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Access to Oral Osteoporosis Drugs among Female Medicare Part D Beneficiaries

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Abstract

Background—For women living with osteoporosis, high out-of-pocket drug costs may prevent drug therapy initiation. We investigate the association between oral osteoporosis out-of-pocket medication costs and female Medicare beneficiaries' initiation of osteoporosis drug therapy.

Methods—We used 2007 and 2008 administrative claims and enrollment data for a 5% random sample of Medicare beneficiaries. Our study sample included age-qualified, female beneficiaries who had no prior history of osteoporosis but were diagnosed with osteoporosis in 2007 or 2008. Additionally, we only included beneficiaries continuously enrolled in standalone prescription drug plans. We excluded beneficiaries who had a chronic condition that was contraindicated with osteoporosis drug utilization. Our final sample included 25,069 beneficiaries. Logistic regression analysis was used to examine the association between the out-of-pocket costs and initiation of oral osteoporosis drug therapy during the year of diagnosis.

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Disclosures: None

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Findings—Twenty-six percent of female Medicare beneficiaries newly diagnosed with osteoporosis initiated oral osteoporosis drug therapy. Beneficiaries' out-of-pocket costs were not associated with the initiation of drug therapy for osteoporosis. However, there were statistically significant racial disparities in beneficiaries' initiation of drug therapy. African Americans were 3 percentage points less likely to initiate drug therapy than whites. In contrast, Asian/Pacific Islander and Hispanic beneficiaries were 8 and 18 percentage points respectively more likely to initiate drug therapy than whites. Additionally, institutionalized beneficiaries were 11 percentage points less likely to initiate drug therapy than other beneficiaries.

Conclusions—Access barriers for drug therapy initiation may be driven by factors other than patients' out-of-pocket costs. These results suggest that improved osteoporosis treatment requires a more comprehensive approach that goes beyond payment policies.

Keywords

oral osteoporosis drugs; initiation; Medicare Part D

Introduction and Background

Osteoporosis is an asymptomatic disease characterized by low bone density that increases the risk of experiencing bone fractures. Half of all women over the age of fifty will experience an osteoporosis-related bone fracture in their lifetime (National Osteoporosis Foundation, 2002). In a study of the older Medicare beneficiaries enrolled in fee-for-service Medicare continuously for six years (Cheng et al., 2009), osteoporosis prevalence was particularly high among women (42.5% vs. 10.1% among men).

The same study found that prevalence rates also varied by race and ethnicity, with the lowest rate among African Americans (16.5% vs. 38.9% among Asian Americans, 32.4% among Hispanic Americans, 30.7% among Whites). Moreover, 18.4% of presumed osteoporosis cases had fracture-related claims. The prevalence of "fracture-only" cases was highest among African Americans (18.6% vs. 6.2% among Asian Americans, 12% among Hispanic Americans, 14.3% among Whites). The low proportion of non-fracture osteoporosis diagnosis codes among African Americans suggests important racial disparities in osteoporosis detection and prevention (Cheng et al., 2009). Similarly, Hamrick et al. (2012) examined racial disparities in primary care physicians screening for and treatment of osteoporosis. Amongst women diagnosed with osteoporosis, African Americans were less likely to receive bone density screening referrals and prescription medications than whites.

Women with osteoporosis can reduce the risk of bone fractures by taking prescription osteoporosis drugs, which can be a cost-effective means of reducing fractures (Qaseem et al., 2008; Tosteson, Burge, Marshall, & Lindsay, 2008; Pfister et al., 2006; Zethraeus, Borgström, Ström, Kanis, & Jönsson, 2007; Hagen et al., 2011; King, Saag, Burge, Pisu, & Goel, 2005; Borgström & Kanis, 2008). According to treatment guidelines and the recommendation from National Osteoporosis Foundation, newly diagnosed osteoporosis patients should receive pharmaceutical osteoporosis treatments. Oral osteoporosis drugs are considered the first-line therapy for those without contraindications and serious allergic reaction (National Osteoporosis Foundation, 2013). Other studies focus on the roles of

compliance and adherence in osteoporosis treatment (McCombs, Thiebaud, McLaughlin-Miley, & Shi, 2004; Brookhart et al., 2007; Weycker, Macarios, Edelsberg, & Oster, 2006; Solomon et al., 2005).

Despite the benefits of osteoporosis medications, some patients with osteoporosis do not receive osteoporosis medication therapy. Among patients who start medication therapy, low adherence rates and high discontinuation rates are common (Brookhart et al., 2007; Weycker et al., 2006; Solomon et al., 2005). In general, higher pharmacy cost sharing is associated with the use of fewer medications especially among older adults (Harris, Stergachis, & Reid, 1990; Smith, 1993; Lillard, Rogowski, & Kington, 1999; Joyce, Escarce, Solomon, & Goldman, 2002; Goldman et al., 2004; Goldman, Joyce, & Zheng, 2007; Karaca-Mandic, Swenson, Abraham, & Kane, 2012a). While Medicare Part D has increased beneficiaries' access to prescription drugs (Licthenberg & Sun, 2007), there are significant differences in drug plans' cost-sharing (Karaca-Mandic et al., 2012a), tiered formulary structures (Hoadley, Hargrave, Merrell, Cubanski, & Neuman, 2007), number of covered drugs (Hoadley, Hargrave, Merrell, Cubanski, & Neuman, 2008), and provision of gap coverage (Hoadley, Cubanski, Hargrave, Summer, & Neuman, 2009). Concerns have also been raised about the adverse effect of the donut hole on medication use (Zhang, Donohue, Newhouse, & Lave, 2009; Raebel, Delate, Ellis, & Bayliss, 2008; Fung et al., 2010; Hsu et al., 2008; Gu, Zeng, Patel, & Tripoli, 2010; Hales & George, 2010). Conwell et al. (2011) found that once beneficiaries with partial or no gap coverage reached the gap they were more likely to discontinue osteoporosis medication use than beneficiaries with full gap coverage because of increased out-of-pocket (OOP) costs.

However the role of OOP medication costs in deterring drug therapy initiation among Medicare Part D beneficiaries is not well understood. This is particularly important, as the U.S. Medicare program is the primary source of health care insurance for Americans above the age of 65 and for individuals with specific disabilities and conditions such as end stage renal disease requiring hemodialysis. Medicare covers the costs of inpatient care through Part A, the costs of outpatient care through Part B, and the costs of prescription drugs through Medicare Part D. While the majority of Medicare enrollees receive their insurance through traditional fee-for-service (FFS) Medicare – where providers bill the Centers for Medicare and Medicaid Services (CMS) directly for any care provided – approximately 25% of Medicare enrollees receive their insurance through Medicare Advantage insurance (otherwise referred to as Part C). Furthermore, Medicare and Medicaid (a means-tested health insurance program) provide a series of subsidies for low-income beneficiaries.

In this study, we examined how plan OOP costs were associated with osteoporosis drug therapy initiation among aged-qualified female Medicare Part D enrollees in stand-alone prescription drug plans (PDPs). We also investigated racial and socioeconomic disparities in therapy initiation.

Methods

Data

We employed the *Prescription Drug Event (PDE)* and enrollment data for the 5% Medicare random sample from 2006 to 2008. These data were combined with the *Medispan Drug Database*. These data were used to identify prescriptions corresponding to National Drug Codes for oral osteoporosis medications (alendronate, ibandronate, risedronate, and raloxifene) and to measure oral osteoporosis drug initiation. We also used the 2005–2008 *Medicare Provider Analysis and Review (MedPAR) files* and the Chronic Condition Data Warehouse (CCW) *Chronic Conditions Summary files* to identify osteoporosis diagnosis and related comorbidities. These data were merged with the *Beneficiary Summary Files*, which contains beneficiaries' demographic information. The *Plan Characteristics Files* that describe cost sharing information by tier type of each plan were used to construct a measure of plan generosity. Appendix Table 1 provides a summary of all data files and relevant variables used in the analysis.

Study Sample

We constructed two distinct cohorts of age-qualified, female Medicare beneficiaries newly diagnosed with osteoporosis during the calendar years of 2007 and 2008 respectively. Osteoporosis diagnoses were identified by relevant flags in the *CCW Chronic Conditions Summary files* and by primary International Classification of Diseases, Ninth Revision inpatient diagnosis codes of 733.00, 733.01, 733.02, and 733.09 in MedPAR files.

To identify new osteoporosis diagnoses with a sufficient period of prior history, we only included women enrolled in traditional fee-for-service Medicare since 2005, or since turning age 65, whichever is earlier. The sample was also restricted to women continuously enrolled in a stand-alone prescription drug plans (PDP) during the cohort calendar year and at least 6 months prior to the calendar year as *CCW Chronic Conditions Summary files* and *MedPAR files* are not available for beneficiaries enrolled in Medicare Advantage (MA) plans.

We constructed each cohort by including women who had no prior osteoporosis diagnosis history and no utilization of oral osteoporosis drugs utilization in the *PDE* files prior to the study cohort year, and had an osteoporosis chronic condition first time in the study cohort year.

We also excluded women who had chronic conditions that prohibited oral osteoporosis drug utilization, such as those with end-stage renal disease and hypercalcemia. Furthermore, we excluded women with chronic conditions that are often treated with osteoporosis drugs, such as Paget's disease of the bone (Halpern et al., 2011), malignant cancer, steroid-induced osteoporosis, bone-related cancers (Halpern et al., 2011; Brandi, 2010), and osteogenesis imperfecta (Rosen, 2013). Among the 5% Medicare random sample, 100% of the women who met the aforementioned inclusion criteria were included in our sample. Our final study sample included 25,069 women.

Measures

Oral osteoporosis drug initiation was defined as observing at least one prescription for a drug containing the active ingredients alendronate, ibandronate, risedronate, or raloxifene during the cohort year. These active ingredients constitute the first-line therapy for treatment of osteoporosis (Rosen, 2013).

Consistent with prior research (Karaca-Mandic et al., 2012a; Karaca-Mandic et al., 2012b, Karaca-Mandic et al., 2010; Goldman et al., 2004), *plan OOP drug costs* were computed for each beneficiary not receiving any low-income-subsidy (LIS) by calculating the average monthly OOP cost for a representative, fixed basket of oral osteoporosis drugs separately for 2007 and 2008 (Karaca-Mandic et al., 2012a; Karaca-Mandic et al., 2012b, Karaca-Mandic et al., 2010). The *Part D Denominator Files*, *Prescription Drug Event Files*, and *Plan Characteristics Files* allowed us to identify beneficiaries' enrollment in specific drug plans, their initiation of oral osteoporosis medications, and their plan's cost-sharing information during the pre-initial coverage limit (pre-ICL) and donut (gap) phases respectively. Our summary measure captures the plan's OOP costs both in the pre-ICL and gap phases independent of any individual beneficiary's oral osteoporosis drug choice or utilization.

We focused on the OOP costs for the standardized basket of oral osteoporosis drugs for each plan rather than average OOP costs by individual beneficiary because the latter would reflect a beneficiary's preferences regarding lower versus higher-cost medications given his/her particular plan design, leading to misleading plan generosity comparisons. For example, consider two plans: Plan A covers both drugs 1 and 2 with a copayment of \$30, while plan B covers drug 1 with copayment of \$30, and drug 2 with a copayment of \$60. If most patients choose the cheaper drug in plan B, there is little difference observed in the average OOP that beneficiaries pay in the two plans. However, a comparison of the benefit designs suggests otherwise; plan A has more generous coverage.

For each active ingredient, we first examined the share of thirty-day equivalent prescriptions dispensed under the following tier types for the overall study sample separately for 2007 and 2008: 1) brand/preferred brand, 2) non-preferred brand, 3) generic/preferred generic, and 4) non-preferred generic. Second, using information on each plan's copayment information for the above tier types, we estimated the expected average OOP cost of each active ingredient in the plan using the shares by tier type (based on use in the full sample as weights). Therefore, utilization weights used to construct the representative basket for each phase varied only by year, not by plan or by beneficiary. This is important because plan or beneficiary level utilization of the active ingredients would be endogenous. In particular, patient responses to OOP prices of active ingredients in the plan would alter the composition of medications in each plan. The fixed basket of medications across individuals allows for a comparison of the OOP costs across different plans. For example, consider an active ingredient that is dispensed under preferred brand tier 95% and non-preferred brand tier 5% across all users. A plan with copayments of \$30 and \$60 for preferred and non-preferred brand tiers respectively, would have average monthly OOP of \$32 ($0.95 \times 30 + 0.05 \times 60$) for this active ingredient. We conducted these estimations separately for the pre-ICL and gap coverage phases and estimated the annual OOP cost as weighted the average OOP cost by

weighting the monthly OOP in the pre-ICL and gap coverage phases by the average number of months beneficiaries' spent in each phase.

The OOP costs of Medicare-Medicaid dual eligible women and recipients of low-income-subsidy (LIS) were based on their copayments. These copayments were determined by the CMS depending on beneficiary income (United States General Accountability Office, 2007; Medpac, 2008). There are three income categories among the dual eligible beneficiaries in general. Income category 1 included "full benefit institutionalized dual eligible beneficiaries" who were "deemed eligible" irrespective of their income and assets. They had no copayments. The second income category included "full benefit non-institutionalized dual eligible beneficiaries" who were also "deemed eligible" based on incomes below 100% federal poverty level (FPL). They had small fixed monthly copayments (approximately \$1 for generic, and \$3 for branded drugs). The third income category included "full-benefit dual eligible beneficiaries" with incomes over 100% FPL and "partial benefit dual eligible beneficiaries" who were also "deemed eligible" because they receive premium and cost sharing assistance from Medicaid. These beneficiaries receive financial assistance through the Medicare Savings Programs and constitute beneficiary categories such as the Qualified Medicare Beneficiary (QMB), Specified Low-Income Medicare Beneficiary (SLMB), and Qualifying Individual (QI). They also faced small fixed monthly copayments (approximately \$2 for generic, and \$5 for branded drugs). The fourth income category included beneficiaries who were not dual eligible, but received LIS because their income fell below 135% FPL and their assets were lower than \$7,790 for an individual or \$12,440 for a couple. They also faced a fixed monthly copayment of \$2 for generics and \$5 for brands. We grouped all other LIS recipient beneficiaries into income category 5. They had income below 150% of poverty limit and assets below \$11,990 for an individual and \$23,970 for a couple. They faced a fixed coinsurance rate of 15% for all prescription drugs. Finally income category 6 included beneficiaries not receiving LIS (highest income group).

Beneficiary characteristics—We controlled for numerous demographic characteristics, including age, race/ethnicity, and income categories (income categories 1–3 for Medicare-Medicaid dual eligible beneficiaries; categories 4–5 for LIS recipients who are not dual eligible; and category 6 for beneficiaries not receiving any LIS). Because beneficiaries can switch income category from month-to-month during the year, we classified beneficiaries based on the category they were most often enrolled in during the year. We also controlled for the number of category transitions within a year to capture income stability. Controlling for income category transitions was important as this is a source of OOP price variation.

We classified women who exceeded the pre-ICL phase and reached the gap during the previous year as having 'high overall medication cost,' and controlled for this in our models. To control for their consumption of other (i.e., non-osteoporosis) drugs we constructed several binary indicators that identified whether or not a beneficiary used prescription drugs from other therapeutic classes during the cohort year. Similarly, we constructed binary indicators for whether or not the beneficiary had cataracts, congestive heart failure, diabetes, ischemic heart disease, and rheumatoid or osteoarthritis by using the *CCW Chronic Conditions Summary files* during the cohort year. Additionally, we controlled for other characteristics of the beneficiary's drug plan, including the presence of gap coverage,

deductible amount, and indicators for prescription drug plan regions. We also controlled for zip-code-level median household income based on beneficiary residence.

Statistical Analysis

We estimated several logistic regression models to identify factors associated with oral osteoporosis drug initiation. Model 1 predicted drug initiation as a function of the OOP cost for a fixed basket of osteoporosis drugs and beneficiaries' demographic characteristics, namely race, ethnicity, age, and income category. Model 2 incorporated risk adjusters for beneficiaries' health status. Risk adjusters included controls for beneficiaries' comorbidities and utilization of non-osteoporosis pharmaceuticals. Models 3–5 allowed price sensitivity to vary across subpopulations. These models included all Model 2 covariates but added interactions between OOP costs and patient characteristics. Model 3 allowed price sensitivity to vary across income categories¹ while Models 4 and 5 allowed price sensitivity to differ by race/ethnicity and health status respectively.

In a sensitivity analysis we constructed a plan OOP measure that varied by whether or not the beneficiary expected to reach the gap. On average, beneficiaries who never exceeded the pre-ICL period spent 12 months in that phase, while those who reached the gap phase spent 7 months in the pre-ICL and 5 months in the gap phases, respectively. For beneficiaries who reached the gap in the previous year—"high medication cost group" (our best estimate for beneficiaries who were likely to reach the gap in the current year as well), we constructed the OOP cost measures as the weighted average of the monthly OOP in pre-ICL and gap phases using 7 and 5 as the weights. For beneficiaries who did not reach the gap in the previous year—"low medication cost group", we used 12 and 0 as weights.

In two other sensitivity analyses, we restricted our study samples to include only women with at least a 3-month period and a 6-month period after diagnosis respectively. The outcome variables in these specifications were defined as initiation of oral osteoporosis therapy during either the 3-month and 6-month follow-up period.

We report the marginal effects, the change in probability of therapy initiation from a unit change for any given explanatory variable, for each of our models. Statistical analyses were performed using STATA 12 (StataCorp, 2011).

Results

Table 1 summarizes the demographic characteristics, co-morbidities, and drug utilization of beneficiaries who did and did not initiate oral osteoporosis drug therapy. Beneficiaries who initiated drug therapy tended to be slightly older than those who did not initiate drug therapy (77.25 vs. 75.80). Non-Hispanic white women had a larger initiation rate relative to African American women (24.35% vs. 23.31%). However, relative to non-Hispanic white women (24.35%), Asian/Pacific Islander (48.17%) and Hispanic (35.2%) women had a larger initiation rate. A smaller share of institutionalized women initiated drug therapy compared

¹ Note that the LIS program fixes prices for those with the lowest incomes. For this population, the price sensitivity parameter is identified by variation as eligibility shifts across categories conditional on the number of income category transitions. Results were consistent across a number of alternative specifications.

with all other beneficiaries. For example, 12.45% of beneficiaries in income category 1 initiated drug therapy compared to 29.92% and 24.57% of beneficiaries in income categories 5 and 6, respectively. Approximately 23% of beneficiaries with diabetes, ischemic heart disease, or rheumatoid/osteoarthritis initiated oral osteoporosis drug therapy.

Table 2 displays the marginal effects of patient characteristics on oral osteoporosis drug therapy initiation based on multivariate logistic regression model estimates. Model 1 results demonstrate that women in income category 1 were 12% less likely to initiate than women in income category 6. The number of income category switches did not have a statistically significant association with probability of initiation. Furthermore, African American women were 3% less likely to initiate drug therapy than non-Hispanic white women. In contrast, Asian/Pacific Islander and Hispanic women were 18% and 7% more likely than non-Hispanic white women to initiate drug therapy, respectively. Women with high overall medication cost status (who reached gap phase in previous year) were 2 to 3 % less likely to initiate oral osteoporosis medication. Finally, OOP costs have no discernible effect on drug therapy initiation when we control for observable patient and plan characteristics.

Model 2 controlled for beneficiaries' co-morbidities as well as their drug utilization for conditions other than osteoporosis. Results were similar to Model 1 estimates for income category 1, African Americans, Asian/Pacific Islander, and Hispanics. Co-morbidities also influence their likelihood of drug initiation. Women with congestive heart failure, diabetes, and rheumatoid/osteoarthritis were 3% less likely than women without these conditions to initiate oral osteoporosis drug therapy. Compared to women without cataracts and ischemic heart disease, women with these conditions were 1% and 2% less likely to initiate drug therapy. High overall medication cost status was also negatively associated with probability of initiation. Interestingly, women who consume a larger number of non-osteoporosis drugs in the cohort year were more likely to initiate oral osteoporosis therapy likely reflecting preferences for medication therapy in general.

Table 3 displays marginal effects from Models 3–5. These models interact beneficiaries' OOP drug costs with income category, race, and health status, respectively to allow for price sensitivity to vary across these characteristics. The marginal effects reported in Table 3 describe the association of OOP price on subpopulations by income category (Model 3), race/ethnicity (Model 4), and health status (Model 5). Model 3 results suggest that women in lower income categories were no more price sensitive than those with higher incomes categories. While the estimated effects are not significantly different from zero, they are sufficiently precise to rule-out a one percent decrease in probability of initiation from a one standard deviation OOP price increase for all income categories. This implies that we precisely estimated parameters that are quite close to zero. As an example, consider income category 2. The estimated marginal effect is -0.06 , and the lower bound of the confidence interval reported in Table 3 (Model 3) suggests we are 95% certain that the largest decrease in the probability of initiation is 23%. Multiplying -23% with 1 standard deviation of OOP in the sample (0.015), we estimate a reduction of 0.35%, a less than 1 percentage point decrease in the probability of initiation. In Model 4, we observe that African Americans were not notably more price sensitive than other beneficiaries. Asian/Pacific Islander and Hispanic women were, however, slightly more price sensitive than non-Hispanic White

women. A \$100 increase in average annual out-of-pocket costs would decrease Asian/Pacific Islander and Hispanic initiation by approximately 3%. Finally, price sensitivity did not depend on patients' comorbidities in Model 5. For each comorbidity, a one standard deviation increase in out-of-pocket prices would decrease initiation by less than one percent. These results provide strong evidence that the initiation differences described in Table 2 are not driven by differential price sensitivity across beneficiary subpopulations.

Table 4 presents a sensitivity analysis by differentiating the plan OOP of women based on their spending in the previous year: low medication cost (those who did not reach the gap in previous year) and high medication cost (those who reached the gap in previous year). Our results are largely comparable to those in Table 2, Model 2. While this approach allows for varying plan OOP by whether the beneficiary expects to reach the gap or not, it suffers from an important potential bias. Unobserved beneficiary characteristics that influence expectations to reach the gap would also be correlated with our OOP measure. Our original approach of using fixed weights across all beneficiaries for plan OOP for the pre-ICL phase and gap phases avoids this bias.

Table 5 presents two sub-sample analyses restricting our study samples to include only women with at least 3 month follow up period and 6 month period after diagnosis respectively. Again, our results are largely similar for initiation of oral osteoporosis therapy during the 3-month and 6-month follow-up periods.

Conclusion and Discussion

Our study confirms prior literature on racial and socioeconomic disparities in osteoporosis treatment. One of the unique features of our study is that these findings are confirmed in the particular context of oral osteoporosis therapy initiation. More importantly, our study contributes by providing estimates of racial and socioeconomic barriers for a generalizable, nationally representative cohort of older American women covered by Medicare.

Amongst female Medicare beneficiaries, we found racial and socioeconomic disparities in oral osteoporosis drug therapy initiation. Compared to non-Hispanic Whites, African Americans were less likely to initiate drug therapy after controlling for comorbidities and other demographic characteristics. Furthermore, lower initiation among African American women was not related to responsiveness to OOP costs. This finding is consistent with results from prior research providing evidence of racial and ethnic disparities in osteoporosis prevention and detection (Hamrick et al., 2012; Mudano et al., 2003). In their study of osteoporosis in postmenopausal women, Hamrick et al. (2012) found significant racial disparities in primary care physicians' propensity to refer women for bone density screenings. Compared to white women, African American women were less likely to be referred for a bone density screening. White women were more likely to receive medication than African American women. Their findings suggest that racial discrimination may be limiting African Americans' access to both bone density screenings and oral osteoporosis drugs. African American women's restricted access could adversely impact their health status and quality of life. Without access to prescription drugs, African American women with osteoporosis are at an increased risk of sustaining bone fractures. Compared to white

women, African American women who sustain a bone fracture experience longer hospital stays and have greater morbidity and mortality (Jacobsen et al., 1992; Furstenberg & Mezey, 1987). Combined findings of previous studies and our study suggests that improving the utilization of osteoporosis medication among African Americans is likely to have great impact on osteoporosis management and fracture prevention.

Dual eligible Medicare Part D beneficiaries in income category 1 (full dual eligible and institutionalized) are less likely to initiate oral osteoporosis drug therapy even though they face no OOP drug costs. This suggests that they face other significant access barriers. Future research could investigate in detail potential access barriers related to being institutionalized. Since women in poverty face above average osteoporosis and bone fractures prevalence (Navarro et al., 2009), medical providers and policy makers should increase osteoporosis medication access within institutionalized population.

High overall medication costs, as indicated by spending into the gap phase during the prior year, were associated with lower likelihood of initiating oral osteoporosis drug therapy. This result is consistent with prior research which demonstrates that beneficiaries falling into the Medicare coverage gap decreased medication utilization (Zhang et al., 2009; Raebel et al., 2008; Fung et al., 2010; Hsu et al., 2008; Gu et al; 2010; Hales et al 2010). Patients tend to reduce “non-essential” drug use rather the “essential” drug use when the financial burden increases as a result of hitting the coverage gap (Goldman, Joyce, & Zheng, 2007). Elderly women newly diagnosed with osteoporosis may consider osteoporosis therapy less essential if they already have high drug costs due to other comorbidities. This is because early osteoporosis is largely asymptomatic, not considered life-threatening. It is also possible that although OOP costs are not associated with drug therapy initiation, they are associated with therapy adherence and continuation among those who initiate which we did not investigate in this paper.

Our study has a number of notable limitations. First, we were unable to exclude beneficiaries who received alternative therapies because of inadequate swallowing function, being bed-ridden. This could be a potential underlying cause of low initiation rate among institutionalized beneficiaries. Secondly, the *PDE* data do not capture the use of alternative treatments such as injectable osteoporosis drugs. Clinical guidelines suggest that injectable ibandronate or zoledronate should be considered when the oral bisphosphates are contraindicated, such as compromised gastrointestinal absorption, or ineffective, such as significantly decreasing in bone mineral density (Rosen, 2013). Another treatment, teriparatide injection, is more expensive than other drugs and tends to be prescribed as sequential therapy with bisphosphates (Conwell et al., 2011; Rosen, 2013). Because our study sample includes only women newly diagnosed with osteoporosis, it is likely that physicians will initially prescribe the first-line oral osteoporosis medications we study rather than the injectable medications. Third, while claims data document the filling of prescribed medications, they do not capture prescriptions that are written but not filled. While this data limitation should not bias the results presented in the manuscript, we cannot test whether changes in treatment initiation are driven by changes in patient or physician behavior. Fourth, there are well known limitations for measuring race and ethnicity from claims data. We use the Research Triangle Institute (RTI) race codes in Medicare enrollment files to

construct race and ethnicity categories. Zaslavsky et al. (2012) found that the Hispanics, Asian, Pacific Islanders, and American Indians were under-identified (sensitivity: 41%, 60%, 39%, 57%) in Medicare enrollment files whereas Whites and African-Americans were highly identified (sensitivity: 99% and 98%). Those mis-classified beneficiaries were categorized as White since it was the largest category (Eicheldinger & Bonito, 2008).

Fifth, unobserved patient characteristics may influence beneficiaries' plan selection (e.g., choosing plans with more generous coverage) and their decision to initiate therapy, resulting in selection bias. Beneficiaries will, in general, choose drug plans based on current health care needs and preferences. Since we examined newly diagnosed beneficiaries, plan selection decisions are likely independent of the diagnosis as these selection decisions were made during November/December of the previous year. In addition, we included a large set of risk adjusters such as binary indicators that identified whether or not a beneficiary use prescription drugs from other therapeutic classes as well as binary indicators for whether or not the beneficiary had various co-morbidities. Our parameters of interest were not affected by including these controls. While this suggests that our results do not suffer from selection bias, we cannot rule out the possibility that other unobserved factors may be correlated with both initiation and plan selection.

Implications for Practice and/or Policy

Our study found evidence of substantial disparities for osteoporosis drug therapy initiation among vulnerable populations. In particular, we found that institutionalized women, African Americans, and patients with major comorbidities were significantly less likely to initiate osteoporosis treatment. Furthermore, initiation was lower among women with higher overall medication costs, as indicated by spending into the gap phase during the prior year. These findings are consistent with the broader literature on osteoporosis treatment disparities. Furthermore, we rejected the hypothesis that these differences were driven by heightened price sensitivity among populations facing access barriers – these access barriers are beyond purely financial considerations.

The Affordable Care Act (ACA) includes provisions that will reduce drug costs for Medicare beneficiaries and provide more support in the coverage gap (United States Department of Health and Human Services, 2012; AARP Public Policy Institute, 2010). While improved gap coverage will likely improve initiation among those with high overall medication costs, these benefits may do little to mitigate access barriers faced by many beneficiaries. In particular, LIS beneficiaries (including those who are dual Medicare and Medicaid eligible) are insulated from the coverage gap under existing policy (CMS, 2011). Furthermore, the institutionalized dual eligible beneficiaries face no copayments and experience the lowest initiation rates. Finally, African American patients and those with major comorbidities were no more price sensitive than other populations.

These results suggest that improved osteoporosis treatment requires a more comprehensive approach that goes beyond payment policies. Because osteoporosis is often initially asymptomatic, vulnerable patient populations may benefit from improved educational initiatives. Prior research suggests that simplified drug dosing regimens and electronic

prescriptions and refills may improve patients' access to osteoporosis drugs (Hilgsmann et al., 2013). These alternatives should be explored and emphasized for high risk populations with low treatment rates.

Finally, we note that while the ACA may not address some barriers to initiation, it may have other benefits that we do not explore. Improved coverage will reduce the financial risk and burden of disease among the elderly. Improved gap coverage will likely have a larger effect on continuation of drug therapy than initiation.

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References

- AARP Public Policy Institute. Health Care Reform Legislation Closes the Medicare Part D coverage gap. 2010. Retrieved on June 10, 2013 from <http://assets.aarp.org/rgcenter/ppi/health-care/fs182-doughnut-hole-reform.pdf>
- Brandi ML. Current treatment approaches for Paget's disease of the bone. *Discovery Medicine*. 2010; 10(52):209–212. [PubMed: 20875342]
- Borgström F, Kanis JA. Health economics of osteoporosis. *Best Practices & Research Clinical Endocrinology & Metabolism*. 2008; 22(5):885–900.
- Brookhart MA, Avorn J, Katz JN, Finkelstein JS, Arnold M, Polinski JM, Patrick AR, Mogun H, Solomon DH. Gaps in treatment among users of osteoporosis medications: the dynamics of noncompliance. *The American Journal of Medicine*. 2007; 120(3):251–256. [PubMed: 17349448]
- Centers for Medicare and Medicaid Services. Medicare Prescription Drug Benefit Manual Chapter 13 – Premium and Cost-Sharing Subsidies for Low-Income Individuals. 2011. Retrieved on June 6, 2013 from <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/Chapter13.pdf>
- Centers for Medicare and Medicaid Services. Chronic conditions among Medicare beneficiaries. 2012. Retrieved on April 30, 2013 from <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf>
- Cheng H, Gary LC, Curtis JR, Saag KG, Kilgore ML, Morrissey A, Matthews R, Smith W, Yun H, Delzell E. Estimated prevalence and patterns of presumed osteoporosis among older Americans based on Medicare data. *Osteoporosis International*. 2009; 20(9):1507–1515. [PubMed: 19189165]
- Conwell LJ, Esposito D, Garavaglia S, Meadows ES, Colby M, Herrera V, Goldfarb S, Ball D, Marciniak M. Out-of-pocket drug costs and drug utilization patterns of postmenopausal Medicare beneficiaries with osteoporosis. *American Journal of Geriatric Pharmacotherapy*. 2011; 9(4):241–249. [PubMed: 21616722]
- Eicheldinger C, Bonito A. More accurate racial and ethnic codes for Medicare administrative data. *Health care financing review*. 2008; 29(3):27. [PubMed: 18567241]
- Fung V, Mangione CM, Huang J, Turk N, Quiter ES, Schmittiel JA, Hsu J. Falling into the coverage gap: Part D drug costs and adherence for Medicare advantage prescription drug plan beneficiaries with diabetes. *Health Services Research*. 2010; 45(2):355–375. [PubMed: 20050931]
- Furstenberg AL, Mezey MD. Differences in outcome between black and white elderly hip fracture patients. *Journal of Chronic Diseases*. 1987; 40(10):931–938. [PubMed: 3038943]

- Goldman DP, Joyce GF, Escarce JJ, Pace JE, Solomon MD, Laouri M, Landsman PB, Teutsch SM. Pharmacy benefits and the use of drugs by the chronically ill. *JAMA: the journal of the American Medical Association*. 2004; 291(19):2344–2350. [PubMed: 15150206]
- Goldman DP, Joyce GF, Zheng Y. Prescription drug cost sharing: associations with medication and medical utilization and spending and health. *JAMA: the journal of the American Medical Association*. 2007; 298(1):61–69. [PubMed: 17609491]
- Gu Q, Zeng F, Patel BV, Tripoli LC. Part D coverage gap and adherence to diabetes medications. *American Journal of Managed Care*. 2010; 16(12):911–918. [PubMed: 21348561]
- Hagen, G.; Wisløff, T.; Falch, J.; Lofthus, C.; Frihagen, F.; Wensaas, K-A.; Granum, L.; Nevjar, J.; Kristiansen, IS.; Klemp, M. Efficacy and cost-effectiveness of alendronate for the prevention of fractures in postmenopausal women in Norway. 2011.
- Hales JW, George S. How the doughnut hole affects prescription fulfillment decisions involving cardiovascular medications for Medicare Part D enrollees. *Managed Care*. 2010; 19(12):36–44. [PubMed: 21291131]
- Halpern R, Becker L, Iqbal SU, Kazis LE, Macarios D, Badamgarav E. The association of adherence to osteoporosis therapies with fracture, all-cause medical costs, and all-cause hospitalizations: a retrospective claims analysis of female health plan enrollees with osteoporosis. *J Manag Care Pharm*. 2011; 17(1):25–39. [PubMed: 21204588]
- Hamrick I, Cao Q, Agbafé-Mosley D, Cummings DM. Osteoporosis healthcare disparities in postmenopausal women. *Journal of Women's Health*. 2012; 21(12):1232–1236.
- Harris BL, Stergachis A, Ried LD. The effect of drug co-payments on utilization and cost of pharmaceuticals in a health maintenance organization. *Medical Care*. 1990; 28(10):907–917. [PubMed: 2232921]
- Hilgsmann M, Salas M, Hughes DA, Manias E, Gwadry-Sridhar FH, Linck P, Cowell W. Interventions to improve osteoporosis medication adherence and persistence: a systematic review and literature appraisal by the ISPOR Medication Adherence & Persistence Special Interest Group. *Osteoporosis International*. 2013:1–12. [PubMed: 23076683]
- Hoadley, J.; Hargrave, E.; Merrell, K.; Cubanski, J.; Neuman, T. Medicare Part D 2008 data spotlight: benefit design. 2007. Retrieved on July 26, 2012 from <http://www.kff.org/medicare/upload/7713.pdf>
- Hoadley, J.; Hargrave, E.; Merrell, K.; Cubanski, J.; Neuman, T. Medicare Part D 2008 data spotlight: formularies. 2008. Retrieved on July 26, 2012 from <http://www.kff.org/medicare/upload/7734.pdf>
- Hoadley, J.; Cubanski, J.; Hargrave, E.; Summer, L.; Neuman, T. Part D plan availability in 2010 and key changes since 2006. 2009. Retrieved on July 26, 2012 from <http://www.kff.org/medicare/upload/7986.pdf>
- Hoadley, J.; Cubanski, J.; Hargrave, E.; Summer, L.; Huang, J. Medicare Part D: a first look at Part D Plan Offerings in 2013. 2012. Retrieved on June 10, 2013 from <http://kff.org/medicare/report/medicare-part-d-first-look-at-2013-plan-offerings/>
- Hsu J, Fung V, Price M, Huang J, Brand R, Hui R, Fireman B, Newhouse JP. Medicare beneficiaries' knowledge of Part D prescription drug program benefits and responses to drug costs. *JAMA: the journal of the American Medical Association*. 2008; 299(16):1929–1936. [PubMed: 18430912]
- Jacobsen SJ, Goldberg J, Miles TP, Brody JA, Stiers W, Rimm AA. Race and sex differences in mortality following fracture of the hip. *American Journal of Public Health*. 1992; 82(8):1147–1150. [PubMed: 1636840]
- Joyce GF, Escarce JJ, Solomon MD, Goldman DP. Employer drug benefit plans and spending on prescription drugs. *JAMA: the journal of the American Medical Association*. 2002; 288(14):1733–1739. [PubMed: 12365957]
- Karaca-Mandic P, Joyce G, Goldman D, Laouri M. Cost sharing, family health care burden, and the use of specialty drugs for rheumatoid arthritis. *Health Services Research*. 2010; 45(5):1227–1250. [PubMed: 20831715]
- Karaca-Mandic P, Swenson T, Abraham J, Kane B. Association of Medicare Part D medication out-of-pocket costs with utilization of statin medications. *Health Services Research*. 2012a 12/2012b. 10.1111/1475-6773.12022

- Karaca-Mandic P, Jena A, Joyce G, Goldman D. Out-of-pocket medication costs, and the use of medications and health care services among children with asthma. *JAMA: the Journal of the American Medical Association*. 2012b; 307(12):1284–1291. [PubMed: 22453569]
- King AB, Saag K, Burge R, Pisu M, Goel N. Fracture reduction affects Medicare economics (FRAME): Impact of increased osteoporosis diagnosis and treatment. *Osteoporosis International*. 2005; 16(12):1545–1557. [PubMed: 15942702]
- Lichtenberg F, Sun S. The impact of Medicare Part D on prescription drug use by the elderly. *Health Affairs*. 2007; 26(6):1735–1744. [PubMed: 17978393]
- Lillard LA, Rogowski J, Kington R. Insurance coverage for prescription drugs: Effects on use and expenditures in the Medicare population. *Medical Care*. 1999; 37(9):926–936. [PubMed: 10493470]
- McCombs JS, Thiebaud P, McLaughlin-Miley C, Shi J. Compliance with drug therapies for the treatment and prevention of osteoporosis. *Maturitas*. 2004; 48(3):271–287. [PubMed: 15207894]
- Medpac. Report to the Congress: Medicare payment policy. 2008. Retrieved on April 1, 2013 from http://www.medpac.gov/chapters/Mar08_Ch05.pdf
- Mudano AS, Casebeer L, Patino F, Allison JJ, Weissman NW, Kiefe CI, Person S, Gilbert D, Saag KG. Racial disparities in osteoporosis prevention in a managed care population. *Southern Medical Journal*. 2003; 96(5):445–451. [PubMed: 12911182]
- National Osteoporosis Foundation. America's bone health: The state of osteoporosis and low bone mass in our nation. 2002.
- National Osteoporosis Foundation. [accessed January 2014] Clinician's Guide to Prevention and Treatment of Osteoporosis. 2013. <http://nof.org/files/nof/public/content/resource/913/files/580.pdf>
- Navarro MC, Sosa M, Saavedra P, Lainez P, Marrero M, Torres M, Medina CD. Poverty is a risk factor for osteoporosis fractures. *Osteoporosis International*. 2009; 20(3):393–398. [PubMed: 18773136]
- Pfister AK, Welch CA, Lester MD, Emmett MK, Saville PD, Duerring SA. Cost-effectiveness strategies to treat osteoporosis in elderly women. *Southern Medical Journal*. 2006; 99(2):123–131. [PubMed: 16509549]
- Pressman A, Forsyth B, Ettinger B, Tosteson AN. Initiation of osteoporosis treatment after bone mineral density testing. *Osteoporosis Int*. 2001; 12(5):337–42.
- Qaseem A, Snow V, Shekelle P, Hopkins R, Forciea MA, Owens DK. Pharmacologic treatment of low bone density or osteoporosis to prevent fractures: A clinical practice guideline from the American college of physicians. *Annals of Internal Medicine*. 2008; 149(6):404–415. [PubMed: 18794560]
- Raebel MA, Delate T, Ellis JL, Bayliss EA. Effects of reaching the drug benefit threshold on Medicare members' healthcare utilization during the first year of Medicare Part D. *Medical Care*. 2008; 46(10):1116–1122. [PubMed: 18815534]
- Rosen, HN. UpToDate. Bisphosphonates in the management of osteoporosis in postmenopausal women. Basow, DS., editor. UpToDate; Waltham, MA: 2013.
- Smith DG. The effects of copayments and generic substitution on the use and costs of prescription drugs. *Inquiry*. 1993; 30(2):189–198. [PubMed: 8314607]
- Solomon DH, Avorn J, Katz JN, Finkelstein JS, Arnold M, Polinski JM, Brookhart MA. Compliance with osteoporosis medications. *Archives of Internal Medicine*. 2005; 165(20):2414–2419. [PubMed: 16287772]
- StataCorp. Stata Statistical Software: Release 12. College Station, TX: StataCorp LP; 2011.
- Tosteson A, Burge RT, Marshall DA, Lindsay R. Therapies for treatment of osteoporosis in US women: cost-effectiveness and budget impact considerations. *American Journal of Managed Care*. 2008; 14(9):605–615. [PubMed: 18778176]
- United States General Accountability Office. Medicare Part D low-income subsidy. 2007. Retrieved on April 1, 2013 from <http://www.gao.gov/new.items/d07555.pdf>
- United States Department of Health and Human Services. Medicare beneficiary savings and the affordable care act. 2012. Retrieved on June 10, 2013 from <http://www.healthcare.gov/news/reports/affordablecareact.html>
- Weycker D, Macarios D, Edelsberg J, Oster G. Compliance with drug therapy for postmenopausal osteoporosis. *Osteoporosis International*. 2006; 17:1645–1652. [PubMed: 16862397]

- Yood RA, Mazor KM, Andrade SE, Emani S, Chan W, Kahler KH. Patient decision to initiate therapy for osteoporosis: the influence of knowledge and beliefs. *Journal of General Internal Medicine*. 2008; 23(11)
- Zaslavsky AM, Ayanian JZ, Zaboriski LB. The validity of race and ethnicity in enrollment data for Medicare beneficiaries. *Health services research*. 2012; 47(3pt2):1300–1321. [PubMed: 22515953]
- Zhang Y, Donohue JM, Newhouse JP, Lave JR. The effects of the coverage gap on drug spending: A closer look at Medicare Part D. *Health Affairs (Millwood)*. 2009; 28(2):w317–25.
- Zethraeus N, Borgström F, Ström O, Kanis J, Jönsson B. Cost-effectiveness of the treatment and prevention of osteoporosis—a review of the literature and a reference model. *Osteoporosis International*. 2007; 18(1):9–23. [PubMed: 17093892]

Table 1

Characteristics of Female Medicare Beneficiaries with Osteoporosis

Variable	Oral Osteoporosis Drug Therapy		
	Initiators	Non-initiators	P-value
Demographic characteristics, n (%)			
Age, mean (sd)	77.25 (0.06)	75.80 (0.09)	<0.001
Non-Hispanic White	4,960 (24.35%)	15,413 (75.65%)	<0.001
African American	408 (23.31%)	1,342 (76.69%)	0.008
Asian/Pacific Islander	435 (48.17%)	468 (51.83%)	<0.001
Hispanic	626 (35.92%)	1,117 (64.08%)	<0.001
Other/unknown race	94 (30.72%)	212 (69.28%)	0.059
Income category 1	211 (12.45%)	1,484 (87.55%)	<0.001
Income category 2	1,565 (35.46%)	2,849 (64.54%)	<0.001
Income category 3	438 (26.87%)	1,192 (73.13%)	<0.002
Income category 4	247 (27.14%)	663 (72.86%)	<0.003
Income category 5	146 (29.92%)	342 (70.08%)	<0.004
Income category 6	3,916 (24.57%)	12,022 (75.43%)	<0.005
Average (sd) number of income category switches during the year	0.045 (0.003)	0.055 (0.002)	0.001
Comorbid conditions, n (%)			
Cataracts	1,844 (26.88%)	5,016 (73.12%)	0.055
Congestive heart failure	1,114 (21.00%)	4,190 (79.00%)	<0.001
Diabetes	1,674 (23.92%)	5,325 (76.08%)	<0.001
Ischemic heart disease	2,030 (23.08%)	6,765 (76.92%)	<0.001
Rheumatoid/osteoarthritis	2,063 (23.56%)	6,695 (76.44%)	<0.001
Medication Utilization, n (%)			
Anti-infective agents	3,844 (25.32%)	11,339 (74.68%)	0.002
Biological agents	123 (28.08%)	315 (71.92%)	0.320
Anti-neoplastic agents	365 (27.69%)	953 (72.31%)	0.153
Endocrine and metabolic drugs	3,265 (25.12%)	9,735 (74.88%)	0.001
Cardiovascular agents	5,579 (26.40%)	15,556 (73.60%)	0.001
Respiratory agents	2,043 (26.37%)	5,704 (73.63%)	0.388
Gastrointestinal agents	2,867 (25.75%)	8,268 (74.25%)	0.390
Genitourinary agents	1,157 (25.09%)	3,454 (74.91%)	0.114
Central nervous system drugs	2,289 (23.90%)	7,287 (76.10%)	<0.001
ADHD/anti-narcotic/anti-obesity/anorexic agents	29 (25.89%)	83 (74.11%)	0.977
Psychotherapeutic/neurological agents	517 (21.68%)	1,868 (78.32%)	<0.001
Analgesic/Anesthetic	3,574 (26.51%)	9,909 (73.49%)	0.055
Neuromuscular agents	1,387 (25.82%)	3,984 (74.18%)	0.720
Nutritional products	969 (22.96%)	3,251 (77.04%)	<0.001
Hematological agents	1,237 (23.55%)	4,016 (76.45%)	<0.001
Topical products	2,915 (25.21%)	8,648 (74.79%)	0.007
Average (sd) number of 30 day equivalent non-osteoporosis drugs during the cohort year	44.84 (0.40)	46.96 (0.25)	<0.001

Oral Osteoporosis Drug Therapy			
Variable	Initiators	Non-initiators	P-value
Plan Benefit Design, n (%)			
Average (sd) out-of-pocket cost, in \$100s of dollars	2.51 (0.01)	2.37 (0.02)	<0.001
Deductible amount, mean(sd)	45.66 (0.73)	43.01 (1.19)	0.058
Plan has gap coverage	536 (24.58%)	1,645 (75.42%)	0.109
Sample size	6,523	18,552	

Notes:

Definition of the Income categories:

Income category 1: Full benefit “deemed” dual eligible, institutionalized

Income category 2: Full benefit “deemed” dual eligible based on incomes below 100% federal poverty level (FPL), non-institutionalized

Income category 3: Full benefit dual eligible based on incomes above 100% FPL and Partial benefit “deemed” dual eligible,

Income category 4: Not dual eligible, but receives Low Income Subsidy because income <135% FPL, Assets < \$7,790 (individual)/\$12,440 (couple)

Income category 5: Not dual eligible, but receives Low Income Subsidy because income <150%FPL, Assets < \$11,990 (individual)/\$23,970 (couple)

Income category 6: Does not receive Low Income Subsidy

Table 2

Marginal effects for patients' sociodemographic characteristics on probability of initiation

Variable	Model 1		Model 2	
	dy/dx	95% CI	dy/dx	95% CI
Out-of-pocket cost (in \$100s of dollars)	-0.006	(-0.020, 0.008)	-0.007	(-0.021, 0.007)
Deductible (in \$100s of dollars)	-0.002	(-0.008, 0.005)	-0.001	(-0.008, 0.005)
Gap coverage	-0.003	(-0.025, 0.019)	-0.003	(-0.025, 0.019)
Income category 1	-0.119***	(-0.164, -0.075)	-0.110***	(-0.156, -0.065)
Income category 2	0.048	(-0.008, 0.104)	0.051	(-0.005, 0.107)
Income category 3	0.004	(-0.047, 0.055)	0.006	(-0.045, 0.056)
Income category 4	0.003	(-0.051, 0.056)	0.001	(-0.052, 0.054)
Income category 5	0.047	(-0.007, 0.101)	0.047	(-0.007, 0.100)
Income category 6	Reference			
Number of income category changes during the year	-0.012	(-0.037, 0.012)	-0.004	(-0.028, 0.020)
Non-Hispanic White	Reference			
African American	-0.026*	(-0.047, -0.005)	-0.024*	(-0.046, -0.002)
Asian/Pacific Islander	0.177***	(0.141, 0.213)	0.175***	(0.139, 0.211)
Hispanic	0.069***	(0.043, 0.094)	0.076***	(0.051, 0.103)
Other/unknown race	0.040	(-0.011, 0.090)	0.041	(-0.010, 0.092)
High overall medication cost status	-0.026***	(-0.039, -0.013)	-0.021**	(-0.036, -0.006)
Age	-0.003***	(-0.004, -0.002)	0.002***	(-0.003, -0.002)
Number of 30 day equivalent non-osteoporosis medications			0.0003*	(0.000, 0.0006)
Cataracts			0.014*	(0.002, 0.026)
Congestive heart failure			-0.034***	(-0.050, -0.018)
Diabetes			-0.032***	(-0.046, -0.018)
Ischemic heart disease			-0.026***	(-0.038, -0.013)
Rheumatoid/osteoarthritis			-0.032***	(-0.044, -0.020)
Sample size	25,069		25,069	

Notes:

* p-value<0.05,

** p-value<0.01,

*** p-value<0.001

Model 1 controlled for cohort year, median family income, and indicators for prescription drug plan region. Model 2 controlled for cohort year, median family income, indicators for prescription drug plan region, indicators for utilization of each other drug class listed in Table 1, and comorbidities.

Definition of the Income categories:

Income category 1: Full benefit "deemed" dual eligible, institutionalized

Income category 2: Full benefit "deemed" dual eligible based on incomes below 100% federal poverty level (FPL), non-institutionalized

Income category 3: Full benefit dual eligible based on incomes above 100% FPL and Partial benefit “deemed” dual eligible,

Income category 4: Not dual eligible, but receives Low Income Subsidy because income <135% FPL, Assets < \$7,790 (individual)/\$12,440 (couple)

Income category 5: Not dual eligible, but receives Low Income Subsidy because income <150%FPL, Assets < \$11,990 (individual)/\$23,970 (couple)

Income category 6: Does not receive Low Income Subsidy

Table 3
Marginal effects of out-of-pocket costs on probability of initiation by income, race, and health status categories.

Variable	Model 3		Model 4		Model 5	
	dx/dy	95% CI	dx/dy	95% CI	dx/dy	95% CI
Income category 1	0.045	(−0.206, 0.110)				
Income category 2	−0.060	(−0.225, 0.104)				
Income category 3	−0.072	(−0.244, 0.099)				
Income category 4	0.164	(−0.031, 0.358)				
Income category 5	0.012	(−0.327, 0.351)				
Income category 6	−0.010	(−0.024, 0.005)				
Non-Hispanic White			−0.007	(−0.020, 0.007)		
African American			0.006	(−0.013, 0.025)		
Asian/Pacific Islander			−0.034 [*]	(−0.066, 0.003)		
Hispanic			−0.029 [*]	(−0.054, 0.003)		
Other/unknown race			0.002	(−0.035, 0.039)		
Cataracts					−0.007	(−0.022, 0.000)
Congestive heart failure					0.002	(−0.012, 0.016)
Diabetes					−0.001	(−0.016, 0.013)
Ischemic heart disease					−0.001	(−0.015, 0.014)
Rheumatoid/osteoarthritis					−0.003	(−0.017, 0.011)
Sample size		25,069		25,069		25,069

Note:

- ^{*} p-value<0.05,
- ^{**} p-value<0.01,
- ^{***} p-value<0.001

All models controlled for the deductible amount, gap coverage, number of income category changes during the year, high overall medication cost status, race, age, cohort year, comorbidities, number of 30 day equivalent non-osteoporosis medications used during the cohort year, indicators for utilization of each other drug class listed in Table 1, median family income and indicators for prescription drug plan regions.

Definition of the Income categories:

Income category 1: Full benefit “deemed” dual eligible, institutionalized

- Income category 2: Full benefit “deemed” dual eligible based on incomes below 100% federal poverty level (FPL), non-institutionalized
- Income category 3: Full benefit dual eligible based on incomes above 100% FPL and Partial benefit “deemed” dual eligible,
- Income category 4: Not dual eligible, but receives Low Income Subsidy because income <135% FPL, Assets < \$7,790 (individual)/\$12,440 (couple)
- Income category 5: Not dual eligible, but receives Low Income Subsidy because income <150%FPL, Assets < \$11,990 (individual)/\$23,970 (couple)
- Income category 6: Does not receive Low Income Subsidy

Table 4

Sensitivity analyses, weighting OOP cost measures by expected medication costs, marginal effects.

Variable	dy/dx	95% CI
Out-of-pocket cost (in \$100s of dollars)	0.002	(−0.004, 0.008)
Deductible (in \$100s of dollars)	0.000	(−0.006, 0.007)
Gap coverage	0.002	(−0.019, 0.022)
Income category 1	−0.085***	(−0.114, −0.054)
Income category 2	0.083***	(0.053, 0.114)
Income category 3	0.033	(0.003, 0.064)
Income category 4	0.028	(−0.007, 0.063)
Income category 5	0.067	(0.023, 0.111)
Income category 6	Reference	
Number of income category changes during the year	−0.003	(−0.027, 0.021)
Non-Hispanic White	Reference	
African American	−0.024*	(−0.046, −0.003)
Asian/Pacific Islander	0.175***	(0.139, 0.212)
Hispanic	0.076***	(0.050, 0.102)
Other/unknown race	0.041	(−0.009, 0.092)
High overall medication cost status	−0.024*	(−0.043, 0.005)
Age	−0.002***	(−0.004, −0.002)
Number of 30 day equivalent non-osteoporosis medications	0.0003*	(0.0001, 0.0006)
Cataracts	0.014*	(0.002, 0.026)
Congestive heart failure	−0.034***	(−0.049, −0.018)
Diabetes	−0.032***	(−0.046, 0.018)
Ischemic heart disease	−0.025***	(−0.038, 0.013)
Rheumatoid/osteoarthritis	−0.032***	(−0.044, −0.020)
Sample size	25,069	

Notes:

* p-value<0.05,

** p-value<0.01,

*** p-value<0.001

This specification controlled for cohort year, median family income, indicators for prescription drug plan region, indicators for utilization of each other drug class listed in Table 1, and comorbidities. The model is the same as Model 2 in Table 2 except for the definition of out-of-pocket (OOP) costs. In both tables, OOP is constructed by weighted the monthly OOP in the pre-ICL and gap coverage phases by the average number of months beneficiaries spent in each phase. In table 2 these weights are extracted from the full sample, and are the same for all beneficiaries. In this Table, the weights are determined separately for high and low cost medication users.

Definition of the Income categories:

Income category 1: Full benefit “deemed” dual eligible, institutionalized

Income category 2: Full benefit “deemed” dual eligible based on incomes below 100% federal poverty level (FPL), non-institutionalized

Income category 3: Full benefit dual eligible based on incomes above 100% FPL and Partial benefit “deemed” dual eligible,

Income category 4: Not dual eligible, but receives Low Income Subsidy because income <135% FPL, Assets < \$7,790 (individual)/\$12,440 (couple)

Income category 5: Not dual eligible, but receives Low Income Subsidy because income <150%FPL, Assets < \$11,990 (individual)/\$23,970 (couple)

Income category 6: Does not receive Low Income Subsidy

Table 5

Sensitivity analyses of initiation within 3 months and 6 months of the osteoporosis diagnosis, marginal effects.

Variable	Initiation within 3 months of diagnosis		Initiation within 6 months of diagnosis	
	dy/dx	95% CI	dy/dx	95% CI
Out-of-pocket cost (in \$100s of dollars)	−0.001	(−0.017, 0.014)	−0.012	(−0.032, 0.008)
Deductible (in \$100s of dollars)	−0.003	(−0.011, 0.005)	−0.006	(−0.015, 0.004)
Gap coverage	−0.004	(−0.029, 0.021)	−0.015	(−0.046, 0.016)
Income category 1	−0.098***	(−0.148, −0.047)	−0.139***	(−0.202, −0.076)
Income category 2	0.071*	(0.009, 0.134)	0.017	(−0.060, 0.095)
Income category 3	0.027	(−0.030, 0.084)	−0.015	(−0.086, 0.057)
Income category 4	0.023	(−0.037, 0.082)	−0.018	(−0.093, 0.056)
Income category 5	0.060	(−0.001, 0.122)	0.025	(−0.050, 0.100)
Income category 6	Reference			
Number of income category changes during the year	0.002	(−0.025, 0.029)	0.010	(−0.024, 0.045)
White	Reference			
African American	−0.019	(−0.043, 0.006)	0.004	(−0.028, 0.035)
Asian	0.167***	(0.126, 0.207)	0.188***	(0.137, 0.239)
Hispanic	0.079***	(0.050, 0.109)	0.095***	(0.058, 0.132)
Other/unknown race	0.020	(−0.037, 0.076)	0.018	(−0.051, 0.088)
High overall medication cost status	−0.010	(−0.027, 0.007)	−0.018**	(−0.038, 0.003)
Age	−0.003***	(−0.003, −0.002)	−0.003***	(−0.004, −0.002)
Number of 30 day equivalent non-osteoporosis medications	0.0004*	(0.000, 0.001)	0.0005**	(0.0002, 0.0009)
Cataracts	0.016*	(0.003, 0.030)	0.017*	(−0.000, 0.034)
Congestive heart failure	−0.026**	(−0.044, −0.008)	−0.030***	(−0.053, −0.008)
Diabetes	−0.031***	(−0.047, −0.015)	−0.038***	(−0.058, −0.019)
Ischemic heart disease	−0.022**	(−0.036, −0.008)	−0.027***	(−0.045, −0.009)
Rheumatoid/osteoarthritis	−0.046***	(−0.060, −0.033)	−0.044***	(−0.060, −0.027)
Sample size	19,149		12,995	

Notes:

* p-value<0.05,

** p-value<0.01,

*** p-value<0.001

Both specifications controlled for cohort year, median family income, indicators for prescription drug plan region, indicators for utilization of each other drug class listed in Table 1, and comorbidities. The models are the same as Model 2 in Table 2 except for the definition of study sample and the initiation outcome. The models presented in Table 2 includes all women diagnosed with osteoporosis in the cohort year while the study samples for the two models presented in this table include only women with at least 3 month follow up period and 6 month period after diagnosis respectively. While the outcome variable in Table 2 is initiation of oral osteoporosis therapy during the cohort year, the outcome variables in these tables are defined as initiation of oral osteoporosis therapy during the 3 month and 6 month follow-up period correspondingly.

Definition of the Income categories:

Income category 1: Full benefit “deemed” dual eligible, institutionalized

Income category 2: Full benefit “deemed” dual eligible based on incomes below 100% federal poverty level (FPL), non-institutionalized

Income category 3: Full benefit dual eligible based on incomes above 100% FPL and Partial benefit “deemed” dual eligible,

Income category 4: Not dual eligible, but receives Low Income Subsidy because income <135% FPL, Assets < \$7,790 (individual)/\$12,440 (couple)

Income category 5: Not dual eligible, but receives Low Income Subsidy because income <150%FPL, Assets < \$11,990 (individual)/\$23,970 (couple)

Income category 6: Does not receive Low Income Subsidy

Appendix Table 1

Summary of data sources and relevant variables

Data Files	Variables	Purpose	Merging Criteria
<i>Prescription Drug Event (PDE) files</i>	<ul style="list-style-type: none"> Oral osteoporosis drug initiation Medication utilization by drug classes 	Drug claims that allowed us to observe drug initiation.	Medicare beneficiary ID, and NDC
<i>Medispan Drug Database</i>	NDC codes for oral forms of alendronate, ibandronate, risedronate, and raloxifene	Identify oral osteoporosis medications.	NDC
<i>Medicare Provider Analysis and Review (MedPAR) files</i>	<ul style="list-style-type: none"> Osteoporosis diagnosis (ICD-9 codes: 733.00, 733.01, 733.02, 733.09) Hypercalcemia (ICD-9 codes: 275.42) HIV (ICD-9 codes: 042.xx) Paget's disease of bone (ICD-9 codes: 731.xx) Malignant cancer (ICD-9 codes: 140.xx-208.xx) Osteogenesis imperfect (ICD-9 codes: 756.51) Breast cancer with raloxifene PDE (ICD-9 codes: V10.3, V16.3, V84.1) 	Identify osteoporosis diagnosis and comorbidities for sample selection, including conditions that prohibited oral osteoporosis drug use.	Medicare beneficiary ID
<i>Chronic Condition Data Warehouse (CCW) Chronic Conditions Summary files</i>	<ul style="list-style-type: none"> Osteoporosis Cataracts Congestive heart failure Diabetes Ischemic heart diseases Rheumatoid/osteoarthritis 	Identify osteoporosis diagnosis for sample selection and related chronic conditions for by chronic condition indicators.	Medicare beneficiary ID
<i>Beneficiary Summary Files</i>	<ul style="list-style-type: none"> Age Race/ethnicity Income categories by LIS recipient status and dual-eligibility of Medicare and Medicaid. 	Identify beneficiary demographic characteristics.	Medicare beneficiary ID
<i>Part D Denominator Files</i>	Beneficiaries plan ID Contraindicated condition: ESRD	Identify beneficiaries' enrollment in specific drug; ESRD indicator for sample selection.	Medicare beneficiary ID, and drug plan ID
<i>Plan Characteristics Files</i>	<ul style="list-style-type: none"> Plan OOP drug costs Plan benefit design variables: deductible amount, has gap coverage 	Identify drug plans' cost-sharing information for OOP construction.	Drug plan ID

OOP: out-of-pocket; NDC: National Drug Codes; ICD-9: International Classification of Diseases, Ninth Revision; HIV: human immunodeficiency virus; LIS: low-income subsidies; ESRD: end stage renal disease