Cite this article as:
Jennifer M. Polinski, Philip S. Wang and Michael A. Fischer
Medicaid's Prior Authorization Program And Access To Atypical Antipsychotic Medications
Health Affairs 26, no.3 (2007):750-760
doi: 10.1377/hlthaff.26.3.750

The online version of this article, along with updated information and services, is available at:
http://content.healthaffairs.org/content/26/3/750

For Reprints, Links & Permissions: http://content.healthaffairs.org/1340_reprints.php
Email Alertings: http://content.healthaffairs.org/subscriptions/etoc.dtl
To Subscribe: https://fulfillment.healthaffairs.org

Health Affairs is published monthly by Project HOPE at 7500 Old Georgetown Road, Suite 600, Bethesda, MD 20814-6133. Copyright © by Project HOPE - The People-to-People Health Foundation. As provided by United States copyright law (Title 17, U.S. Code), no part of may be reproduced, displayed, or transmitted in any form or by any means, electronic or mechanical, including photocopying or by information storage or retrieval systems, without prior written permission from the Publisher. All rights reserved.

Not for commercial use or unauthorized distribution
Medicaid’s Prior Authorization Program And Access To Atypical Antipsychotic Medications

Does Medicaid have the resources to respond to new drug safety issues?

by Jennifer M. Polinski, Philip S. Wang, and Michael A. Fischer

ABSTRACT: State Medicaid programs use prior authorization (PA) to control drug spending by requiring that specific conditions be met before allowing reimbursement. The extent to which PA policies respond to new developments concerning medication safety is not known. In April 2005 the Food and Drug Administration (FDA) issued an advisory describing increased mortality among elderly people with dementia taking atypical antipsychotics. More than a year later, no state had changed its PA policy in response. We discuss the roles of Medicaid and other insurers in responding to emerging drug safety issues and their challenges in weighing drug risks and benefits. [Health Affairs 26, no. 3 (2007): 750–760; 10.1377/hlthaff.26.3.750]

Medicaid provides health insurance coverage for low-income Americans. Between 1997 and 2002, Medicaid drug spending increased an average of 20 percent annually, reaching $23.7 billion in 2002.1 Medicaid and other insurers have responded to rising drug costs with various cost-control measures.2 One of the most popular is prior authorization (PA), which requires that patients meet specific criteria before payment for a drug is granted; generally, these are costly medications for which low-cost alternatives exist.3 Criteria are most often clinical, but recent legal cases have affirmed states’ rights to make PA decisions based on economic conditions alone.4 Although these policies are generally motivated by economic concerns, their clinical impact might reshape care for a large population of patients who often have low socioeconomic status,
poor health, and poor health outcomes. One unresolved issue is the extent to which insurers—whether public or private—can or should incorporate risk and benefit decisions into payment policies such as prior authorization.

- **Approved use of atypical antipsychotic drugs.** Between 1996–97 and 2001–02, annual Medicaid payments for antipsychotic drugs increased 154 percent: Total annual spending topped $1.68 billion in 2001–02. This dramatic increase is likely due to the introduction of three new drugs known as atypical antipsychotic medications (APMs), a drug class that includes aripiprazole (Abilify), clozapine (Clozaril), quetiapine (Seroquel), olanzapine (Zyprexa), risperidone (Risperdal), and ziprasidone (Geodon). Atypical APMs are approved by the Food and Drug Administration (FDA) for the treatment of schizophrenia and bipolar mania, and Medicaid programs have an interest in keeping atypical APMs available for patients with these diagnoses.

- **Unapproved use of atypical APMs.** In addition to their FDA-approved indications, atypical APMs are often prescribed to ameliorate the behavioral symptoms and disturbances of dementia. For this reason, a disproportionately large amount of APM prescribing occurs in the elderly and in long-term care settings; one recent study estimates that one-quarter of Medicare beneficiaries in nursing homes were taking atypical APMs. Use of these drugs for dementia-related agitation and disturbances in the elderly is questionable: They are not approved for this indication, and they have never proved to be very effective for these symptoms.

- **Safety concerns.** The safety of atypical APM use in the elderly with dementia is also of concern. In 2003 the FDA issued a safety alert regarding increased rates of cerebrovascular adverse events among elderly participants in risperidone trials. Health Canada issued similar alerts for risperidone (2002) and olanzapine (2004). Then, in April 2005 the FDA issued an advisory that atypical APMs increase mortality 1.6–1.7-fold in older patients with dementia and added black-box warnings to the atypical APMs’ labels. The black-box warning noted the increased mortality risk and further stated that the atypical APMs were not FDA approved for the treatment of behavioral disorders in elderly patients with dementia. The advisory did not cover the older, conventional APMs primarily because of insufficient clinical trial data on the mortality associated with them.

- **An opportunity for Medicaid.** Following the FDA advisory, state Medicaid agencies were presented with an opportunity: They might both evaluate the appropriate use of these medications and develop more-nuanced policies that might selectively restrict questionable use (such as for dementia in the elderly) while preserving appropriate clinical use (such as for treatment of schizophrenia and bipolar mania).

We examined state Medicaid programs’ reactions to the FDA advisory by evaluating PA policies for atypical APMs at three points in time. We hypothesized that following the advisory, state Medicaid programs would place new limits on the use of atypical APMs in the elderly with a diagnosis of dementia and that without clear clinical guidance, PA policies would vary widely among the states.
Study Data And Methods

- Prior authorization policy data. We contacted all state Medicaid agencies between June and August 2005 to determine whether the state Medicaid program had a PA policy for APMs. Arizona, which has a decentralized Medicaid program, was not included; our analyses include the other forty-nine states and the District of Columbia. We gathered and reviewed all manuals, instructions, bulletins, and submission forms for the PA process, including information specific to the APMs. We collected historical information, beginning with the inception of the PA policy for APMs in each state, as well as current information. We relied on available historical documents, Web-site information, telephone and e-mail communications with Medicaid personnel regarding past and current policies, and information from the National Pharmaceutical Council. We repeated the data collection process in May and June 2006 to determine further changes to PA policies for APMs.

- Analysis of PA policies. We focused our attention on the extent to which PA policies restricted access to the newer, atypical APMs pre-FDA warning, within four months, and one year following the warning. We excluded preparations that combine APMs and medications from other classes from our analyses. All other APMs were considered. For a small number of medications, particularly intramuscular preparations and oral solutions, it was unclear from publicly available data whether prior authorization was required. In the absence of specific statements, we assumed that these medications did not require it. Policies were evaluated using two measures of restriction. We defined the first measure as administrative restriction, in which programs restricted access to atypical APMs for undisclosed reasons, perhaps economic in nature. This type of restriction was generally implemented as a stepped-therapy approach, in which one or more specific APMs (for example, those available in a low-cost generic form) needed to have been prescribed before payment for any other APM would be authorized. We defined the second measure as clinical restriction, in which one or more elements of clinical data regarding the patient—beyond just previously prescribed medications—were required for authorization. The clinical measures were further divided into those applied uniformly, to restrict the use of all atypical APMs, or selectively, to restrict only a subset of atypical APMs while exempting others from those constraints. States might use more than one of these measures simultaneously.

Policies were further examined for evidence of specific actions taken following the FDA warning, such as special bulletins and letters to physicians, and of the implementation of specific criteria to restrict or change use of atypical APMs in the elderly with dementia (for example, the exclusion of dementia as an appropriate diagnosis for prescription or documentation of behavioral improvement as a requirement for payment).

- APM utilization data. Aggregate state-level data for prescriptions covered by Medicaid were obtained from the State Drug Utilization Data files available from the Centers for Medicare and Medicaid Services (CMS). The data include the total
number of prescriptions filled, pills dispensed, and dollars paid in each state Medicaid program for each drug, by calendar quarter. We extracted from these data the total use of APMs and use of each individual atypical APM for 2005 and the first quarter of 2006. These analyses include the twenty-three state Medicaid PA policies for atypical APMs that were in place as of 31 March 2006. We calculated each Medicaid program’s spending for atypical APMs as a portion of total drug spending. Spending by Medicaid programs with PA restrictions for atypical APMs was contrasted with spending by programs without policies. Data were analyzed using STATA version 9.

Study Results

- **Prevalence and characteristics of PA programs.** Of the fifty programs, twenty-two (44 percent) had PA programs regarding APMs in place at the time of the FDA advisory (Exhibit 1). Of these twenty-two states, 95 percent had PA mechanisms in place for one or more atypical APMs; one program restricted conventional APMs but not atypical APMs. In contrast, 36 percent of PA states restricted access to one or more conventional, older APMs. Notably, Colorado provided exemptions from prior authorization for patients age sixty-five or older, and Michigan did not require it for patients living in long-term care settings.

- **Changes in PA programs.** As of August 2005, four months after the FDA advisory, no state had changed its atypical APM policy in any way. By the middle of 2006, twelve Medicaid programs had changed their PA policies for atypical APMs. Among those twelve programs were eight that changed existing policies and four that had introduced new PA requirements for the APMs. In their new policies, none of the twelve states directly addressed the FDA advisory—for example, by removing dementia as an appropriate diagnosis or by requiring clinical documentation of behavior improvement with atypical APM use.

- **Reimbursement criteria.** The twenty-one programs with PA policies used various criteria to determine payment for these medications. As described above, we divided Medicaid programs’ approaches into five categories. Eight programs (38 percent) restricted atypical APM use based on administrative criteria. Uniformly applied, nonselective clinical criteria described two programs’ (9.5 percent) approach, while three programs (14 percent) imposed clinical criteria selectively. Finally, eight programs (38 percent) used a combination of administrative and selectively applied clinical criteria.

  Clinical criteria varied in both content and level of detail specified. In all programs, treatment of behavioral and psychological symptoms of dementia was either explicitly listed as an appropriate diagnosis or implicitly accepted as a result of the absence of dementia exclusions. Three states had more specific criteria that limited the authorization of specific drugs to patients with documented diagnoses of schizophrenia, psychotic disorder, or bipolar mania. Four states required that a specialist, usually a psychiatrist, initiate the atypical APM prescription.
Two states included specific drug safety information with the PA documentation.

Atypical APM spending. Exhibit 2 displays atypical APM spending as a percentage of total drug spending for each state Medicaid program during 2005 and the first quarter of 2006. This cross-sectional spending snapshot reveals the heterogeneity of atypical APM spending among states, regardless of whether or not the state had a PA policy in place. On average, states with PA policies spent a slightly smaller percentage of their prescription drug budgets on atypical APMs than did states without policies; atypical APMs accounted for 13.4 percent of drug spending in states with PA policies and 15.1 percent of drug spending in states without them.

Several states with a high proportion of total spending accounted for by atypical APMs merit mention. In Michigan, the PA exemption for patients in long-term care settings likely plays a role in the high proportion of drug spending accounted for by atypical APMs. In contrast, Colorado’s PA exemption for patients age sixty-
five and older might contribute to additional spending on atypical APMs, but this spending is comparable to other states with more restrictive PA requirements. In
Minnesota, the atypical APMs that require prior authorization are few: only Clozaril, Fazaclo, Risperdal M, and Zyprexa Zydis. These minimal PA requirements would likely also contribute to the higher proportion of spending on atypical APMs. Because Oregon does not have a PA policy for atypical APMs, it is more difficult to explain this state’s higher spending. Based on the data, Oregon does not pay more for its drugs; rather, it seems to have a greater volume of atypical APM and total drug spending. Because of variations among the states, we cannot conclude from these data that the presence of any specific policy was actually responsible for any differences in spending.

Discussion

The policy problems posed by the APMs are complex for all insurers, but especially so for Medicaid. Psychiatric medications account for a large portion of Medicaid spending, and controlling drug spending is a priority for state programs. Clinical decision making for APMs is complicated: Each of the several agents has slightly different properties. Ample evidence-based prescriptions are written for patients with schizophrenia and bipolar mania, but many are written for questionable off-label uses. Furthermore, much risk is associated with these drugs: Underuse, whether as a result of clinical or policy factors, could increase psychiatric hospitalizations, while overuse might expose patients—especially older patients—to an increased risk of adverse drug events. This balance is especially delicate for Medicaid, which is responsible for providing coverage to a vulnerable, low-income elderly population with dementia—people who are likely unable to advocate for themselves within the health care system. With the advent of Medicare Part D, the private insurers who enrolled “dual eligibles,” with both Medicare and Medicaid coverage, also face this responsibility.

- Balancing safety restrictions with clinical need. We used the FDA advisory regarding atypical APMs and Medicaid programs’ subsequent response as a case study of how policymakers might balance the restriction of problematic atypical APM use with the need to maintain access for appropriate indications. Our review found that PA policies for atypical APMs were present in only about half of the states and that there were no changes to PA policies in response to the FDA warning within four months and one year following the advisory. No program excluded behavioral symptoms or agitation of dementia as an indication. Further, broad heterogeneity in state policies reveals important limitations in current drug policy development in state Medicaid programs and offers important insights for other drug insurance programs, especially Medicare Part D.

- Clinical implications of PA policies. Research has shown that some PA poli-
cies have a real clinical impact on Medicaid recipients. Generally, policies that restrict access to drugs for which there are few or no comparable alternatives result in poorer clinical outcomes than for drugs that have comparable alternatives (such as statins and proton pump inhibitors). In contrast, if a restricted drug is one of several drugs with similar clinical efficacy, patients can be switched to the unrestricted drugs with little or no change in clinical outcomes.

Within the atypical APM drug class, the clinical implications of PA policies are not clear. A systematic review concluded that in managing the psychological and behavioral symptoms of dementia, olanzapine and risperidone are more effective than placebo, with limited or no evidence for other atypical APMs. A more recent clinical trial found no significant differences among Alzheimer’s disease patients who received olanzapine, quetiapine, risperidone, or placebo. Further complicating the clinical landscape is the concern that the older, conventional APMs might confer the same or even greater risk of morbidity and mortality than the atypicals, a question acknowledged in the April 2005 advisory. Given the data available, it is challenging to promulgate a rational, evidence-based prescribing strategy to respond to new drug safety issues.

Medicaid’s lack of response. The apparent absence of Medicaid programs’ response to the 2005 FDA advisory raises questions regarding how rapidly Medicaid programs should respond to emerging clinical evidence to ensure that the drugs for which they preferentially pay are the most effective and safest for beneficiaries and what processes should be used to make such complex decisions. To our knowledge, there are no legal requirements that Medicaid programs respond to FDA advisories; however, when efficacy and safety data align, the impetus to change policy to improve health is strong. The process of change is less certain: An examination of thirty Medicaid programs’ response to FDA warnings regarding antidepressants and suicidal tendencies in children found that only two states had policies that responded to the FDA’s guidance.

Policy recommendations. We suggest a policy response to new drug safety information that includes the following components: (1) acknowledgement of the drug safety issue in a communication to clinicians, including a description of the process Medicaid will undertake to evaluate drug risks and benefits; (2) discussion/meetings with experts and policymakers to review the evidence and formulate a policy strategy; (3) after policy development, execution of administrative mechanisms and training to implement the new policy; (4) as administrative preparations progress, including issuance of a second communication to clinicians and patients explaining the new policy and providing support services for clinicians or patients with questions; and (5) implementation of the policy change. A large amount of time might be needed to accomplish these steps, and we cannot tell from our results how much time should be expected. Four months might well be too brief, but within a year we would expect to see changes if policy response mechanisms were in place.

Resources for Medicaid to draw upon. It is unclear whether Medicaid and
other insurers have the tools they need to shoulder responsibility for incorporating drug safety concerns into policy decisions. Existing resources could provide a starting point. Groups such as the Agency for Healthcare Research and Quality’s (AHRQ’s) Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) Network can provide comparative effectiveness data to inform drug policy. Through a second AHRQ initiative, fifteen states collaborate with and use evidence and analyses compiled by the Drug Effectiveness Review Project (DERP); seven of these states had PA policies for atypical APMs as of August 2005. Still, the translation from research to practice remains fraught with obstacles: The seven states collaborating with the DERP had widely varying APM policies, and because only fifteen states participate in the DERP, the proportion of PA policies for APMs is not very different among DERP and non-DERP states (7 of 15 [47 percent] versus 15 of 35 [43 percent]).

Implications for Medicare Part D. All insurers must struggle with payment policy and risk evaluation for complex medication classes such as the APMs. Although we only studied Medicaid, there is likely to be similar heterogeneity in other settings, and the problems for Medicare Part D plans might be especially profound. Although Medicaid policies apply to an entire state, Medicare Part D is implemented through numerous private plans in each local market. When the criteria for a given drug vary across plans, 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 requires prior authorization and is overly expensive or not covered at all; receiving more expensive medications can diminish adherence, especially for vulnerable elderly patients. It is not clear whether clinical problems that result from patients’ not filling prescriptions might also be a risk-management issue for insurers or providers.

Study limitations. There are limitations that must be considered when interpreting these results. We obtained data via Medicaid provider manuals, the National Pharmaceutical Council, and personal communications with Medicaid representatives. Programs varied in their degree of responsiveness, quantity of information available, and level of detail provided. These missing data elements could introduce bias into our results. In addition, actual implementation at the level of the patient and pharmacy might vary from the official description of PA policies, and our data would not reflect such variations.

Medicaid policies for prior authorization have traditionally served as budget-control tools, but by restricting access to a subset of medications, these policies have an important influence on clinical practice patterns as well. Policy debates to date have not clarified whether that influence creates an obligation to respond to emerging drug safety issues, and it is uncertain to what extent PA policies can adequately address these concerns. An improved infrastructure and guidelines for the evaluation of drug safety, timeli-
ness of response, and communication about risk, as recommended in the recent Institute of Medicine drug safety report, could provide a critical underpinning for the development of rational drug payment policy in the future, for Medicaid and for all drug insurance programs.30

An earlier version of this paper was presented at the International Society of Pharmacoepidemiology Meeting in Lisbon, Portugal, in August 2006. The authors thank Amber Servi, Liz Robinson, Jessica Agnew-Blais, and Liljana Kaci for their assistance in data collection.

NOTES


15. NPC, “Pharmaceutical Benefits.”

16. Ibid.


18. Because the underlying Medicaid population could shift from quarter to quarter, we took a weighted average of the five quarters of data for each state, using as weights the total volume of drug use per quarter. This weighted measure gives a more appropriate measure of drug use and spending in each state.


24. Schneider et al., “Effectiveness of Atypical Antipsychotic Drugs.”


