Testimony on SB 341 Senate Committee on Public Health
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Senator Pilcher-Cook, members of the Public Health committee:

I am the representing Stormont-Vail Health where I supervise 123 primary care and psychiatric providers in 16 locations across Northeast Kansas. My comments also relate to the practices of most of our 250 physicians in a diverse number of specialties throughout the Stormont-Vail Health system. I have personally practiced Internal Medicine, Pain, and Addiction medicine in Topeka for 32 years.

Stormont-Vail Health joins the legislature in its concern over the increasing costs of pharmaceutical medication, but removing the prohibitions on step therapy is simply not the way to accomplish this task. The net effect of removing the prohibition is that insurance companies, and their contracted pharmaceutical benefits managers (PBM) will initiate "Step Therapy" processes which necessitate prior authorizations (PA's).

Like all healthcare delivery systems, Stormont-Vail Health is inundated by the virtual tidal wave of the current requirements of Prior Authorizations. This PA process is costly and extremely time-consuming of our staff. We have tracked the impact upon our system, and found that Prior Authorizations require an average of 20-60 minutes of staff time to perform. Often the PA's amount to a game with the PBM of our staff trying to guess what criteria are necessary to gain approval of a given medication.

The PBM's may also require discontinuation of an historically effective medicine and thus require starting over in the "Step Therapy"process. This can result in accidental or intentional discontinuation of effective medication as well as delay in the initiation of good control. Imagine the impact on severely ill psychiatric patients or severely delayed effective treatment for diabetics. The move would supposedly save money for Medicaid at least initially, but it does so by shifting the burden to healthcare providers to beg and plead for the medications.

The PA process also **puts the insurance companies in control of medical decision-making** rather than skilled medical providers that sit face-to-face with the patients. As someone who has fought this battle too many times to count, even if a provider objects and appeals the decision of the PBM, it can be a long and harrowing process. This may require fighting through layers of appeals with individuals who literally know nothing about medication and are reading from predetermined scripts created by the PBM's.

Sadly, the PA process also directs the use of medications that the PBM's have been able to negotiate "special pricing" from the pharmaceutical companies thus enhancing their profits at the expense of our staff and physician time.

While some savings may exist in some medication classes in the short run, we must be careful of the longer term effects such as relapses of illness, complications, and net downstream costs that the healthcare delivery system will carry while the PBM's remain insulated from such costs. One example of unintended consequences resulted in $31 increase in per-member-per-month psychiatric costs when the step therapy resulted in changes in medication or discontinuations.(See attachment). With our critically stressed psychiatric health-care delivery already at the breaking point, we cannot afford a destabilization or reduction of medication availability.

The older generics and non-trade-name medicines might be reasonable to consider for some disorders in some patients, but providers already consider generics and older medications. Physicians may intentionally go early to newer and more effective medications as a clinical judgment, and that clinical judgement is rarely allowed as part of the "Step Therapy". I advance that such decisions need to be **made by clinicians, not insurance companies**. It might be more useful for providers to be given information of relative cost.

If the legislature chooses to proceed with the removal of the prohibition on step therapy, then I recommend you continue to prohibit step therapy on patients that have been managed effectively on medication chronically. Such controls would only allow using step therapy on newly started medications.

I strongly urge that you also require **full public disclosure** of the money saved, and what percentage of such dollars is actually returned to the state in savings.

Finally, in a move that would be celebrated by healthcare providers across the state, I suggest you request a study of the use of Step Therapy and the workload and financial impact on healthcare providers in Kansas.

Thank you for your attention.

Eric A. Voth, M.D., FACP

Unintended Impacts of a Medicaid Prior Authorization Policy on Access to Medications for Bipolar Illness

Christine Y. Lu, PhD,† Stephen B. Soumerai, ScD,* Dennis Ross-Degnan, ScD,* Fang Zhang, PhD,* and Alyce S. Adams, PhD*‡*

Objectives: Prior authorization policies (PA) are widely used to control psychotropic medication costs by state Medicaid programs and Medicare Part D plans. The objective of this study was to examine the impact of a Maine Medicaid PA policy on initiation and switching of anticonvulsant and atypical antipsychotic treatments among patients with bipolar disorder.

Methods: We obtained Maine and New Hampshire (comparison state) Medicaid and Medicare claims data for 2001 to 2004; the Maine PA policy was implemented in July 2003. Among continuously enrolled patients with bipolar disorder (Maine: n = 5336; New Hampshire: n = 1376), we used an interrupted times series with comparison group design to estimate changes in rates of initiating new episodes of bipolar treatment and generalized estimating equations models to examine rates of switching therapies among patients under treatment.

Results: The Maine PA policy was associated with a marked decrease in rates of initiation of bipolar treatments; a relative reduction of 32.3% (95% CI: 24.8, 39.9) compared with expected rates at 4 months after policy implementation. This decrease was driven primarily by reductions in the initiation of nonpreferred agents. The policy had no discernable impact on rates of switching therapy among patients currently on treatment (RR: 1.03; 95% CI: 0.76, 1.39).

Conclusions: The findings of this study provide evidence that PA implementation can be a barrier to initiation of nonpreferred agents without offsetting increases in initiation of preferred agents, which is a major concern. There is a critical need to evaluate the possible unintended effects of PA policies to achieve optimal health outcomes among low-income patients with chronic mental illness. In addition, more research is needed to understand how these barriers arise and whether specific seriously mentally ill populations or drug classes should be exempted from PA policies.

Key Words: Prior authorization, medication access, interrupted time series, bipolar disorder, Medicaid

(*Med Care* 2010;48: 4–9)

In recent years the growth in Medicaid prescription drug expenditures has outpaced trends for other Medicaid services and has been one of the main contributing factors to overall increases in program costs.[1] Medicaid spending on prescription drugs grew approximately 15.4% per year between 1994 and 2004.[2] To grapple with the challenges of funding prescription medicines, state Medicaid programs commonly use prior authorization (PA) policies to manage medication use and costs.[3] Many Medicare Part D plans also employ this strategy for some expensive medications, including antipsychotic agents.[4] Under PA, reimbursement of a nonpreferred medication is permitted only if a prescriber requests and obtains prior approval from the Medicaid program.[5] Despite the widespread use of PA policies, little is known about their effects on initiation and switching of clinically essential medications, particularly among patients with mental illness.[6]

Bipolar disorder is a severe and recurrent condition with manic and depressive episodes. Primary pharmacotherapies for the acute- and long-term management of this chronic illness include traditional mood stabilizers (eg, lithium), antipsychotics (eg, aripiprazole, olanzapine, risperidone, and quetiapine) and anticonvulsant agents (eg, valproate, lamotrigine, and carbamazepine).[7]

Psychotropic medications account for a disproportionate share of pharmaceutical spending in Medicaid.[8] In July 2003, the Maine Medicaid program implemented a PA policy affecting patients initiating treatment with a number of second-generation antipsychotic and anticonvulsant medications. For second-generation antipsychotics, a step therapy ("fail first") was implemented which required prescribers to provide evidence that a patient had not been adequately controlled by preferred agent(s).[9] Individuals already under treatment with second-generation antipsychotics or anticonvulsants ("estab-

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Retrospective Assessment of Medicaid Step-Therapy Prior Authorization Policy for Atypical Antipsychotic Medications

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ABSTRACT

Background: Antipsychotic medications account for more prescription expenditures in Medicaid than any other therapeutic category. This has made them an attractive target for states hoping to curtail rising expenditures.

Objective: The objective of this study was to document the effects of a step-therapy prior authorization (PA) policy for atypical antipsychotic medications on: (1) Medicaid prescription expenditures among all Medicaid beneficiaries and (2) prescription and health service expenditures among patients with schizophrenia.

Methods: Prescription, inpatient, outpatient, and long-term care State Medicaid Research Files from Georgia and Mississippi from January 1, 1996, to December 31, 1997, were used to model an interrupted time-series analysis. We compared a step-therapy PA policy implemented in Georgia to a nonequivalent/no-treatment control group (Mississippi) over 10-month prepolicy, 11-month policy, and 3-month postpolicy periods. Segmented regression was used to estimate antipsychotic prescription expenditures among all eligible Medicaid beneficiaries. We used generalized estimating equations to model prescription and other health service expenditures with difference-in-difference regressions among a cohort of patients with schizophrenia.

Results: Compared with Mississippi, Georgia saved ~$7 million in atypical antipsychotic expenditures over the 11-month policy period. Among patients with schizophrenia, the PA policy was associated with a $19.62 per member per month (PMPM) decrease in atypical antipsychotic expenditures and a $2.20 PMPM increase in typical antipsychotic expenditures (both, $P < 0.001$). Among the same patients with schizophrenia, however, the reduction in atypical antipsychotic expenditures was accompanied by a $31.59 PMPM increase in expenditures for outpatient services ($P < 0.001$).

Conclusion: Although PA of atypical antipsychotics was associated with significant prescription savings to the Georgia Medicaid program, among a vulnerable cohort of patients with schizophrenia, an increase in outpatient expenditures was associated with overall savings. (*Clin Ther.* 2008;30:1524–1539) © 2008 Excerpta Medica Inc.

Key words: Medicaid, antipsychotic, prior authorization, psychiatric health, schizophrenia.

INTRODUCTION

Antipsychotic medications currently account for more drug expenditures in Medicaid than any other therapeutic category.[1] This has made them an attractive target for state Medicaid programs attempting to curb growth within their prescription drug budgets. Spending for antipsychotic drugs currently is dominated by second-generation "atypical" antipsychotic agents. In comparison to first-generation "typical" antipsychotic medications, the newer atypical antipsychotic medications have been associated with greater efficacy in treating the negative symptoms of schizophrenia (eg, depression), with a lower risk for extrapyramidal adverse effects (eg, involuntary muscle movements, tremors, restlessness).[2,3] However, these clinical advantages carry an additional expense, with atypical

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Effects of Prior Authorization on Medication Discontinuation Among Medicaid Beneficiaries With Bipolar Disorder

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Objective: **Few data exist on the cost and quality effects of increased use of prior-authorization policies to control psychoactive drug spending among persons with serious mental illness. This study examined the impact of a prior-authorization policy in Maine on second-generation antipsychotic and anticonvulsant utilization, discontinuations in therapy, and pharmacy costs among Medicaid beneficiaries with bipolar disorder.** *Methods:* **Using Medicaid and Medicare utilization data for 2001–2004, the authors identified 5,336 patients with bipolar disorder in Maine (study state) and 1,376 in New Hampshire (comparison state). With an interrupted time-series and comparison group design, longitudinal changes were measured in second-generation antipsychotic and anticonvulsant use; survival analysis was used to examine treatment discontinuations and rates of switching medications.** *Results:* **The prior-authorization policy resulted in an 8–percentage point reduction in the prevalence of use of nonpreferred second-generation antipsychotic and anticonvulsant medications (those requiring prior authorization) but did not increase use of preferred agents (no prior authorization) or rates of switching. The prior-authorization policy reduced total pharmacy reimbursements for bipolar disorder by $27 per patient during the eight-month policy period. However, the hazard rate of treatment discontinuation (all bipolar drugs) while the policy was in effect was 2.28 (95% confidence interval=1.36–4.33) higher than during the pre-policy period, with adjustment for trends in the comparison state.** *Conclusions:* **The small reduction in pharmacy spending for bipolar treatment after the policy was implemented may have resulted from higher rates of medication discontinuation rather than switching. The findings indicate that the prior-authorization policy in Maine may have increased patient risk without appreciable cost savings to the state. (*Psychiatric Services* 60:520–527, 2009)**

Because of recent rapid inflation in expenditures for prescription drugs, especially psychoactive medications, state Medicaid programs have increasingly relied on prior authorization to control Medicaid drug spending. A 2005 survey of 36 states and the District of Columbia found that all had attempted to control Medicaid drug costs by requiring prior authorization for some medications and that more than one-third of Medicaid programs and Medicare Part D plans required prior authorization for one or more second-generation antipsychotic medications (1–4). A prior-authorization program requires physicians to obtain special approval before they can prescribe restricted (nonpreferred) medications. Prior-authorization policies have been shown to be very effective at reducing pharmacy expenditures while not increasing adverse outcomes when applied to drug classes in which drugs are highly substitutable and more expensive drugs are not necessarily more effective (5–7). However, the economic and clinical effects of prior-authorization policies for essential psychiatric medications are poorly understood, especially for vulnerable, low-income beneficiaries with bipolar disorder.

Bipolar disorder affects 2.6% of the American general population age 18 and older in any given year and costs $45 billion per year (including direct medical costs and indirect economic costs) in the United States (8,9). Pri-

During the conduct of this study, Dr. Y. Zhang was a research fellow at the Drug Policy Research Group at Harvard Medical School, Boston; she is now with the Department of Health Policy and Management, University of Pittsburgh. Dr. Adams, Dr. Ross-Degnan, and Dr. F. Zhang are affiliated with the Department of Ambulatory Care and Prevention, Harvard Medical School, and with Harvard Pilgrim Health Care, Boston. Send correspondence to Dr. Soumerai, Department of Ambulatory Care and Prevention, Harvard Medical School, 133 Brookline Ave., 6th Floor, Boston, MA 02215 (e-mail: ssoumerai@hms.harvard.edu).

The Effects of Antihypertensive Step-Therapy Protocols on Pharmaceutical and Medical Utilization and Expenditures

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Objective: To examine the effects of antihypertensive step therapy on prescription drug utilization and spending, and other medical care utilization and spending.

Study Design: Pre/post design.

Methods: Employers who had implemented step therapy were compared with employers who had not implemented step therapy. Data were drawn from the 2003 through 2006 MarketScan Research Databases. The study sample included employees and dependents who used antihypertensives (11,851 patients whose employer implemented a step-therapy protocol and 30,882 patients in the comparison group without step therapy). Multivariate generalized estimating equation models were used to estimate the immediate and time-varying effects of step therapy on medical and prescription drug spending and utilization, while controlling for important covariates and adjusting for clustering by patient.

Results: Results showed an initial 7.9% reduction in antihypertensive medication days supplied and an initial 3.1% reduction in medication costs among antihypertensive users in the step-therapy plans. However, these percentages grew in each subsequent quarter. Antihypertensive users in step-therapy programs also experienced an increase in inpatient admissions and emergency room visits. After an initial decline in spending, the step-therapy group incurred $99 more per user in quarterly expenditures than the comparison group.

Conclusions: The intended effect of step therapy is to substitute cheaper and equivalently effective medications for more expensive medications. As this study demonstrates, step therapy may create barriers to receiving any medication, resulting in higher medical utilization and costs. Further research is needed to understand why these unintended consequences occur and how they might be avoided.

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For author information and disclosures, see end of text.

Managed care organizations and insurance plans are increasingly adopting step therapy in an effort to contain costs by steering patients away from more costly pharmacotherapies. Step therapy requires a member to try the first-line medication(s) within a drug class, often a generic alternative, prior to receiving coverage for a second-line agent, usually a branded product.[1] Currently, most pharmacy benefit managers implement step therapy using "smart edit" logic and grandfathering those members who had obtained a prescription for the target (second-line) drug in the recent past. At the point of service, the smart edit reviews the member's claims history (both electronically and in real time) for evidence of prior use of the first-line agent(s). If a claim is found, the system covers the second-line agent; otherwise, the claim is rejected. After claim rejection, members have the opportunity to have their prescriber change the prescription to the first-line agent or to submit a request for coverage of the second-line agent through a prior authorization.[1]

There is a small but growing literature on step-therapy programs. In 2007 Yokoyama and colleagues evaluated hypertension-related pharmacy use and costs for 3 managed care plans that implemented an angiotensin receptor blocker (ARB) step-therapy intervention compared with 1 health plan with no ARB step-therapy intervention.[2] The step-therapy intervention used a smart edit of patient pharmacy claim history in the preceding 3-month period. The ARB claim was rejected if there was no prior use of these drugs, in which case the pharmacist or patient had to contact the prescriber to obtain an alternative to the ARB or a prior authorization. The researchers found that within 12 months of follow-up, a step-therapy intervention for ARBs was associated with an 18% ratio of ARB users to the total number of patients using angiotensin-converting enzyme (ACE) inhibitors or ARBs compared with a 31% ratio in a health plan without the ARB step-therapy intervention. Of the patients who attempted to obtain an ARB and were rejected in the step-therapy group, 44.6% of patients went through the prior authorization process and received an ARB as initial therapy, 48.8% received other antihypertensive therapy, and 6.6% did not receive any antihypertensive therapy. Antihypertensive drug costs were about 13% lower for the ACE/ARB patients in the intervention group.

Motheral and colleagues examined the effect of prescription

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