Impact of Medicaid Prior Authorization on Angiotensin-Receptor Blockers: Can Policy Promote Rational Prescribing?

Most state programs are ineffective at controlling either use of or spending for this costly class of drugs.

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ABSTRACT: Prescription drug cost containment is a key health policy priority. State Medicaid programs have implemented policies requiring prior authorization before paying for angiotensin-receptor blockers (ARBs), a costly class of blood pressure medications. We examined the impact of these policies on drug use. We found that policies using a stepped-therapy approach reduced ARB use by 1.6 percent when first implemented and decreased the subsequent trend in ARB use by 1.3 percent per quarter; alternative approaches were unsuccessful. These findings have important implications for the development of rational drug reimbursement policy under Medicare Part D and other health insurance plans. [Health Affairs 26, no. 3 (2007): 800–807; 10.1377/hlthaff.26.3.800]

Drugs are the fastest-growing component of health care costs in most developed countries, and the development of effective strategies to manage drug spending is a priority for public and private insurance programs. One common method to constrain the use of high-cost medications is prior authorization (PA), a policy requiring physicians to submit clinical information justifying use of a more expensive drug before the health insurance plan will pay for its use. Medicaid, which provides health coverage for low-income Americans, has struggled with rising drug spending. State Medicaid programs are legally precluded from establishing closed formularies, under which some drugs are not available, but programs such as prior authorization are permitted and have been frequently used for high-cost medications.

Drugs to treat hypertension. Hypertension is one of the most common adult diseases. The total costs associated with hypertension in 2006 have been estimated at $63.5 billion, including more than $24 billion on drugs. One important component of antihypertensive therapy is blockade of the renin-angiotensin-aldosterone system (RAAS). The benefits of blocking the RAAS were originally demonstrated in trials of angiotensin-converting enzyme (ACE) inhibitors, which are especially beneficial for patients with diabetes, congestive heart failure, coronary artery dis...
ease, and peripheral vascular disease. More recent studies have demonstrated similar benefits when angiotensin-receptor blockers (ARBs) are used. For most patients, these two drug classes can be used interchangeably. Some patients will develop a cough on ACE inhibitors; in research studies, 5–20 percent of patients did so, and 2–5 percent of patients stopped taking ACE inhibitors because of this side effect. For such patients, ARBs are often a useful alternative.

**ARBs: a logical target for PA policies.** ACE inhibitors and ARBs differ greatly with respect to cost. Over the past several years, a number of ACE inhibitors have become generically available and are now very inexpensive. As of the end of 2005, all ARBs were available only in brand-name form. From the perspective of payers, when blockade of the RAAS is needed, ACE inhibitors represent a less costly option than ARBs do for patients who do not have a specific reason for not using ACE inhibitors. ARBs thus represent a logical target for PA policies. Because ARB use has expanded rapidly since they were introduced, PA strategies’ ability to control costs of RAAS-blocking drugs is of great policy relevance. In this paper we examine the effect of Medicaid PA programs on the use of ARBs.

**Study Data And Methods**

**Data sources.** We contacted fifty state Medicaid agencies during January–April 2005 to determine whether the state Medicaid program had any PA policy regarding ARBs. Agencies were asked to provide all manuals, instructions, and submission forms for the PA process. These policies applied to fee-for-service Medicaid plans: Medicaid managed care plans generally develop prescription drug policies independently. Based on information provided by the agencies, we determined to what extent the PA program restricted access to ARBs. Two major components were considered: (1) whether prior treatment with ACE inhibitors or documentation of problems with such therapy, or both, was required, and (2) whether a preferred drug list (PDL) was used, and, if so, which drugs were on it. Many state Medicaid programs use a PDL to identify a subset of a drug class that can be prescribed without any PA requirement, while other drugs in the class require prior authorization.

**Outcome measures.** For each quarter we assessed measures of use and spending. We used World Health Organization (WHO) classifications to convert ACE inhibitor and ARB units dispensed to defined daily doses (DDD) so that use of each medication class could be compared precisely. We summed the total DDDs of RAAS-blocking medications used quarterly by each state Medicaid program and calculated the proportion of that total accounted for by ARBs. This ratio formed our primary outcome measure; we evaluated its absolute change in all of our models.

We evaluated Medicaid spending on ARBs as a secondary endpoint. Because states with more-restrictive PA requirements for ARBs also had a much lower price per unit for ACE inhibitors (50 percent below control states) in the post-PA period, we examined ARB spending as a proportion of all spending on antihypertensives as our cost outcome.

**Data analysis.** We identified the implementation date of PA programs for ARBs in all states that had such policies. We used as our intervention states those with prior authorization implemented by the third quarter of 2004, to allow for at least three quarters of post-implementation data. The time frame for each state’s data was standardized relative to the quarter in which the PA policy was initiated. The weighted average of the ARB utilization trend in states without PA programs was used as a comparator, while states that had implemented prior authorization for ARBs after the
third quarter of 2004 were not included.

We developed general linear models, using generalized estimating equations to adjust for repeated observations. We assumed autoregressive correlation structure with one-quarter lag time. The models included terms indicating the temporal relationship of each quarter to implementation of the state’s PA policy. Interaction terms between the level and slope indicators and the PA indicator were included to estimate the time trend–adjusted effects of the PA policies. We used z-test results based on regression betas and standard errors from the generalized estimating equations to determine statistical significance at $p < 0.05$. In secondary analyses, we stratified by whether the PA program criteria were less restrictive (using only the PDL) or more restrictive (requiring a prior trial of ACE inhibitors). We further analyzed whether policies requiring a trial of ACE inhibitors were associated with increased use of ACE inhibitors as a proportion of all antihypertensive medications. All analyses were done using Stata, Release 9.0.

**Study Results**

Data were available from forty-nine states and the District of Columbia (Arizona has a decentralized Medicaid program and does not provide statewide data or policy information). Total prescribing for hypertension in Medicaid more than doubled from 1996 to 2005, from about eight million prescriptions per quarter to more than seventeen million. Over this period, the total number of Medicaid recipients increased about 50 percent.13 The prescribing of RAAS-blocking agents increased from two million to more than six million prescriptions per quarter, increasing their share of antihypertensive prescriptions from about 25 percent to more than 35 percent. Total spending on antihypertensives increased similarly, reaching $2.4 billion for 2004, more than $1 billion of which (43 percent) was accounted for by RAAS-blocking drugs.

**ARB prescribing.** Within the RAAS-blocking agents, ARBs have accounted for a dramatically increasing share of prescribing and spending. As a percentage of prescriptions and DDDs, ARBs grew from 4 percent of prescriptions and 3 percent of DDDs at the beginning of 1996 to 32 percent of prescriptions and 29 percent of DDDs in 2005. The growth in share of spending has been even larger, with ARBs accounting for more than half of spending on RAAS-blocking agents by the second quarter of 2005.

We found considerable variation across states in the patterns of ARB prescribing. In Hawaii, more than 45 percent of RAAS-blocking prescriptions were for ARBs, and several other states had rates higher than 33 percent, while in Massachusetts less than 15 percent of RAAS-blocking prescriptions were accounted for by ARBs; Indiana and Maine also had rates below 20 percent.

**Prevalence of PA programs.** As of the third quarter of 2004, nineteen states had PA programs for ARBs in place and had adequate postimplementation data to be included in the intervention series. Eighteen states with no PA policy constituted the control series. Thirteen states had PA policies for ARBs that began after the third quarter of 2004 or that had not yet been implemented; we excluded these states from the remainder of our analysis.

**Inclusion of ARBs on PDLs.** All but two PA states included ARBs on their PDLs; in these states, a preferred ARB had to be tried before authorization could be obtained for a nonpreferred ARB. All seventeen of these states included at least two different ARBs and two different ARB/diuretic combination agents on their PDLs. Four states included almost all ARBs on their PDLs, only classifying candesartan and candesartan/hydrochlorothiazide as nonpreferred.

In four states, prior authorization for an ARB could not be obtained without first documenting a prior trial of an ACE inhibitor. In two of these states (Massachusetts and Washington), no ARB was defined as preferred once prior ACE inhibitor use was demonstrated. The other two states (Maine and Indiana) did use a PDL for ARBs, so that patients were required first to try an ACE inhibitor and then a preferred ARB before a nonpreferred ARB could be authorized.
ARB use with and without PA policies. We compared ARB use in the nineteen intervention states with PA policies to ARB use in the eighteen control states that did not have such a program. Even during the pre-policy period, the states that used ARB prior authorization had lower rates of ARB prescribing than the control states (Exhibit 1). Implementation of PA programs had no impact on ARB prescribing as a proportion of all RAAS-blocking drugs. In PA states, the proportion of all DDDs for RAAS-blocking drugs that were accounted for by ARBs increased from 18.2 percent to 22.8 percent over the study period, while in the control states, the increase was from 21.3 percent to 28.7 percent.

In the interrupted time-series analysis, the immediate impact of prior authorization was a reduction of 0.4 percent (not significant) in the proportion of RAAS-blocking-agent DDDs accounted for by ARBs. Likewise, there was no effect on the subsequent trend in ARB use (slope effect 0.0 percent; not significant).

ARB use by type of PA program. We present results stratified by the type of PA program (PDL versus ACE inhibitor trial required) in Exhibit 2. The control series includes the same states as in Exhibit 1, but the intervention states are now separated into the fifteen with prior authorization using only a PDL and the four requiring a prior ACE inhibitor trial. The four states with ACE inhibitor requirements had an increase in ARB prescribing from 16.5 percent to 19.1 percent of RAAS-blocking drugs in the pre-PA period, with a drop to 14.8 percent in the two quarters after PA implementation. In addition, while the use of ARBs in both the control states and the other PA states continued to increase slowly over the final six calendar quarters studied, the rate of ARB use in the four states requiring ACE inhibitor trials stayed essentially stable. The interrupted time-series models showed a statistically significant one-time decrease in ARB use of 1.6 percent \((p = 0.026)\) after PA implementation that included an ACE inhibitor requirement, and a statistically significant decrease of 1.3 percent per calendar quarter \((p < 0.001)\) in the slope of the trend in ARB use relative to controls in the postimplementation period. In the states with PDL approaches to prior authorization, there was actually a slight but statistically significant increase of 0.5 percent per quarter \((p = 0.007)\) in the slope of the trend in ARB use relative to the control states.

Impact of PA programs on ARB spending. We next evaluated the impact of prior authorization on spending for ARBs as a proportion of all spending on antihypertensives (Exhibit 3). In this analysis the implementation of a PA requirement using only a PDL was actually associated with an increase

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**EXHIBIT 1**
Proportion Of Renin-Angiotensin-Aldosterone System (RAAS)–Blocking Defined Daily Doses (DDDs) Accounted For By Angiotensin-Receptor Blockers (ARBs) Before And After The Implementation Of Medicaid Prior Authorization

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<th>Percent ARB use</th>
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<th>Control states</th>
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Quarters before and after prior authorization start


**NOTE:** Level effect: –0.4 percent (NS); slope effect: 0.0 percent (NS).
in proportionate spending on ARBs for which both the level effects (0.4 percent; $p = 0.049$) and slope effects (0.3 percent per quarter; $p < 0.001$) were statistically significant. For the four PA states that required initial use of an ACE inhibitor, the coefficients for the level effects (−1.0 percent; $p = 0.003$) and slope effects (−0.7 percent per quarter; $p < 0.001$) both indicated a reduction in ARB spending. In additional models we found a small and nonsignificant increase in ACE inhibitor use in states that required an initial trial of ACE inhibitors (level effect 0.2 percent, $p = 0.7$; slope effect 0.2 percent, $p = 0.08$).

**Discussion**

We found that use of ARBs in Medicaid and associated spending on these agents have in-
creased rapidly in the past several years. In this setting, thirty-two states have implemented or scheduled for implementation PA requirements for ARBs. Our study of the nineteen states with ARB PA policies implemented by late 2004 shows that most states adopted a strategy based on a PDL alone, so that only a subset of ARBs required prior authorization while the preferred ARBs could be prescribed without restriction. In those states, ARB use actually increased after prior authorization began, compared with states having no PA programs. In the four states with ARB PA programs that required a prior trial of ACE inhibitors, use of ARBs decreased after PA implementation. Even in those four states, spending on ARBs as a proportion of all antihypertensives continued to increase, although more slowly than in states without PA policies.

■ Previous studies. Previous studies of PA programs have generally found that the use of the targeted agent decreased after the requirement was first implemented. For example, analysis of national samples of Medicaid PA requirements for COX-2 selective non-steroidal anti-inflammatories found a 15 percent reduction in use in states that had implemented PA programs, with corresponding reductions in spending.

■ ARB use in states with formulary-type drug lists. Although all of the policies that we studied here are classified by state Medicaid programs as PA approaches, the PDLs that were used for ARBs function more like formularies, allowing the easy prescribing of at least one drug from this class. Following logically from this approach, we found that the use of ARBs actually increased in states that adopted this sort of PA policy, with correspondingly increased spending on ARBs in those states.

■ PDLs and state rebates. It was not apparent from our review why so many states chose to use a PDL approach for ARB prior authorization instead of requiring initial treatment with an ACE-I. Prior authorization centered on a PDL is an effective cost containment strategy for drug classes with one or more generic options that can be designated as preferred and might even promote evidence-based prescribing when a clear first-choice agent can be promoted via the PDL. This is not the case for ARBs; the brand-name members of this class have similar efficacy and costs.

One possible explanation is in state rebates. Drug companies are required to provide rebates to state Medicaid programs, but the extent of these rebates can be negotiated between the parties, and details of such agreements are not publicly available. States might obtain rebates for use of the preferred ARBs, which might make these strategies more financially favorable than they appear from our analyses. We cannot rule out the possibility that rebates end up saving more money than would be saved with strategies requiring initial use of an ACE inhibitor.

In principle, ARBs as a class should be an excellent target for PA strategies requiring prior ACE inhibitor use. Most patients with an indication for RAAS blockade can be effectively treated with an ACE inhibitor at low cost. For patients who cannot tolerate ACE inhibitors, ARBs represent an important treatment option, but most reliable estimates place the rate of cough and angioedema with ACE inhibitors at 10 percent, with a maximum of 20 percent. The high proportion of RAAS-blocker prescriptions accounted for by ARBs suggests that many patients are being prescribed ARBs without evidence of ACE inhibitor intolerance, and the majority of PA programs we reviewed do not mandate such trials of ACE inhibitors. States that required prior use of ACE inhibitors did see a reduction in ARB use, and that reduction appeared to be sustained over time, with not only an immediate level effect on ARB use but also a slope ef-
fect reflecting a sustained difference into the subsequent quarters studied.

**Implications for drug cost containment policy.** These findings provide important information for the design of effective prescription drug cost containment policy. Stepped-therapy approaches, such as requiring a trial of ACE inhibitors before authorizing an ARB, use policy in a manner that can reshape clinical care. When applied appropriately, these techniques might promote more evidence-based prescribing. PA strategies using a PDL to pick some agents from a relatively similar group, on the other hand, represent more of a drug pricing strategy. Although some states might have made rebate arrangements that yielded favorable economic outcomes, this approach is unlikely to promote increased evidence-based prescribing or more-cost-effective care. Even if there are initial economic gains from such policies, they might not be sustained over time. Rebate arrangements that drive current policy might not be renewed in the future, but by the time such changes occur, physicians might have established prescribing habits, making it more difficult to reduce the use of expensive medications such as ARBs.

An additional problem with PDL approaches is that prescribing physicians care for patients with a wide variety of insurance coverage options. When Medicaid and other plans choose a preferred ARB based on rebate arrangements, physicians must try to guess which agent is preferred for a given patient’s coverage. In this circumstance, patients are much more likely to arrive at the pharmacy and find that they have received a prescription that is overly expensive, rather than a less expensive ACE inhibitor; receiving more costly medications can diminish adherence, especially for vulnerable elderly patients. This concern is especially pressing for the recently implemented Medicare Part D prescription drug benefit, under which patients in a given region are likely to be covered by a variety of Medicare drug plans, with potentially different menus of preferred drugs. Better prescription drug payment policies would steer patients toward an equally effective drug that is inexpensive for both patients and insurers.

**Limitations to consider.** Some limitations must be considered in interpreting these results. The states that required an ACE inhibitor trial as part of ARB prior authorization had lower baseline levels of ARB use and also used less expensive ACE inhibitors overall. It may be that the Medicaid programs in these states take a more stringent overall approach to managing drug spending, which could limit our ability to measure the impact of prior authorization. As with the drug rebates discussed above, aspects of PA policy might not be made public and thus could not be incorporated into our analyses. States might vary in how strictly they enforce the PA criteria and in what kind of appeal processes were allowed for rejected PA requests; we did not capture these data elements. Our analyses were based on data aggregated at the state level, and we could capture neither differences at the patient or physician level nor details regarding the indication for individual prescriptions. Accordingly, we cannot comment on the clinical appropriateness of the prescriptions written and the PA decisions made. Finally, although our results were statistically significant, the absolute reductions in ARB use were quite small.

Our review of Medicaid PA policies for ARBs found that most state programs are ineffective at controlling either utilization or spending, likely as a result of relying only on the selection of a preferred ARB. The small number of states that required a prior trial of ACE inhibitors had much greater success. These results provide important lessons for public and private health insurance plans as they seek methods to control prescription drug spending in a clinically appropriate manner, and they should be of particular policy relevance with the ongoing implementation of Medicare Part D.

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NOTES


18. Dickstein et al., “Effects of Losartan and Captopril”; and Pfeffer et al., “Valsartan, Captopril, or Both.”