limited. Prior to the passages of DATA 2000, the use of opioid medication to treat opioid addiction was primarily limited to methadone treatment programs (Ling, 2009). While opioid dependence is steadily increasing in

the United States, the number of federally licensed methadone maintenance treatment slots remains unchanged (at approximately 250,000) and unevenly distributed geographically (Walley, Alperen, Cheng, Botticelli, Castro-Dolan, Samet, et al., 2008). Consequently, numerous potential patients who want opioid agonist treatment cannot access licensed treatment facilities.

Six predominately rural states (Idaho, Mississippi, Montana, North Dakota, South Dakota, and Wyoming) do not offer any licensed opioid agonist treatment (Saxon & McCarty, 2005). New Hampshire, Vermont, and West Virginia instituted their first programs in 2001 (Saxon & McCarty, 2005). Resistance within larger urban or metropolitan areas, neighborhoods, and communities is manifested with multiple attempts to bar licensed clinics (Cooper, 1995). Inadequate treatment capacity creates a substantial barrier for potential patients who do live in reasonable proximity to a licensed clinic (Schwartz, Brooner, Montoya, Currens, Hayes,1999).

Despite the approval of buprenorphine for addiction treatment, fewer than 20% of opioid dependent individuals are enrolled in substance abuse treatment programs (Cunningham et al., 2008). Currently, the demand for opioid dependency treatment is estimated at 800,000 treatment spaces, far out numbering the treatment slots available (McCance-Katz, 2004).

Treating Opioid Dependence

Opioid Dependence Medications: Buprenorphine, Naltrexone, & Methadone

Buprenorphine and methadone are the two established opioid substitution drugs licensed for the treatment of opioid dependence (Wittchen, Apelt, Buhringer, Gastpar, Backmund, Golz, et al., 2005). Maintenance (substitution) therapy involves replacing abused opioids with medically prescribed opioids that are long acting and have less potential for abuse (Collins &

McAllister, 2007). Maintenance medications prevent withdrawal and compete for opioid receptor binding sites, blocking the effects of any self-administered opioids (Collins & McAllister, 2007).

Methadone

Methadone maintenance therapy became widely accepted in the mid 1960's (Collins & McAllister, 2007). Today, methadone is still used for this purpose and is considered the standard treatment for opioid dependence (Boothby & Doering, 2007). Moreover, at roughly $13 per patient per day, methadone maintenance treatment is relatively inexpensive (Walters, 2000).

Methadone is a full mu antagonist, meaning it stabilizes the brain neurochemistry of an opioid dependent individual and prevents withdrawal (Marsch, Bickel, Badger, Jacobs, 2004). Also, methadone blocks the euphoric effects of self-administered opioids, consequently, decreasing the desire to use heroin or prescription opioids (Marsch et al., 2004). As prescribed, methadone is taken once a day to eliminate opiate withdrawal symptoms for 24 to 36 hours (Strain, Stitzer, Liebson, Bigelow, 1994).

As a full opioid-receptor agonist, methadone also has the potential for abuse and diversion (Boothby & Doering, 2007). Deaths related to methadone use have risen sevenfold in the last decade (Fingerhut, 2008). In 2005, Washington State had one of the highest deaths per 100,000 population ratio in the nation at 4.3 deaths per 100,000 (Fingerhut, 2008).

Methadone maintenance treatment is highly regulated by state and federal laws, restricting the use of opioid dependence treatment outside the confines of methadone clinics (Boothby & Doering, 2007). Since it can only be prescribed for addiction treatment within licensed outpatient clinics, methadone maintenance treatment is covered by insurance as a treatment service rather than as a prescription medication (Marsch et al., 2004).

Naltrexone

Naltrexone is an opiate antagonist that precipitates acute withdrawal (Horgan, Reif, Hodgkin, Garnick, Merrick, 2008). It was approved by the FDA for opiate addiction treatment in 1984 (Horgan et al., 2008). However, because Naltrexone precipitates acute withdrawal, poor compliance and treatment retention often results (Horgan et al., 2008). Consequently it is rarely used for continued treatment of opioid dependence (Minozzi, Vecchi, Davoli, Kirchmayer, Verster, 2006). Naltrexone is also available for alcohol dependence in brand name, (ReVia) and generic formulations, as well as, in a long lasting injectable form, Vivitrol (Horgan et al., 2008).

Buprenorphine

Buprenorphine received FDA approval for opioid dependence treatment in two different formulations. Subutex (buprenorphine only), is primarily used during the monitoring initiation phase of buprenorphine treatment, while Suboxone (Buprenorphine and Naloxone) is used during maintenance phase (Smith, Bailey, Woody, Kleber, 2007). Suboxone's formulation consists of buprenorphine hydrochloride with naloxone dihydrate. Suboxone is manufactured by Reckitt Benckiser Healthcare Ltd. and is the most widely prescribed formulation of buprenorphine to treat opioid dependence in the United States (Ling, 2009). Suboxone was designed specifically to minimize diversion, pulverization, and injection, making the drug suitable for office-based treatment (Stein, Cioe, Friedmann, 2005).

Subutex, like methadone, has the potential for intravenous misuse. In fact, buprenorphine was moved from a schedule V to a Schedule III narcotic of the Controlled Substances Act as the DEA expressed concern over the potential for diversion (Cicero et al., 2005). However, Suboxone, because of the addition of naloxone to buprenorphine, lowers the abuse liability of

this drug (Orman & Keating, 2009). Suboxone is administered sublingually, (under the tongue); if the tablets are crushed and injected, the naloxone produces withdrawal, thus deterring diversion (Orman & Keating, 2009).

Suboxone has been shown to be as efficacious as methadone (Wittchen et al., 2005). Buprenorphine may have several advantages over methadone including; dosing scheme (2 or 3 per day dosage regimen), safety issues (reduced risk of accidental overdose due to ceiling effect), and lower dependence potential (tolerance & withdrawal) (Wittchen et al., 2005). There is a ceiling to the opioid agonist effects of buprenorphine, which prevents further doses increases to produce addition effects (McCance-Katz, 2004). Consequently, this leads to a lower potential for abuse of the drug, compared to full agonist (Fiellin, Friedland, Gourevitch, 2006).

Federal Regulation Changing the Way Opioid Dependence Medication is Administered: The Drug Addiction Treatment Act 2000 (DATA 2000)

Congress, recognizing the need to address the growing problem of both heroin and prescription drug abuse of opioid analgesics, passed the Drug Addiction Treatment Act of 2000 (Congressional Record, 2000). The legislation promoted buprenorphine as an alternative to methadone maintenance treatment option. This treatment option was supported by successful experiences abroad and several domestic pilot programs (Turner, Laine, Lin, & Lynch, 2005).

The primary goal of DATA 2000 was to increase access to opioid dependent (Thomas et al., 2008). The legislation proposed treatment in an office based setting in order to reduce stigma and unmet needs (SAMHSA, 2010). For the first time since 1914, when the Harrison Narcotics Act banned doctors from treating opiate addiction directly, DATA 2000 allows clinicians in the USA to treat opioid dependence in the general practice setting (Ling, 2009). Two years after the

passage of DATA 2000, the FDA, in October of 2002, approved both Subutex and Suboxone as sublingual formulations of buprenorphine (SAMHSA, 2010).

Currently, to prescribe Schedule III opioid medications specifically approved by the FDA, federal law requires physicians to complete at least eight hours of approved opioid treatment training, or meet certain experience qualifications, to obtain a "waiver" from the special registration requirements mandated by the Narcotic Treatment Act of 1974. (SAMHSA, 2010). A physician must also have the capacity to provide or refer patients for appropriate psychosocial counseling. Each treatment facility or individual physician is limited to treatment of 100 patients concurrently. Also, upon induction a patient must stay at the physician's office for 2-8 hours after the first medication dose (West, Kosten, Wilk, Svikis, 2004).

Advocates of the law anticipated a proliferation of providers offering buprenorphine treatment in rural areas. These regulations expected to create greater access for opioid dependency treatment in areas where methadone clinics rarely exist. However, almost a decade after the approval of buprenorphine as an addiction treatment, it is unclear whether the legislative objective has been accomplished (Thomas et al., 2008).

Alcohol Dependency: A Growing Problem

Approximately 8 million individuals in the United States currently satisfied the diagnostic criteria for alcohol dependence (Anton et al., 2003). The economic cost of alcohol dependence was estimated at more than $184 billion over a decade ago (Williams, 2005) and is a leading preventable cause of morbidity and mortality (Hollingworth et al., 2005). Persons older than age 64 comprise the fastest growing sector of the U.S. populations. While this population does not currently abuse alcohol at the rate of other age cohorts, specialized health care services

for elderly persons with at-risk drinking behavior should be available (Kirchner et al., 2007). Alcohol misuse is a growing public concern for older adults, particularly among primary care patients (Kirchner et al., 2007).

In the primary care setting, the prevalence of alcohol use disorders varies from 20% to 36% (Anton et al., 2003). However, most of these patients are never treated for their addiction (Anton et al., 2003). Primary care physicians could play a significant role in addressing alcohol abuse (Anton et al., 2003).

Treating Alcohol Dependence

Alcohol Dependence Medication: Campral, Vivitrol, ReVia, & Antabuse

Similar to opiate addiction medications, advances in the development of pharmacotherapies for the treatment of alcohol dependence and the prevention of relapse are relatively new (Abraham, Ducharme, & Roman, 2009). Counseling and 12-Step programs have provided the main treatment options for the alcohol dependent populations. (Williams, 2005). There are four US Food and Drug Administration (FDA)-approved pharmacotherapies for the treatment of alcohol dependence; disulfiram (Antabuse), oral naltrexone (ReVia), acamprosate (Campral), and, most recently, an extended-release (30-day) injectable suspension formulation of naltrexone (Vivitrol) (Pettinati & Rabinowitz, 2006).

Antabuse – Disulfiram

Disulfiram is an FDA approved prescription medication clinically in the management of patients with alcohol dependence for over 50 years (Petrakis, Poling Levinson, Nich, Carrol, Rounsaville, 2005). Patients taking Antabuse must refrain from consuming all types of alcohol,

including over the counter cold medicines and mouthwashes containing alcohol (Polydorou & Levin, 2008). Ingesting even small amounts of alcohol precipitates vomiting, headache, tachycardia and hypotension (Polydorou & Levin, 2008). The severity of these effects results in high rates of patient nonadherence when taking Antabuse, which has discouraged its use in treatment (Pettinati & Rabinwitz, 2006).

ReVia – Oral Naltrexone

ReVia, approved in 1994, was the second medication permitted by the FDA for treatment of alcohol dependence (Petrakis et al., 2005). Naltrexone, an opioid agonist, is believed to reduce heavy drinking by blocking the euphoric effect that many alcohol dependent individuals experience when they consume alcohol (Pettinati & Rabonowitz, 2006). Nonetheless, ReVia has failed to achieve widespread acceptance as a treatment for alcohol dependency (Mitchell, Bergen, Chen, Rowbotham, Fields, 2009).

ReVia's failure for mainstream acceptance has been attributed to several variables including; expense, perceived ineffectiveness, unpleasant side effects, and low patient compliance (Mitchell et al., 2009). Among these factors, perhaps the most influential is patient nonadherence (Pettinati & Rabinowiz, 2006). The daily dosing requirements of ReVia require clinical vigilance to ensure that patients do not skip doses or fail to take the medication all together (Pettinati & Rabionwitz, 2006).

Vivitrol – Injectable Naltrexone

Vivitrol, approved in April of 2006, is an innovative treatment option that delivers non-interrupted treatment of naltrexone for one month (Pettinati & Rabinowitz, 2006). Monthly injections alleviate the patient's daily decision to take their medication, as well as, relieve the

physician of the responsibility of monitoring adherence (Pettinati & Rabinowitz, 2006). Research has demonstrated the efficacy and safety of this treatment option (Garbutt, Kranzler, O'Mally, et al, 2005). Vivitrol, as of 2006, is the most expensive prescription among these treatment options for alcoholism (Mark et al., 2008).

Acamprosate – Campral

Acamprosate has shown to be safe and effective in the populations of patients motivated to have a treatment goal of abstinence (Mason, Goodman, Chabac, & Lehert, 2006). Campral acts as an N-methyl-D-aspartate agonist and is believed to promote abstinence by alleviating the physical and psychological discomfort experienced many alcoholics when attempting to quit drinking (Pettinati & Rabonwitz, 2006). As of 2007, Acamprosate had the highest sales volume among alcoholism medications (Mark et al., 2008).

Barriers to Opioid Dependence & Alcohol Dependence Treatment Medications

Barriers for Opioid Dependence Medications

Research has identified several barriers impeding wide-spread implementation of buprenorphine treatment for opioid addiction and dependency. These barriers include: state and federal regulatory requirements (Ling, 2009); physician attitudes towards addiction treatment as a legitimate form of treatment and/or stereotypes about opioid dependent populations (McMurphy, Shea, Switzer, and Turner, 2006, Knudsen, Ducharme, Roman, Link, 2005); characteristics of organizational leadership (Friedmann, Jiang, Alexander, 2009); and financial barriers, including reimbursement (McMurphy et al., 2006, Netherland et al., 2009).

Barriers for Alcohol Dependence Medications

Similar barriers impede ubiquitous office based treatment for alcohol dependence. Barriers preventing the adoption and implementation of these prescription treatment medications in routine clinical practice include structural factors such as program licensing requirements, personnel factors including access to physicians, concerns regarding patient compliance, the cost of the medications; and financing factors, particularly insurance coverage for medications (Abraham et al., 2009).

In rural areas, barriers to dependency treatment for elderly Americans may be magnified. Obstacles to health care among rural older adults include transportation difficulties, limited medical facilities, social isolation, and significant financial constraints (Carrie et al., 2006).

Moreover, insurance coverage is a predictor in utilization of medication and services (Card, Dobkin, Maestas, 2008). The current body of literature does not examine the impact of Medicare coverage as a potential barrier to access medications necessary for the treatment opiate and alcohol addiction medications. This study examines Medicare's coverage policy in respect to MAPs and PDPs and attempts to determine whether these policies inhibit or promote access to opioid and alcohol dependency medications.

Medicare Plans

Medicare is a social insurance program, enacted in 1965 under the Title XVIII of the Social Security Act (Kaiser Family, 2009). The evolution of Medicare has led to an expansion of beneficiaries covered under the program (i.e. permanently disabled, and adults with ESRD or ALS) and the options for covering the numerous beneficiaries (Allhealth, 2006). Approximately

45 million individuals rely on Medicare for health insurance coverage, with 38 million people over the age of 65 and 7 million beneficiaries under the age of 65 (Kaiser Family, 2009).

Medicare consists of four different parts. Part A covers inpatient hospital services, skilled nursing facility, home health, and hospice care (Allhealth, 2006). Part B provides supplemental medical insurance which helps pay for physician, outpatient, home health, and preventative services (Kaiser Family, 2009). Part C, now known as Medicare Advantage, offers beneficiaries the option to enroll in a private managed plan and most include a prescription drug benefit (Kaiser, 2007). Part D, Medicare's prescription drug benefit, allows Medicare beneficiaries to enroll in a standalone prescription drug plan (Kaiser, 2007).

Characteristics of Medicare Advantage Plans

The Medicare Modernization Act of 2003 (MMA) established the Medicare Advantage program to increase the role of private health insurers (Moffit, 2008). Since the 1970s, private plan HMOs have been offered through Medicare, albeit with limited options (Kaiser, 2007). The Balanced Budget Act of 1997 expanded upon previous Medicare managed care by creating the Medicare+ Choice program, which gave beneficiaries the option of preferred provider organizations (PPOs), provider sponsored organizations (PSOs), private fee-for-service (PFFS), or medical savings account (MSAs), beyond the traditional health maintenance organization (HMO) plans (Biles, Nicholas, Guterman, 2006). Enrollment in these plans peaked in 1999, then decreased 12 percent by 2003 (Biles et al., 2006). The MMA replaced Medicare+ Choice program, created new regional PPOs, and added Special Needs Plans (Kaiser, 2007).

Medicare Advantage allows enrollment in plans offered by private health insurance companies (Health Assistance Partnership, 2010). Nearly 10.1 million of the approximately 45

million Medicare beneficiaries are currently enrolled in a private MA plan (Medicare Advantage Program Facts, 2009). All beneficiaries, whether in urban or rural areas have multiple MA choices, including several PFFS contracts, one or more MSA plans, and for 87% of the nation, at least one Regional Preferred Provider Organization (RPPO) contract (Gold, 2008). In Washington State, 2008 enrollment in MA plans totaled 200,434 beneficiaries (Medicare Advantage Facts, 2009).

The majority of beneficiaries are enrolled in Coordinated Care Plans (CCPs). Coordinated Care Plans available through Medicare Advantage consist of (HMOs), (PPOs), (PSOs), and Special Needs Plans (SNPs). Private Fee-For-Service (PFFS) plans are also available from MA. These plans differ from CCPs in that PPFs are not required to manage or establish a network of providers (Frakt, Pizer, Feldman, 2009). As a result, PFFS plans have been willing to enroll beneficiaries in rural areas that other MA plan types avoid due to the high cost of network contracting in those areas (Frakt et al., 2009).

PFFS plans are available nationwide, and are not limited to a MA region or to a county as with Coordinated Care Plans (Health Assistance Partnership, 2010). MA enrollment in rural counties has increased 376 percent since MMA (Medicare Advantage Program Facts, 2009). Currently, over half of all rural beneficiaries in MA plans are enrolled in PFFS plans (Medicare Advantage Program Facts, 2009). However, in 2009, only slightly more than 13% of rural Medicare beneficiaries were enrolled in an MA plan, a much smaller share of Medicare beneficiaries than were enrolled in MA plans in urban areas (27%) (Kemper et al., 2009).

Capitation: The Financial Incentives of Medicare Advantage Plans

Medicare Advantage plans control health care cost through two different mechanisms: competition and capitation (Chernew, Jacobson, Hofer, Aaronson, Fendrick, 2004). CMS fosters competition among managed care organizations (MCOs) through a bidding system that awards MCOs the right to enroll Medicare beneficiaries (Cawley & Whitford, 2007). Capitation provides a method for paying a provider a fixed price per person, for a defined range of services, for a specified period of time. Capitation thus has three main elements: (1) care is prepaid with a predetermined, agreed-upon price, (2) the provider is at financial risk if expenditures exceed payments and thus has an incentive to manage care, and (3) payment is tied to specific capitated patients (Mechanic & Aiken, 1989). As a result, capitation creates incentives for health plans to take broader accountability for the care and outcomes of their beneficiaries and enable insurance companies to benefit from doing so and also to improve care coordination and reduce fragmentation in the delivery system (Guterman, 2009). This mechanism may promote MCOs to encourage treatment of addiction through antiaddiction medications, in order to prevent the long term costs associated with untreated addiction (Gerson, et al, 2001).

Rurality of Medicare Advantage Plan Beneficiaries

Rural Medicare beneficiaries generally did not have access to HMOs prior to the MMA. In 2001, less than a third of rural beneficiaries had access to a private plan for Medicare services, contrasted with 94 percent of beneficiaries in urban areas (Medicare Advantage Program Facts, 2009). Nine years later, 99 percent of rural constituents have access to either an HMO or PPO (Medicare Advantage Program Facts, 2009).

Although choice has increased in rural areas, residents in these areas still have limited CCPs available (Gold, 2008). In 2008, only 17% of rural constituents live in counties with three or more local CCP contracts; market penetration in rural counties is only 2.6 percent (Gold, 2008). Low population density, small number of providers, and provider resistance to MA contracting, limit CCP availability in rural areas (Gold, 2008).

Characteristics of Medicare Part D Plans

Medicare Part D, established in 2003 as part of the MMA, increased access for prescription medication to Medicare beneficiaries (Flaer, Donderiz, Younis, 2007). The program is administered through more than 1,800 (PDPs) (Summer, Nemore, Finberg, 2008).

CMS allows the private organizations to develop their own benefit structures and formularies within the guidelines provided by law (Heaton, Carino, Dix, 2006). The rationale for this structure is that private sector plans will compete with one another on price and benefits, and beneficiaries will enroll in a plan that best satisfies their needs (Jacobson & Anderson, 2010).

The Doughnut Hole, Formularies, and Cost Control Techniques

CMS requires PDPs to offer a defined standard benefit; however, insurers are free to deviate from the standard plan by eliminating deductibles and other mechanisms (Jacobson & Anderson, 2010). Most PDPs utilize cost management tools in the form of formularies, tiered pricing, and coverage restrictions, such as, step therapy, quantity limits, and prior authorization. (Kaiser, 2006). Prior authorization requires the prescribing physician to obtain approval from the insurer before prescribing the medication (Heaton et al., 2006). Step therapy requires specific (lower cost) medications to first be prescribed, and determined unsuccessful, before the insurer approves use of another medication (Heaton et al., 2006). Part D formularies and

utilization management tools have the potential to keep program costs down, but also restrict access (Summer, et al., 2008).

The doughnut hole is a gap in prescription drug coverage. Initially, the beneficiary must pay a deductible of $250 per year. Medicare then pays 75% of the cost of drugs until the total amount paid by Medicare and the patient reaches $2,250 (Dahel, 2009). At that point, the individual enters the coverage gap, and must pay all drug costs out of pocket until they reach the catastrophic limit of $5,100 (Heaton et al., 2009). After incurring $5,100 in total drug costs, Medicare pays 95% of further prescription drug costs (Evans-Molina, Regan, Henault, Hylek, Schwartz, 2007). Zhang, et. al. (2009) found that only 5% of seniors falling into the doughnut hole received catastrophic coverage.

MAPs utilize a 4-tiered formulary structure, while PDPs employ a 5-tiered formulary design. "Preferred" medications are placed on lower tiers; while "non-preferred" medications are reside in the third, fourth or fifth tiers within prescription drug plans. Health insurance plans construct tiering structures to provide financial incentives for patients to choose drugs that are less costly to the plan (Huskamp, Deverka, Landrum, Epstein, McGuigen, 2007). Formulary designs also increase a plans bargaining power for obtaining discounts from pharmaceutical manufactures as they can offer increased sales volume for "preferred drugs" (Huskamp, et al., 2007).

Drug benefit plans that utilize cost sharing, placement of drugs on formularies, and prior authorization rules can significantly impact the use of medications (Heaton et al., 2006). Tiered formulary structures incentivize physicians to prescribe or patients to request "preferred medications," (generics or low cost older medications), over "non-preferred" (patent protected,

newer medication) by shifting the cost of the drug to the patient when utilizing a "non-preferred" medications (Shrank, Hoang, Ettner, Glassman, Nair, Delapp, Dirstine, 2006).

Individuals with chronic conditions, such as drug and alcohol addiction, may forego needed medications because of drug costs (Heaton et al., 2006). The beneficiaries most likely to stop taking their medications when out-of-pocket expenses increase are those with the lowest income, those with the largest out-of-pocket expenses, and those with multiple chronic conditions (Dahel, 2009). A lapse in maintenance medication for opioid or alcohol dependence is highly problematic, given the already high rates of recidivism in drug and alcohol dependent populations.

CMS Drug Coverage Requirements - The Protect List

The MMA restricts plan formularies and other cost management techniques by requiring that a plan's bid be rejected if the plan design and benefits are "likely to substantially discourage enrollment by certain part D eligible individuals" (Kaiser, 2006). Further, plans must include coverage of certain medications including; antidepressants, antipsychotics, and anticonvulsants, anticancer, immunosuppressant, and HIV/AIDS categories to be covered under PDPs (Huskamp, Stevenson, Donohue, Newhouse, 2007). For these six "protected" classes, plans must cover "all or substantially all" distinct drugs, but they are not required to cover both the generic and brand versions (Huskamp et al., 2007). Antiaddiction medications, however, are not a currently protected class. When a medication is not on a plan's formulary, beneficiaries must pay for the drug out of pocket, switch to an alternative, or request an exception (Kaiser, 2006).

Potential Contribution of the Proposed Research & Gaps in the Literature

The availability and restrictiveness of opioid and alcohol dependency pharmacotherapies in Medicare Advantage and Medicare Part D is not known. It is important to determine if coverage and cost restrictions create a barrier to office-based treatment of opioid dependency and alcohol dependency. It is also crucial to determine if access differs in urban and rural localities. This research will contribute to the current body of literature by determining whether and how MAPs and PDPs cover Suboxone, Campral and Vivitrol. Prior to this research the literature is void of research examining the availability and cost structure of substance dependency pharmacotherapies in Medicare PDPs and MADPs.

CHAPTER THREE

METHODOLOGY

This chapter describes the research design of this study. The framework was adopted from a previous study by Wang, et al (2007). The study population, research constructs, dependant and independent variables, and the statistical approach are also presented in this chapter.

Study Design

This is a descriptive study that examines MAPs and PDPs coverage of seven different opioid and alcohol dependence medications; Buprenorphine (Suboxone®), Methadone (Methadose®), Naltrexone (ReVia®, Vivitrol®, and the generic formulation) Disulfiram (Antabuse®), and Acamprosate (Campral®). Cost structure, formulary restrictions, and availability of plans in rural and urban areas are contrasted by drug and plan type.

Data Source

The data for this study was obtained for the Center of Medicare and Medicaid Services (CMS) website (www.medicare.gov) via the Medicare Prescription Drug Plan Finder section. This link provides coverage levels, coverage restrictions, and cost data pertaining to each plan. This data was gathered in February 2010.

Study Population and Plan Identification

Plan Identification

PDPs are statewide, therefore the availability of these plans do not vary by locality. In 2010, there were 44 PDPs available in Washington State. MAPs are not statewide. Consequently, in order to collect statewide data for MAPs, zip codes were classified by ruralilty, and zip codes were randomly selected in each strata.

Rural Definition

There is no universal definition of "rural," rather there are several methods which highlight specific geographic "form" (i.e. populations size and/or density) or functional criteria (commuting flows, proximity to large urban centers) (Grymonpre & Harwick, 2008).

For this study, rurality is defined using Rural Urban Commuting-Areas (RUCAs) zip code approximation taxonomy. RUCA categories are based on the size of the community as delineated by the Census Bureau and the functional relationships between places as commuting data (Hart, Larson, Lishner, 2005). Commuting flows are important factor when determining to access to medical treatment. For this research question this methodology serves as an appropriate indicator of the "degrees of rurality" for each zip code. This taxonomy is widely used for policy and research purposes, including used by CMS (Hart, et al., 2005).

RUCA values of 1-10 determine the degree of rurality for a specific zip code. A value of ten represents the most rural areas according to this taxonomy, while a value of one distinguishes the most metropolitan areas. In Washington there are a total of 733 RUCA2 zip codes. From this population five sample groups were constructed to represent the varying degree rurality across the State. Zip codes with values of (10-10.9), (7-7.9), (5-5.9), (3.-3.9), and (1-1.19) were

compiled. Five zip codes, one from each sample, were randomly selected to represent different ranges of population density across Washington State.

The selected zip codes are as follows in order of most rural to most urban; 99151, (Marcus, in Stevens County), 99350, (Prosser, in Benton County), 99363 (Wallula, in Franklin County), 98557 (McCleary, in Grays Harbor County), and 98498 (Lakewood, in Pierce County).

Dosing Definition

The most common daily dose for each drug was established by consulting local addiction specialist in Spokane, Washington (Table 1). Substitution therapy creates a difficulty in precisely assigning a general dose. Since addiction treatment attempts to replace the addiction drug with the prescription medication, and then slowly reduce the pharmaceutical until treatment is no longer necessary, variation of daily dose exists among patients. For this study, the most common daily dose during maintenance treatment was used.

Table 1. Opioid and Alcohol Dependence Medication & Dosage Information

Medications	Dosage
Branded Drugs	
Buprenorphine / Naltrexone (Suboxone®)	16 mg daily
Naltrexone -Injectable (Vivitrol®)	380 mg daily
Disulfiram (Campral®)	250 mg daily
Naltrexone (ReVia®)	50 mg daily
Generic & Mainstay Drugs	
Methadone (Methadose®)	120 mg daily
Naltrexone (Generic)	50 mg daily
Acamprosate (Antabuse®)	666 mg 3times/daily

Source: Field experts including: Treatment Specialist & Pharmacists

Sample Size

The initial sample size of PDPs was 44 plans. Three PDPs had not reported plan information to CMS at the time of data collection; consequently, they were excluded from the sample.

The initial sample size of MAPs totaled 82 plans. The 82 MAPs represents an aggregation of available plans across all five zip codes. For example; in zip code 99151, 15 MAPs are available, in 99350, 14 MAPs are available, in 99363, 14 MAPs are available, in 98557, 13 MAPs are available, and in zip code 98498, 26 MAPs are available. The sum of these available plans is 82. Five MAPs failed to report sufficient information to CMS. Consequently, the sample size was reduced to 77 MAPs. To prevent duplication, identical MAPs that were offered in each zip code were eliminated. After this reduction, the sample size totaled 45 unique MAPs.

When contrasting the availability of MAPs for Medicare beneficiaries residing in differing localities, the unit of analysis is the number of plans available in each zip code. Within each individual zip code there exist no redundancy of MAPs; therefore, it was not necessary to reduce the sample size. The sample size for each zip code is only reduced for MAPs not reporting sufficient information to CMS. The final sample size for each zip code is as follows: zip code 99151 (n=14), zip code 99350, (n=14), zip code 99363 (n=14), zip code 98557 (n=13), and zip code 98498, (n=24). The sum of these plans total 77 (Table 2).

Table 2. Number of PDPs and MAPs for different degrees for rurality in WA 2010

	Most Rural →				Most Urban	
	99151	99350	99363	98557	98498	Total
Number of PDPs	41	41	41	41	41	41
Number of MAPs	14	13	13	13	24	77

Source: CMS website for Washington State collected in February 2010

† PDPs are offered statewide and do not differ based on locality

†† 44 PDPs are available; however data for 3 PDPs were not reported to CMS at time of collection

††† The number of MAPs not reporting information is enumerated in the parentheses following the corresponding zip codes: 99151 (1); 99350 (1); 99363 (1); 98498(2)

Measures & Variables

The measures used to test the hypotheses include medication exclusions, formulary tiering, and utilization management tools. The operational definition of each measurement is provided below.

1. Medication Exclusion: A medication is considered excluded from an MAP or a PDP when the plan did not include; Suboxone, Vivitrol, Campral, generic naltrexone or brand naltrexone (ReVia), methadone (Methadose), and disulfiram (Antabuse) on its formulary.

2. Formulary Tiering: If a drug is included on the formulary, the placement of the medication is determined. MAPs employ a four tier structure and PDPs utilize a five tier structure. This structure consists of: Tier 1 (generics), Tier 2, (preferred brand name drugs), Tier 3 (non-preferred generics and brand name drugs), Tier 4 and Specialty Tier (specific expensive medications).

3. Utilization Management Tools: MAPs and PDPs employ three different utilization management tools: prior authorization, quantity limits, and step therapy.

Table 3. Research Variables

Dependant Variables	***Unit of Measurement***
Formulary Restrictions	
Level of Coverage	Tiers (1 and 2) or (3, 4, and 5)
Prior Authorization Required	Yes / No
Quantity Limits	Yes / No
Step Therapy	Yes / No
Cost Sharing Structure	
Medication Costs	Full Cost of Drug Costs of Initial Coverage Costs of Catastrophic Coverage
Annual Deductible Charges	Annual Deductible
Monthly Premium Charges	Monthly Premium
Independent Variables	
Drug Type: Buprenorphine, Methadone, Naltrexone, Disulfiram, Acamprosate	Mean, Median, Standard Deviation
Plan Type: 2010 MAP / PDP	Mean, Median, Standard Deviation
Locality: Urban / Rural by RUCA zip code approx	Mean, Median, Standard Deviation

Statistical Analysis

The information for both PDPs and MAPs were aggregated into multiple Microsoft Excel spreadsheets. This allowed for analysis of the data regarding the percentage of plan covering each medication. The mean, median, range, and standard deviation of each cost-sharing structure

characteristic was also employed to assess central tendency and variation of the date within in the plans. This data is presented in Tables 4 – 6.

CHAPTER FOUR

RESULTS

This chapter presents the results of this study. The chapter is organized around the three study hypotheses (coverage antiaddiction medications, plan type, and rurality of beneficiaries).

MAPs and PDPs in Washington State in 2010

PDPs are available statewide. Medicare beneficiaries in Washington State have the choice between 41 different plans. The availability of number of MAPs differs by county. Table 1 represents the number of MAPs identified by zip code. This table, moving left to right, represents MAPs available in the most rural locality to the number of MAPs available for the most urban population.

Patent Protected Status v. Mainstay & Generic Substance Dependence Medications

The results indicate that both PDP and MAP coverage of substance dependence medications vary by patent protection status. Suboxone, Vivitrol, Campral, and ReVia, are frequently restricted in both MAPs and PDPs. Two thirds of PDPs and almost half of MAPs exclude Vivitrol, while ReVia faces formulary exclusion from 80% of PDPs and 50% of MAPs. Yet, generic naltrexone, a substitute for ReVia, is included on every PDP and MAP formulary. Methadose is the only generic medication subjected to formulary exclusion (Table 3).

Although Suboxone and Campral are included on the formularies of most PDPs and MAPs, the tiering coverage of these drugs are typically higher than generic medications. Suboxone is included in either Tiers 3 or 4 in 60% of Medicare plans. Campral is usually placed in the highest two tiers, while Vivitrol is placed almost exclusively in Tiers 3 or 4. ReVia is

included on the top tier of every PDP and MAP formulary. Conversely, Methadose and generic naltrexone are included on Tiers 1 or 2 in all Medicare drug plans.

No distinct pattern regarding prior authorization exists among coverage of generic and patent protected medications. Suboxone, Campral, and Methadose require prior authorization in approximately a third of the insurance plans. Vivitrol, when included on a plan's formulary, rarely requires prior authorization, while Antabuse, ReVia, and generic naltrexone do not require prior authorization in either MAPs or PDPs.

Table 4. Cost and Coverage of Substance Dependence Medications

	Patent Protected Medications								Mainstay & Generic Medications					
	Suboxone		Vivitrol		Campral		ReVia		Methadose		Antabuse		Naltrexone	
	PDPs	MAPs	PDPs	MAPs	PDPs	MAPs	PDPs	MAPs	PDPs	MAPs	PDPs	MAPs	PDPs	MAPs
Coverage of Medication														
Formulary Inclusion	95%	100%	34%	53%	90%	82%	20%	51%	88%	96%	98%	100%	100%	100%
If Included on Formulary														
Tier 3, 4, or Specialty Tier	62%	60%	100%	88%	54%	62%	100%	100%	0%	0%	15%	20%	0%	0%
Prior Authorization	31%	31%	12%	0%	37%	32%	0%	0%	34%	14%	0%	0%	0%	0%
Gap Coverage	0%	0%	0%	0%	0%	0%	0%	0%	19%	40%	0%	0%	10%	24%

Source: CMS website data for Washington State in February 2010.

† PDPs (n=41), MADPs (n=45)

Table 5. Cost of Substance Dependence Medications

	Patent Protected Medications								Mainstay & Generic Medications					
	Suboxone		Vivitrol		Campral		ReVia		Methadose		Antabuse		Naltrexone	
	PDPs	MAPs	PDPs	MAPs	PDPs	MAPs	PDPs	MAPs	PDPs	MAPs	PDPs	MAPs	PDPs	MAPs
Initial Coverage Level														
mean (std)	$86 ($55)	$55 ($23)	$280 ($29)	$294 ($135)	$55 ($22)	$54 ($21)	$53 ($19)	$63 ($32)	$7 ($6)	$7 ($2)	$37 ($18)	$38 ($18)	$11 ($11)	$12 ($12)
median	$46	$56	$276	$285	$45	$56	$43	$43	$6	$6	$34	$35	$7	$7
range	$22 - $265	$14 - $90	$238 - $317	$29 - $490	$22 - $104	$25 - $80	$40 - $95	$10 - $115	$0 - $35	$4 - $14	$11 - $91	$14 - $80	$0 - $40	$4 - $40
Full Cost Coverage														
mean (std)	$355 ($4)	$356 ($6)	$941 ($45)	$932 ($63)	$141 ($4)	$143 ($5)	$73 ($63)	$105 ($86)	$39 ($5)	$32 ($11)	$104 ($3)	$104 ($3)	$55 ($19)	$51 ($11)
median	$354	$356	$954	$965	$140	$142	$43	$43	$40	$35	$105	$104	$48	$50
range	$346 - $362	$329 - $362	$837 - $979	$837 - $980	$136- $150	$138 - $153	$40 - $225	$40 - $235	$21 - $46	$0 - $43	$98 - $108	$101 - $108	$39 - $105	$40 - $75
Catastrophic Coverage														
mean (std)	$18 ($0)	$18 ($0)	$47 ($2)	$47 ($3)	$7 ($0)	$7 ($0)	$7 ($2)	$8 ($2)	$3 ($1)	$3 ($0)	$6 ($0)	$6 ($0)	$3 ($1)	$3 ($1)
median	$18	$18	$48	$48	$7	$7	$6	$6	$3	$3	$6	$6	$3	$3
range	$17 - $18	$17 - $18	$42 - $50	$42 - $49	$7 - $8	$7 - $8	$6 - $11	$6 - $12	$3 - $6	$3 - $4	$6 -$7	$6 - $7	$3 - $6	$3 - $6

Source: CMS website data for Washington State collected in February 2010.

† PDPs (n=41), MAPs (n=45)

Medicare Advantage Drug Plan v. Prescription Drug Plan Coverage of Substance Dependence Medications

The study finds only a slight variation between MAPs and PDPs in coverage of opioid and alcohol dependence medications: (Table 4) contrasts the coverage of each medication by plan type; and (Table 5) compares cost structures between the two types of plans.

PDPs and MAPs provide virtually identical coverage of patent protected and generic medications. Medicare Advantage Drug Plans and PDPs also have similar cost structure (Table 4). The findings indicated that there exists minimal variation in either, initial drug cost coverage, full drug cost coverage, and catastrophic coverage. The proportion of plans excluding medications differs only slightly. The tiering structure and prior authorization are also similar. .

Vivitrol is the exception. PDPs exclude Vivitrol from two thirds of the plans and, when these plans provide coverage, Vivitrol is placed on either Tiers 3, or 4, or on a Specialty Tier. MAPs provide coverage in slightly more than half the available plans. Most MAPs place Vivitrol in the highest tiers; but, a few categorize Vivitrol as a Tier 2 medication. MAPs do not require prior authorization for Vivitrol, while several PDPs require this management utilization tool.

PDP and MAP coverage between the two classes of protected and generic medications differs with regards to gap coverage assistance. Plans offering gap coverage assistance provide partial coverage of the beneficiary's medication cost when a enrollee's costs has exceeded $2250. PDPs and MAPs provide gap coverage for only two medications, Methadose and generic naltrexone.

Medicare Advantage Drug Plan Coverage of Substance Dependence Medications in Rural v. Urban Areas

The results indicate that there is little difference between MAP coverage of substance dependence medication in urban or rural localities. Table 6 illustrates that throughout the five zip codes representing varying "degrees of rurality," substance dependence medications are available to all MAP enrollees in the rural and urban counties in Washington State.

Table 6. Coverage of Substance Dependence Medications among MAPs in Washington State for 2010

	Most Rural	→			**Most Urban**
	99151 (n = 14)	**99350 (n = 13)**	**99363 (n = 13)**	**98557 (n = 13)**	**98498 (n = 24)**
Included on the Formulary					
Patent Protected Medications					
Suboxone	**100%**	**100%**	**100%**	**100%**	**100%**
Vivitrol	**43%**	**54%**	**54%**	**54%**	**58%**
Campral	**79%**	**77%**	**77%**	**77%**	**79%**
ReVia	**50%**	**46%**	**62%**	**62%**	**50%**
Mainstay & Generic Medications					
Methadose	**100%**	**85%**	**100%**	**100%**	**100%**
Antabuse	**100%**	**100%**	**100%**	**100%**	**100%**
Naltrexone	**100%**	**100%**	**100%**	**100%**	**100%**

Source: CMS website data for Washington State collected in February 2010.

† Combined MAPs for 5 zip codes = 82. Information was not available for 5 MAPs at time of collection. n=77

CHAPTER FIVE

CONCLUSION – LIMITATIONS - RECOMMENDATIONS

This chapter provides a synopsis of key findings, presents policy implications, highlights limitations of this study, and provides recommendations for future research.

Conclusion

In the past 10 years, advances in addiction neurobiology have led to the availability of three new FDA approved medications for treatment of opioid and alcohol dependence, Suboxone, Campral, and Vivitrol (Mark et. al., 2008). Previous studies have focused on adoption, efficacy, and diffusion of these treatments options; however, no other study has examined the availability and cost structure of substance abuse medications in Medicare PDPs and MAPs.

This research proposes three distinct hypotheses: (1) PDP and MAP coverage of opioid and alcohol dependence medications will vary by patent protection status, (2) coverage of opioid and alcohol dependence medications will vary by plan type, and (3) access to MAPs will be restricted in smaller markets.

The findings suggest that rural beneficiaries in Washington have access to MAPs that provide opioid and alcohol dependence pharmacotherapies. Our results suggest that the locality of a Medicare beneficiary's residence is not one of these barriers. Beneficiaries in rural counties may face other challenges to access including; limited availability of psychosocial treatment, lack of prescribing physicians, or social stigma (Horgan, 2008; Mark, 2009).

Moreover, MAPs and PDPs did not significantly differ in their coverage or cost structure. Consequently, Medicare beneficiaries are not forced to choose between either type of plan to obtain coverage of these antiaddiction medications. Despite rural and urban beneficiaries having sufficient access to coverage, this research suggests that the cost of the medication is probably a barrier to access for Medicare enrollees.

Both MAPs and PDPs place patent protected medications on higher cost sharing tiers, which discourages utilization. This is of particular importance for Suboxone, Campral, and Vivitrol, as substitutes for these medications are not currently available. Horgan and colleagues (2008), found that when buprenorphine was included on the formulary, it was assigned most often to Tier 3. This study is consistent with Horgan's research (2008), finding that, when covered Suboxone is usually categorized as a Tier 3 or 4 drug. Horgan also found that one third of private insurance plans excluded buprenorphine from their formularies, while very few plans did so for brand or generic naltrexone. However, this study found that Suboxone was excluded from only 5% of PDPs, and was included on the formulary of every MAP. This suggests that Suboxone has gained increasing acceptance as an appropriate and effective treatment for opioid dependence.

Implications for Policy

The parity of coverage among PDPs and MAPs, and among rural and urban MAPs suggests that Medicare plans are currently providing adequate coverage for these antiaddiction medications. Policymakers assessing access for Medicare beneficiaries should focus their attention to whether beneficiaries of these plans can afford these medications. As patent

protected medications are exceedingly expensive, financial access becomes a significant issue (Horgan, 2008).

Policies are important to promote patient and physician awareness of potential treatment modalities. Knowledge of available treatments can drive participation by physicians and other addiction specialists. CMS should also explore whether Medicare Advantage Plans are working as intended. If the objective of managed care is to reduce medical costs, then MAPs should readily provide affordable antiaddiction treatment via effective pharmacotherapies. CMS should consider incorporating reimbursement mechanisms to influence coordinated care of beneficiaries.

MAPs and PDPs currently fail to provide gap coverage for expensive patent protected medications. This highlights the need for the current health care reform legislation. The Patient Protection and Affordable Care Act includes provisions to close the doughnut hole. Beginning in 2011, Part D enrollees who reach the coverage gap will receive a 50 percent discount on the total cost of their patent protected medications (Kaiser, 2010). Medicare will gradually phase in additional subsidies for patent protected medications. By 2020, MAP and PDP enrollees will be responsible for only 25 percent of the total cost of their drugs out of pocket (Kaiser, 2010).

Limitations of This Research

This research examines the coverage and cost structure of substance dependence medications provided by MAPs and PDPs. While this research suggests that Medicare beneficiaries throughout Washington State have access to opioid and alcohol dependence pharmacotherapies, this study does not assess whether beneficiaries can afford the expensive, patent protected medications.

We should note that our findings are premised upon a random sample of Washington State MAPs within varying "degrees of rurality". By not assessing the entire population, perhaps a few MAPs were not analyzed in this study. Further, due to insufficient data reported to CMS several plans were excluded from this study. The number of enrollees in the respective PDPs and MAPs were not analyzed.

Recommendations for Future Research

Future research should study affordability directly. Moreover, in light of the current health care reform legislation, research should also examine the number of PDP and MAP beneficiaries who enter and exit the doughnut hole, to determine whether recent changes to gap coverage, provided for in the Patient Protection and Affordable Care Act is working as intended.

During the completion of this study Reckitt Benckiser's patent for Suboxone expired. This research suggests that both MAPs and PDPs place generic medication in the least expensive cost sharing tiers, rarely employ utilization management tool restrictions, and provide gap coverage for these medications. When generic buprenorphine/naloxone is introduced, research should study the coverage and cost structure of this generic formulation within PDPs and MAPs, and private plans.

In order to fully assess the availability and access to opioid and alcohol dependence medications, future research should examine the availability of physicians prescribing and pharmacies filling these antiaddiction medications. Assessment of available psychosocial services, especially in rural areas, is also crucial to understanding the availability of effective treatment for addiction or whether fragmentation of services exists in these areas.

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