BRIEF REPORTS

Angiotensin Receptor Blockers on the Formularies of Medicare Drug Plans

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BACKGROUND: The presence of angiotensin receptor blockers (ARBs) on the formularies of Medicare Part D prescription drug plans (PDPs) is vitally important to the health of seniors who cannot tolerate angiotensin-converting enzyme (ACE) inhibitors.

OBJECTIVE: To determine whether ARBs are present on the formularies of PDPs and how the prescription cost-sharing for ARBs under Part D compares to cost-sharing before Part D.

DESIGN/PARTICIPANTS: Cross-sectional analyses of March 2006 Medicare Part D formularies ($n=1,446$) and of ARB utilization and cost-sharing for adults over the age of 64 included in the nationally representative Medical Expenditure Panel Survey.

MAIN OUTCOME MEASURES: (1) Presence of ARBs on Part D formularies. (2) Average out-of-pocket costs for 30-day supply of ARBs before and after Part D (both in 2006 dollars).

RESULTS: All PDP formularies included at least 1 ARB. Most plans covered 2 ARBs (41%) and 35% covered all 7. The average monthly copay for the most commonly used ARB, valsartan, is \$28 under part D, \$14 before Part D for individuals with prescription coverage, and \$53 before Part D for individuals without coverage.

CONCLUSIONS: Whereas ARBs are present on all Part D formularies, many seniors will pay more for these drugs under Part D. Any savings in copayments under Part D may be erased by the monthly premium and by more expensive cost-sharing when seniors reach the 'donut hole'.

KEY WORDS: Medicare; health insurance; formularies; angiotensin receptor blockers.

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INTRODUCTION

The new Medicare Part D prescription drug benefit created a system in which private organizations would offer stand-alone prescription drug plans (PDPs) with unique formularies. The United States Pharmacopeia (USP) developed model guidelines for these formularies containing a list of medication categories and classes. The USP model guidelines are just that—guidelines—and the development of the final formulary was left to each plan, subject to the approval of the Department of Health and Human Services.¹ The legislation does require that PDPs cover at least 2 drugs in each class defined by the formulary, except for 6 exempted classes, including atypical antipsychotics and antidepressants where all or most drugs must be covered.

As Part D has been unveiled, much attention has been paid to difficulties in signing up seniors for their coverage. The ultimate success of this legislation for the average senior, however, will depend on whether they have any savings once enrolled in a plan and whether their access to necessary medications improves. Reports indicate that, whereas the average plan includes 91 of the 100 most commonly prescribed drugs, some PDPs may not have met the minimum formulary or cost-sharing standards required by CMS.^{2,3}

Within the category of "cardiovascular agents" in the USP guidelines, both angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) fall into the class of "renin-angiotensin-aldosterone system inhibitors". ARBs are 1 of the key drug types in this class identified by the USP, but depending on how broadly each plan defines the class, a formulary could contain 2 ACE inhibitors and no ARBs.⁴ This arrangement would have a detrimental effect on many patients who cannot tolerate less-expensive ACE inhibitors. ARBs are an important tool in the treatment of hypertension and congestive heart failure and in the prevention of end-stage renal disease for seniors who cannot take ACE inhibitors.⁵⁻⁷ Whereas angioedema is a rare occurrence with ACE inhibitors, estimates of discontinuation of ACE inhibitor therapy caused by cough from 1 study are almost 10% in blacks and 3% in other racial groups.^{8,9}

Whereas patients have the right to ask for exceptions to the formulary, the process is likely to be burdensome and some requests may be denied. Recent work has shown that there are clear benefits in adherence when patients with chronic disease are prescribed a generic or preferred brand-name agent

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compared to higher cost nonpreferred agents.¹⁰ We used the presence of ARBs on the formularies of stand-alone Medicare drug plans as an example to study the adequacy of PDP formularies nationwide. Prescription cost-sharing information for ARBs was obtained for every PDP across the US and compared to cost-sharing among seniors before Part D.

METHODS

Data/Sample

This analysis is based on formulary information contained on the March 2006 PDP Formulary and Pharmacy Network public use file. We abstracted information on copay and formulary tier for the 7 approved ARBs—losartan, irbesartan, valsartan, candesartan, eprosartan, telmisartan, and olmesartan—for all stand-alone PDPs in the country ($n=1,446$). Copays were calculated for a 30-day supply. If a plan used coinsurance rather than a fixed copay (263 plans), coinsurance was applied toward the standard 30-day <http://www.drugstore.com> price for each ARB to estimate the copay.

Tiered formularies are commonly used in managed care plans in an effort to steer patients toward certain products because a higher tier usually corresponds to higher out-of-pocket costs.¹¹ Each of the PDPs has flexibility in developing its own tiering system, but in most cases, tier 1 typically includes generic drugs, tier 2 drugs are preferred brand-name drugs, and tier 3 drugs are nonpreferred brand-name drugs. Some plans also include fourth or fifth tiers for specific nonpreferred drugs (e.g., “lifestyle drugs”) with higher cost-sharing required. Because all the ARBs are brand-name and most fall into tier 2 or 3, the tiers were combined into 2 groups—tier 1–2 versus tier 3 and above—to examine if plans categorized the ARBs into preferred or nonpreferred drugs.

To provide a recent estimate of the number of seniors (age over 64 years) using ARBs and their associated copays, data from the 2002 and 2003 Medical Expenditure Panel Surveys (MEPS) were analyzed. MEPS is a nationally representative survey of the US civilian, noninstitutionalized population conducted by the Agency for Healthcare Research and Quality (AHRQ). We calculated average prescription cost-sharing for a 30-day supply (assuming once per day dosage) for each ARB separately for: (1) seniors who had no drug coverage and paid completely out-of-pocket and (2) seniors with private insurance that paid a percentage of their drug costs. Approximately one-quarter of US seniors lack prescription coverage.¹² MEPS was also used to estimate the proportion of seniors taking ARBs whose expenditures for all drugs would be high enough that they would be subject to the ‘donut hole’—a gap in coverage for part of the year present in most plans during which beneficiaries are required to pay 100% of the drug costs. Medicaid patients were excluded from the sample because Medicare/Medicaid dual eligibles face lower copayments than other Part D enrollees. All dollar amounts are inflated to 2006 dollars using the general consumer price index.¹³ The term “prescription cost-sharing” is used throughout the paper to refer to the out-of-pocket costs required by a beneficiary to fill a specific prescription: copays and coinsurance under Medicare Part D represent the per-prescription cost-sharing under Part D, whereas the prescription cost-sharing reported in MEPS represents either

the copay paid by an insured individual or the full purchase price of the drug for the uninsured.

Analysis

Data analysis focused on 2 issues: (1) examining whether ARBs are present on the formularies of PDPs and (2) comparing average monthly prescription cost-sharing for each ARB under the PDPs with cost-sharing for seniors in 2002–2003 before Part D obtained from MEPS. The 3 least commonly used ARBs were combined in the final analysis of copays because of small sample sizes in MEPS. All analyses were performed using the SAS (SAS Institute, Cary, NC) and incorporated sampling weights to reflect the US civilian, noninstitutionalized population.¹⁴

RESULTS

ARBs on the Formulary

ARBs were present on each of the 1,446 plans nationwide. Most plans covered 2 ARBs on their formulary (41% of plans). Of the plans, 13% covered 6 ARBs and 35% covered all 7. In 2003, 70% of seniors who filled a prescription for an ARB used either valsartan or losartan—approximately 2,389,472 seniors nationwide, whereas only about 160,000 seniors (<5% of ARB users) used 1 of the 3 least commonly used ARBs (eprosartan, telmisartan or candesartan) (Table 1). Valsartan and losartan, the 2 most commonly used ARBs, were also the most commonly covered on formularies—92% of plans covered valsartan and 77% covered losartan compared to only 36% that covered eprosartan (Fig. 1). The most commonly used ARBs were more likely to be in tier 2 compared to tier 3.

Prescription Cost-Sharing

Valsartan and losartan also had relatively low average Part D cost-sharing (\$28.40 and \$34.55, respectively), whereas the least commonly used ARB, eprosartan, had the highest (\$47.35) (Table 1). Seniors who paid for their medications completely out-of-pocket (self-pay) before Part D may pay a lower amount on average for their ARB if they join a PDP. Conversely, individuals who had supplemental drug coverage paid between \$11.76 and \$15.58 on average for their 30-day supplies would therefore pay substantially more under Part D for their ARB. In analyses of MEPS data, it was estimated that approximately 46% (in 2002) to 51% (in 2003) of seniors who take ARBs will be affected by the ‘donut hole’ at some point during the year and will then have to pay the full cost of their ARB prescription if they do not have gap coverage through their plan.

DISCUSSION

This analysis of Part D plans shows that at least 1 ARB was present on the formularies of all plans in 2006. Seniors who paid fully out-of-pocket for their ARBs before Part D would have lower per-prescription cost-sharing on average if they were to join a PDP, although premiums and lack of gap

Table 1. Prescription Cost-Sharing for ARBs Among Seniors Before Part D and Average Cost-Sharing Under Medicare Part D Plans

Angiotensin receptor blocker	Approximate number of seniors taking ARBs	Mean per-prescription cost-sharing for seniors before Part D (95% confidence interval) [*]		Mean per-prescription cost-sharing for Part D plans (interquartile range) [†]
		Self-pay	Copay [‡]	
Valsartan	1,330,518	\$52.96 (51.35, 54.57)	\$14.34 (11.63, 17.05)	\$28.40 (20.00–30.00)
Losartan	1,058,954	54.60 (53.02, 56.18)	15.35 (12.46, 18.23)	34.55 (20.00–53.00)
Irbesartan	672,884	55.08 (50.65, 59.51)	11.76 (8.37, 15.15)	33.86 (23.00–49.80)
Olmesartan	182,619	43.42 (39.22, 47.62)	15.58 (5.29, 25.87)	35.02 (22.00–50.00)
Other [§]	159,299	52.91 (47.49, 58.32)	14.24 (3.69, 24.79)	41.67 (27.00–57.15)

^{*}Estimated using MEPS 2002–2003. All numbers inflated to 2006 dollars.

[†]For 30-day supply, from the CMS national formulary file.

[‡]Copay for seniors with drug coverage before Part D.

[§]The 3 least commonly used ARBs—candesartan, telmisartan, and eprosartan—are included in this category. The average cost-sharing for each of these individual ARBs across Part D plans were \$40.95, \$39.10, and \$47.35, respectively.

coverage may erase these gains. The average senior with private insurance before Part D will experience an increase in cost-sharing for their ARBs.

The most commonly used ARBs, valsartan and losartan, are also the most common on formularies nationwide. Whereas this concordance will limit the number of seniors who must experience therapeutic substitution to maintain ARB coverage, some seniors will have to switch ARBs when they join a PDP. Our results were similar to a Kaiser Family Foundation report that included analysis of 14 national formularies using the <http://www.Medicare.gov/> website, although that study included information on only the lowest-premium plans.³ Whereas therapeutic substitution is often difficult for patients, it may be less of an issue with ARBs, which are generally equivalent in their antihypertensive effect.¹⁵ This therapeutic switching may be more clinically significant for medications like antidepressants or statins under Part D, which deserve further research.

The average prescription cost-sharing under Part D for each of the ARBs ranges from \$28 to \$47. A prior study limited to 15 national PDPs that excluded plans that only offered coinsurance, rather than copays, found a mean copay for valsartan of

\$33.¹⁶ Our study adds to this work by examining all the ARBs for every plan across the country and puts these findings in the context of current spending through MEPS. These copays represent an increase compared to what seniors who have private insurance, including retiree benefits, currently pay for their ARBs. Average copays are more than twice as high for the Part D plans compared to current coverage. Whereas beneficiaries with retiree prescription coverage may opt out of Part D, if employers were to drop or cut retiree drug benefits, more seniors on ARBs would be subjected to higher cost-sharing in Part D plans. In a report on retiree health benefits last year from the Kaiser Family Foundation and Hewitt Associates, 80% of employers surveyed said they were likely to increase premium contributions for retiree coverage in 2007.¹¹ In addition, 36% said they were likely to increase drug copays or coinsurance.

Conversely, seniors who currently pay for their ARBs out-of-pocket will experience lower cost-sharing for a month's supply of medication on average, although they will have the added expense of a monthly premium. It is important to note that these cost-sharing amounts under Part D are before reaching the 'donut hole' where seniors will likely be paying

Figure 1. Distribution of ARBs on Part D formularies and formulary tier. Percentages indicate the proportion of Part D plans that include drug on formulary. ARBs are arranged in order of prevalence of current use among seniors. Drugs on tier 3 or above of a tiered formulary are generally less preferred brands with higher cost-sharing/copays

the full cost of their ARBs. Recent work showed that only 1 or 2 PDPs in most regions offered brand-name gap coverage in 2006 and their premiums averaged \$61/month compared to \$37/month for average plans nationwide.^{16,17} Some regions had no options for brand-name gap coverage. This is important considering that approximately one-half of seniors who take ARBs will be affected by the 'donut hole' and there will be no generic ARBs until at least 2009 when the patent on losartan (Cozaar) expires. Therefore, average cost-sharing under Part D per prescription across the year will be significantly higher than what is noted in Table 1 for individuals who reach the 'donut hole'. Studies have repeatedly shown that increased out-of-pocket costs and drug benefit caps are associated with worsened medication adherence and potentially increased adverse events and emergency room visits.¹⁸⁻²⁰

LIMITATIONS

Part D plans may change their formulary over time and, whereas this is a cross-sectional study, these data reflect formulary coverage at the beginning of 2006 when seniors were deciding whether to enroll in Part D and are nationally representative. Although we focused on ARB use by seniors, most seniors on ARBs will likely be on additional medications and their choice of PDP and ultimate out-of-pocket costs will be determined by the combination of these medications. We use ARBs here as 1 clinically relevant example to study the adequacy of formularies. Finally, to adjust for general price inflation we use the CPI to inflate MEPS expenditures into 2006 dollars. If ARB prices were rising particularly rapidly, we may underestimate the true payments seniors pay before Part D.

CONCLUSION

ARBs are present on all Medicare stand-alone PDP formularies, which will benefit seniors who cannot tolerate ACE inhibitors. The most commonly used ARBs, valsartan and losartan, are well-covered on formularies. On average, seniors who had private insurance may pay more for their ARBs under Part D and individuals without drug coverage may experience some savings after taking into account the Part D premium. Very few plans offer any brand-name gap coverage, so many seniors will end up paying the full cost of these medications once they reach the 'donut hole'. It will be important to assure that seniors have affordable access to needed drugs as the formularies of these private drug plans continue to evolve.

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