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Medicare Part D Plan Generosity and Medication Use among Dual Eligible Nursing Home Residents

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Abstract

Background—In 2006, dual-eligible nursing home residents were randomly assigned to a Medicare Part D prescription drug plan (PDP). Subsequently, residents not enrolled in qualified

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plans at the start of the next year were re-randomized. PDPs vary in generosity through differences in medication coverage and utilization management. Therefore, residents' assigned plans may be relatively more or less generous for their particular drugs. The impact of generosity on residents' medication use and health outcomes is unknown.

Methods—Using 2005–2008 data, we estimate logistic regression models of the impact of coverage and utilization management on the risk for medication changes and gaps in use, hospitalizations, and death among elderly nursing home residents using one of six drug classes, adjusting for patient characteristics.

Results—Few current medication users faced non-coverage of their drug (0.4%–8.7%) or prior authorization or step therapy requirements if the drug was covered (1.1%–37.4%). After adjusting for individual-level covariates, residents with non-covered drugs were more likely than residents with covered drugs to change medications in most classes studied (e.g., for 2006 angiotensin receptor blocker users, the adjusted average probability of medication change was 0.35 when uncovered vs. 0.11 when covered). Those subject to prior authorization or step therapy were more likely to change in a subset of classes. There were no statistically-significant differences in rates of hospitalization or death after correcting for multiple comparisons.

Conclusions—The Part D benefit's special protections for nursing home residents may have ameliorated the health impact of coverage limits on this frail elderly population.

Keywords

Part D; plan generosity; nursing home; dual eligible

Introduction

Beginning in 2006, Medicare Part D extended prescription drug coverage to all Medicare beneficiaries, including the 1.3 million who reside in nursing homes¹. Medicare beneficiaries residing in nursing homes are typically frail, suffer from multiple chronic conditions, have more severe cognitive impairment, and take more medications than community-dwelling beneficiaries^{2–6}. Historically, nursing homes have struggled to manage the medication needs of this medically-complex population^{7–9}.

Part D dramatically changed how medications are financed for the approximately two thirds of nursing home residents who are dually eligible for Medicare and Medicaid¹⁰. Before Part D's implementation, dual eligible residents received drug coverage from Medicaid. At the time of Part D's inception, all dual eligible residents were randomized to one of the multiple Part D prescription drug plans (PDPs) serving dual eligibles in their region, i.e., plans with premiums at or below the regional benchmarks. Subsequently, individuals enrolled in plans that lost benchmark status or left the market were re-randomized to another plan. Because PDPs vary with respect to coverage and utilization management requirements for specific medications, a dual eligible resident may be randomly assigned to a plan that is relatively more or less generous for the drugs that individual is taking.

The impact of PDP generosity on a nursing home resident's medication use is not currently known. Evidence from both Medicaid enrollees and privately-insured individuals suggests that coverage restrictions and utilization management tools like prior authorization and step therapy result in medication changes and discontinuation, and can lead to higher hospitalization rates and higher health care spending^{11–18}. There is also evidence that medication changes and discontinuations in an elderly nursing home population can lead to adverse drug events, hospitalization, or death^{19–21}. Part D, however, includes special protections for dual eligible nursing home residents: longer transition fill policies that

allowed PDPs to fill prescriptions for non-covered drugs while alternate therapies were considered; no beneficiary cost sharing; and the ability to change PDPs monthly.

We assess the impact of PDP coverage and utilization management on medication use, hospitalization, and death among dual eligible nursing home residents. We relied on the randomization of residents to PDPs to address the potential selection bias that is common in observational studies of how plan generosity affects use. We focus on six medication classes that are commonly used in this population and often subject to PDP coverage limitations¹⁰.

Methods

Our study population is dual eligible nursing home residents age 65 or older who reside in facilities that contract with Omnicare, a long-term-care pharmacy serving over 60% of nursing home residents in the U.S., to dispense prescription medications. We link 2005–2008 data from: drug claims from Omnicare; demographic characteristics from Medicare Beneficiary Summary Files; dates of hospitalizations from MedPAR; death date from the Minimum Data Set (MDS); and PDP formulary coverage and utilization management requirements from the CMS Prescription Drug Plan Formulary and Pharmacy Network Files. We exclude individuals who died on January 1st of the year in question or who did not have at least one MDS assessment (used to confirm date of death).

We focus on two groups of residents: 1) those residing in nursing homes at the time Part D was implemented and thus randomized to a PDP with enrollment effective January 1, 2006; and 2) those randomized to a new plan effective January 1, 2007 or January 1, 2008 because their prior plans' premium bids exceeded regional benchmarks. For 2007 and 2008, we exclude individuals who elected to change plans in the previous year, since these individuals are not automatically re-randomized when their current plan loses benchmark status. We pool individuals re-randomized for 2007 and 2008 because of smaller sample sizes and the consistency of transition policies that applied to nursing home residents during those two years compared with 2006.

We focus on residents currently using a medication in one of the following six classes as of January 1st in each year: angiotensin receptor blockers (ARBs), cholinesterase inhibitors, long-acting opioids, osteoporosis medications, antidepressants, and antipsychotics. Antidepressants and antipsychotics are “protected classes,” meaning that plans must cover at least one formulation of every molecule. For the other four classes, plans are required to cover at least one molecule. We define “current users” as those who filled at least two prescriptions in the class with 10 or more days of supply each or three prescriptions with any number of days supplied during the 100 days before enrollment on January 1st of the year in question. The median number of days supplied for prescriptions in each medication class and year was 28–30, with the exception of opioids, with a median of 15 days. To ensure interpretable drug class-level outcomes we exclude the small proportion of individuals who were currently using more than one drug in the class during the 100-day period (e.g., in 2006, <8% for all classes except antidepressants, which was 19.6%).

We examine four outcomes. First, we assess medication changes within the class, identified by a prescription claim for a drug in the class other than the drug that the resident was currently taking during the 100 days before January 1st. Changes between brand and generic formulations of the same drug (e.g., brand paroxetine tablet to generic paroxetine tablet) are not considered a “change.” Among individuals who changed, we also assess the proportion of residents who subsequently had a prescription claim for their original pre-period drug.

Second, we identify gaps in use within the class of 31 or more days (e.g., no antidepressants for 31 or more days). Outcomes were measured from January 1st to 240 days later for 2006

current users and from January 1st to 150 days later for 2007/2008 current users. We selected the window's duration to account for the transition policies in place each year allowing residents to continue current medications regardless of PDP coverage rules (up to 210 days in 2006 and 120 days in 2007 and 2008), with an additional 30 days for drug supply to be exhausted after the transition policy ends²². For individuals who were hospitalized or died, we truncated the windows at the date of hospitalization or death. If a resident experienced both a medication change and a gap in use during the period, we count only the event that occurred first.

Third, we assess whether a resident was hospitalized in the year after enrollment in the randomized plan. Finally, we identify deaths within the year after an individual's enrollment in the randomized plan.

The two main independent variables are whether the resident's current medication was not covered (vs. covered) by the new PDP to which the resident was randomized and whether the PDP required prior authorization or step therapy if the drug was covered (vs. covered without these limits). We combine prior authorization and step therapy into a single variable since plans typically use one tool or the other for a given drug but not both.

Models were adjusted for the following covariates: resident age as of January 1st; male (vs. female); nonwhite (i.e., "black" or "other", vs. white); region (midwest, northeast, or south, vs. west); and dummy variables for the drug the resident was taking before randomization. For pooled 2007/2008 models, we include a binary variable indicating 2007 enrollment (2008 is the reference category).

We estimate logistic regression models for each outcome by drug class and year, and then calculate the average probability of each outcome under each coverage restriction (non-coverage and prior authorization/step therapy), adjusted for the covariates noted above. To transform estimates from the log-odds ratios under the logistic regression model to an easily understood metric, we estimate the average probability (or "risk") of each outcome for a given coverage restriction by evaluating the fitted regression model supposing that every patient was assigned or not assigned that restriction and then averaging the results across patients. The difference in the resulting average estimated probability is an average risk difference. These analyses include residents who could have been current users across more than one of the six medication classes. We were unable to estimate models for 2007/2008 antipsychotic users because of the small number of individuals whose antipsychotic medication was uncovered.

A concern with analyzing four outcomes (medication change, gap in use, hospitalization, and death) and testing the effect of two benefit design measures (non-coverage and prior authorization/step therapy) for each of six drug classes, yielding 48 tests in total (not accounting for any stratification of the data across years), is that the chance of finding a significant result when in fact none exists is much higher than the 0.05 level of a single test. We used the Bonferroni correction to correct for the fact that we are conducting multiple tests²³. Using this correction, a p-value in any test must exceed 0.00104 to report a significant finding in order to be assured that the test has a level no greater than 0.05.

As a robustness check, we estimated survival models of the number of days to a medication change, adjusting for the same covariates used in the logistic regression models. An advantage of fitting the survival models is that we account for differential amounts of follow-up of individuals, which could lead to bias.

Results

Our sample includes 92,813 dual eligible residents who were current users of one or more of the six classes for 2006, and 32,315 current users as of 2007 or 2008 (Table 1).

Only a minority of current users faced non-coverage of their medication or prior authorization or step therapy, although these rates varied across classes (Table 2). For example, for the 2006 group, non-coverage rates varied from 0.4% (antipsychotics and osteoporosis medications) to 8.7% (opioids), while prior authorization/step therapy rates for covered drugs varied from 1.9% (antidepressants) to 13.5% (cholinesterase inhibitors).

Medication changes were much more likely among residents with non-covered drugs than those whose drug was covered after adjusting for individual-level covariates for 4 of 6 classes in 2006 and 4 of 5 classes in 2007/2008 (all but antipsychotics and opioids in 2006 and opioids in 2007/2008, for which there were no statistically significant differences after correcting for multiple comparisons). For example, among 2006 ARB current users, the adjusted risk of medication change was 0.35 among those with non-covered drugs versus 0.11 among those with covered drugs ($p = 0.0001$) (Table 3). Similarly, gaps in use were more likely among residents whose current drug was uncovered than among those whose drug was covered for 4 of 6 classes in 2006 (all but osteoporosis medications and antipsychotics, for which there was no statistically significant difference) and 2 of 5 classes in 2007/2008 (all but cholinesterase inhibitors, osteoporosis medications, and opioids, with no statistically significant differences) (Table 3).

Among residents whose current medication was covered by their new PDP, those whose drug required prior authorization or step therapy were more likely to change medications than those without such requirements within 2 of 6 classes in 2006 (all but opioids, for which residents without prior authorization/step requirements were significantly more likely to change than those with such requirements, and antipsychotics, cholinesterase inhibitors, and antidepressants, with no statistically significant difference) and 3 of 6 classes in 2007/2008 (all but ARBs, antidepressants, and opioids, with no statistically significant differences) (Table 3). Gaps in use were more likely among those with prior authorization or step therapy requirements than those without for 2 of 6 classes in 2006 (all but opioids, antidepressants, osteoporosis medications, and antipsychotics, with no statistically significant differences) and 0 of 6 classes in 2007/2008.

A sizeable proportion of residents who changed medications after enrollment in their new PDP subsequently had a claim for the original medication they had been taking previously (Table 4). In 2006, for instance, 54%, 53%, and 46% of opioid, antidepressant, and antipsychotic current users, respectively, who changed medications after randomization later filled a prescription for their pre-period drugs.

After correcting for multiple comparisons, there were no statistically significant differences in hospitalization or death rates based on either coverage or prior authorization or step therapy (conditional on coverage).

Results from the survival models of time to medication change were similar to results on the probability of a medication change using logistic regression models (see online Technical Appendix for detail). For parsimony and ease of interpretation, we present only the adjusted rates derived from the logistic regression models.

Discussion

Random assignment to plans with differing levels of coverage and utilization management requirements influenced prescribing patterns for elderly dual eligible nursing home residents. Our findings suggest higher rates of medication use disruptions among residents facing Part D coverage restrictions for their drugs relative to similar residents not facing such restrictions. We found at least some evidence of medication disruptions resulting from coverage policies in every medication class studied, including Part D “protected” classes (antidepressants and antipsychotics) and non-protected classes (ARBs, cholinesterase inhibitors, opioids, and osteoporosis medications), and classes with a relatively higher (e.g., ARBs) vs. lower (e.g., antidepressants) degree of therapeutic similarity. Interestingly, the higher rates of medication use disruptions did not appear to lead to higher rates of hospitalizations or deaths in this frail elderly population.

Our study extends prior research describing the effects of Part D implementation. These previous studies generally have documented increased medication use, lower out-of-pocket spending, and lower non-drug medical utilization and expenditures after implementation^{24–32}. However, almost all of these studies have focused on community-dwelling beneficiaries. Of studies specific to nursing home residents, one found that Part D implementation resulted in a small decrease in the average number of prescriptions filled among long-stay residents in 2006 relative to 2005³³. A study of 569 case histories collected via email from nursing home clinicians about post-Part D medication changes for non-medical reasons found that approximately 75% reflected decreased efficacy after the change³⁴.

Our analyses are shaped by features of how Part D works in the nursing home setting. Perhaps most important for our study design, all dual eligible residents nationwide were randomly assigned to PDPs in 2006, and 1.1 million and 2.1 million were re-randomized in 2007 and 2008, respectively, due to their plans losing benchmark status or leaving the Part D market³⁵. Random assignment enables us to assess the effects of coverage on use independent of unobserved patient characteristics that could influence treatment and plan choice in observational studies.

Beyond the randomized plan assignment, several policy features likely influence our findings. First, federal regulations require nursing homes to provide all care included in residents’ care plans regardless of coverage. Consequently, residents may be somewhat buffered against adverse coverage provisions. Moreover, this regulatory requirement may be further reinforced by communication challenges between pharmacy staff, PDPs, and prescribing clinicians, who often operate off-site³⁶. Together, these factors may partially explain why many residents facing coverage restrictions did not change drugs or experience a gap. Nonetheless, because facilities must absorb the cost of non-covered medications in the care plans, these regulations give facilities a strong incentive to encourage physicians to change to a drug not subject to restrictions. A second policy unique to the nursing home setting is CMS’s guidance on transition policies (described previously), serving to further protect residents from medication changes that can result from coverage determinations. Third, residents do not face medication copayments and thus have no direct incentives to choose drugs preferred by their PDP. As a result, plans rely solely on formulary coverage and utilization management to influence use among residents. Finally, two of the six protected classes, antipsychotics and antidepressants, are commonly used among residents nationwide^{37, 38}.

Although these policies are likely influential, they are not necessarily determinate. Despite coverage restrictions, especially non-coverage, being relatively modest overall, they

nonetheless affected use. The fact that patterns of changes and gaps among those facing restrictions were found both for drugs in protected and non-protected classes suggests that the protections may not ensure that all formulations needed by nursing home residents (e.g., dissolvable tablets, solutions) are available, or possibly that utilization management could negatively affect access in some cases. If policymakers determine that access in certain protected classes was problematic for residents, Part D policies could be modified (e.g., CMS could require coverage of specific medications or formulations).

Although our findings focus on dual eligible nursing home residents, they have broader implications for other Part D populations. First, dual eligibles living in the community or congregate settings like assisted living facilities face similar assignment dynamics to randomly-assigned duals in nursing homes (i.e., some are randomized to plans where their drugs are covered less well) *without* the nursing home specific protections. Moreover, unlike nursing home residents, duals living in other settings are additionally affected by cost sharing (between \$1.15 and \$6.60 per prescription for generic and brand medications, respectively).

Some have argued for an alternative plan assignment process that would consider the medications residents are currently taking, attempting to match beneficiaries to PDPs with relatively generous coverage of those drugs. For example, in late 2005, Maine officials used a “beneficiary-centered assignment” process that considered formulary coverage to reassign nearly half of the state’s dual eligibles³⁹. Random assignment was adopted initially with the hope of ensuring adequate PDP participation; participating plans would be guaranteed an equal share of dual eligible beneficiaries and a random draw of health risks (i.e., individuals with high vs. low drug expenditures). If formulary coverage of residents’ medications were considered in plan assignment, plans might have an incentive to avoid covering medications used by residents with relatively high drug spending if the risk adjustment system didn’t adequately account for these differences, which in practice it did not⁴⁰. Although only a few states have adopted beneficiary-centered assignment, they have reported no market disruptions resulting from it⁴¹.

More broadly, some have criticized the reliance of Part D on a consumer-choice oriented model for beneficiaries living in nursing homes¹⁰. The underlying premise is that informed consumers will choose the plan that best meets their needs and that competition among plans will be spurred as a result. Although randomized initially, dual eligibles are permitted to change plans monthly, for example if particular PDPs are not well-matched to their needs. Yet, the high prevalence of cognitive impairment in this population undermines the potential for informed decision-making, and many residents do not have engaged family members or responsible parties to assist them with these choices. In addition, Federal regulations restrict the ability of nursing homes to direct residents to particular PDPs in order to minimize a facility’s ability to steer residents in financially beneficial ways.

Prescription drug claims lack detailed clinical information on beneficiaries’ health status and functioning. As a result, we are not able to identify the indications for which drugs were used, comorbidities that could have influenced use, or outcomes. While we found no statistically significant differences in rates of hospitalizations or death after correcting for multiple comparisons, it may be that cognitive and functional outcomes are the more relevant clinical outcomes affected by Part D coverage restrictions. Our data cover the first three years of Part D implementation. Reports have documented increased use of utilization management tools like prior authorization among PDPs since our study period, and plan practices may have evolved over time⁴². We lack data on how strictly utilization management is applied by PDPs (e.g., the proportion of residents who sought prior authorization who obtain it). Strengths of our study include the large national sample of dual

eligible nursing home residents; the ability to link data on prescription drug use and PDP coverage; and the randomization of residents to PDPs.

The Part D benefit represented a substantial departure from how prescription drugs had been financed and administered to dual eligible nursing home residents. Our findings show that coverage and utilization management rules can result in higher rates of medication changes and gaps in use, even in so-called “protected classes” like antidepressants and antipsychotics. At the same time, the Part D benefit offers many special protections for nursing home residents that potentially ameliorate the health impact of PDP coverage limits on this frail population, something for which our analyses offer initial, confirmatory evidence. Nonetheless, the impact of Part D coverage policies on the health and functioning of frail elderly nursing home residents should be monitored going forward, both to assess the impact of coverage policies on a range of more targeted outcomes and to ensure that the changing PDP marketplace continues to meet the needs of this frail population.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Sample characteristics of dual-eligible nursing home residents currently using one or more of six medication classes at the time of Medicare Part D plan randomization, by year

	2006 (n=92,813)	2007 and 2008 (n=32,315)
Sex:		
Female	77.1% (71,531)	76.3% (24,645)
Male	22.9% (21,282)	23.7% (7,670)
Age:		
65–69	7.5% (6,918)	7.5% (2,414)
70–74	10.9% (10,111)	10.7% (3,455)
75–79	17.2% (15,962)	16.2% (5,228)
80–84	23.8% (22,078)	22.4% (7,243)
85–89	22.2% (20,606)	22.8% (7,382)
90–94	13.7% (12,711)	14.7% (4,760)
95–99	4.2% (3,933)	5.0% (1,616)
100+	0.5% (494)	0.7% (217)
Region:		
Midwest	48.0% (44,531)	17.8% (5,742)
Northeast	22.0% (20,437)	40.3% (13,020)
South	21.4% (19,830)	23.5% (7,581)
West	8.6% (8,015)	18.5% (5,972)
Race:		
White	85.8% (79,673)	81.5% (26,350)
Black	11.2% (10,419)	12.0% (3,861)
Other	2.9% (2,721)	6.5% (2,104)
Number of current users:		
ARBs	8,792	3,543
Cholinesterase inhibitors	30,020	9,651
Opioids	11,329	3,345
Osteoporosis medications	18,270	5,254
Antidepressants	53,993	19,593
Antipsychotics	33,634	11,646
Hospitalized during calendar year after randomized enrollment:		
Yes	34.9% (32,421)	34.8% (11,258)
No	65.1% (60,392)	65.2% (21,057)
Died during calendar year after randomized enrollment:		
Yes	19.1% (17,705)	18.1% (5,841)
No	80.9% (75,108)	81.9% (26,474)

Note: We exclude individuals who used more than one medication in the class in the 100 days before randomization to a new plan. Individuals may be current medication users of more than one drug class, so the sum of current users across the six classes exceeds the total number of individuals in the study population (i.e., 92,813 in 2006 and 32,315 in 2007/2008).

Table 2

Proportion of dual eligible nursing home residents facing coverage limitations for drugs used in the months prior to their random assignment to a new plan, 2006–2008

	2006	2007 and 2008
Non-Coverage:		
ARBs	3.9% (341)	7.4% (242)
Cholinesterase inhibitors	2.3% (686)	0.4% (39)
Opioids	8.7% (987)	0.9% (26)
Osteoporosis medications	0.4% (74)	0.3% (16)
Antidepressants	4.9% (2,616)	1.4% (266)
Antipsychotics	0.4% (127)	0.01% (1)
If Covered, PA and/or Step Therapy Was Required:		
ARBs	3.4% (289)	37.4% (1,268)
Cholinesterase inhibitors	13.5% (3,990)	1.1% (105)
Opioids	5.7% (604)	10.4% (344)
Osteoporosis medications	4.4% (799)	9.9% (521)
Antidepressants	1.9% (984)	8.8% (1,715)
Antipsychotics	12.8% (4,303)	3.5% (413)

Note: We exclude individuals who used more than one medication in the class in the 100 days before randomization to a new plan. Current medication users for 2007 and 2008 were pooled.

Table 3

Adjusted rates of the probability of changing medications and the probability of having a gap in medication use among dually-eligible nursing home residents by coverage status and presence of prior authorization or step therapy requirements, 2006–2008

	2006			2007 and 2008			2006			2007 and 2008		
	Covered	Not Covered	P-value	Covered	Not Covered	P-value	No PA or Step	PA or Step	P-value	No PA or Step	PA or Step	P-Value
	Adj. Rate	Adj. Rate		Adj. Rate	Adj. Rate		Adj. Rate	Adj. Rate		Adj. Rate	Adj. Rate	
ARBs												
Change	0.11	0.35	<0.0001*	0.06	0.30	<0.0001*	0.11	0.35	<0.0001*	0.08	0.09	0.54
Gap	0.21	0.30	<0.0001*	0.18	0.36	<0.0001*	0.20	0.38	<0.0001*	0.18	0.22	0.03
Cholinesterase Inhibitors												
Change	0.06	0.12	<0.0001*	0.05	0.17	<0.0001*	0.07	0.06	0.02	0.05	0.12	<0.0001*
Gap	0.24	0.35	<0.0001*	0.17	0.22	0.31	0.22	0.35	<0.0001*	0.17	0.18	0.70
Opioids												
Change	0.24	0.32	0.0002	0.17	0.39	0.02	0.25	0.20	0.004	0.17	0.15	0.39
Gap	0.27	0.41	<0.0001*	0.22	0.27	0.52	0.28	0.28	0.99	0.22	0.23	0.46
Osteoporosis Medications												
Change	0.18	0.40	<0.0001*	0.05	0.79	0.0001*	0.18	0.29	<0.0001*	0.05	0.15	<0.0001*
Gap	0.33	0.40	0.26	0.24	0.55	0.02	0.33	0.38	0.01	0.24	0.23	0.47
Anti-depressants												
Change	0.20	0.37	<0.0001*	0.13	0.48	<0.0001*	0.21	0.24	0.03	0.13	0.17	0.0002
Gap	0.18	0.22	<0.0001*	0.15	0.32	<0.0001*	0.18	0.20	0.20	0.15	0.16	0.61
Anti-psychotics												
Change	0.14	0.22	0.02	--	--	--	0.14	0.14	0.84	0.09	0.17	<0.0001*
Gap	0.25	0.35	0.03	--	--	--	0.26	0.24	0.07	0.20	0.22	0.16

* Results that remain statistically significant after correcting for multiple comparisons using the Bonferroni correction.

Notes: Prior authorization and step therapy are only required for covered drugs, so we assess whether prior authorization or step therapy was required conditional on plan coverage. We were unable to estimate models for atypical antipsychotic users in 2007/2008 due to a very small number of individuals whose atypical antipsychotic medication was not covered by their new plan.

Table 4

Proportion of dual eligible nursing home residents who changed medications after randomized enrollment who later filled a prescription for their pre-period drug, 2006–2008

	2006	2007 and 2008
ARBs	13.4% (110)	11.6% (27)
Cholinesterase inhibitors	23.9% (364)	14.3% (52)
Opioids	54.1% (1,086)	55.5% (249)
Osteoporosis medications	15.5% (349)	15.4% (34)
Antidepressants	53.3% (4,909)	46.4% (1,019)
Antipsychotics	45.8% (1,625)	42.2% (363)