

Choice is Beneficial to Patients, Healthcare Systems and Society

Restricted Access to Medication and Unintended Negative Consequences in Patient Care and Health Systems

As a result of rising U.S. healthcare costs,¹ and in a time of increased fiscal tightening, stakeholders across the healthcare system, from providers to insurers, continue to seek ways to reduce spending. Two areas that insurers have identified are drug formularies and formulary restrictions, including prior authorization and step therapy. While these restrictions may reduce medication costs in the short term, they have also been shown to possibly contribute to worse patient outcomes and higher overall healthcare systems spending. This is particularly true when it comes to treatment for individuals with serious mental illness (SMI) such as schizophrenia, schizoaffective disorder and bipolar I disorder.

RESTRICTED ACCESS TO MEDICATION CAN LEAD TO POOR OUTCOMES:

In general, experts note that a variety of treatment options are needed due to a wide range of patient responses and circumstances. Restrictions on choice have been shown to have a host of unintended negative consequences including adverse medical outcomes and increased costs and burdens for patients, healthcare providers, the healthcare system and society. These include:

- Missed doses of medication, or discontinued use of medication^{2,3}
- Adverse side effects associated with changes in medications, such as weight gain or drowsiness^{4,5}
- Declines in health status⁶
- Increased patient costs for outpatient services⁷
- Increased hospitalization and use of inpatient services³
- Increased administrative burden for health care providers and staff, which leads to diminished time for direct patient care^{8,9}

SIGNIFICANT IMPACT ON THOSE WITH SERIOUS MENTAL ILLNESS

The impact of formulary restrictions can be even more damaging for the almost 10 million American adults who suffer from SMI,¹⁰ including those with schizophrenia, bipolar disorder and schizoaffective disorder. Individuals in this unique population have individualized treatment needs, respond in a unique way to different medications, and often need to adjust medications.^{3,4,11,12,13,14}

In addition, these individuals are more likely than others to be confused by administrative barriers to care, and to have multiple comorbidities, so they are disproportionately affected by formulary restrictions.² Continuous and consistent access to the medication that is preferred by the provider and best tolerated by the patient is often necessary to effectively manage SMI.

Individuals with SMI who face restricted medication access may experience setbacks in their health status, have more frequent hospitalizations, have a greater number of encounters with the criminal justice system, including incarceration,³ and utilize more emergency services.⁶ In addition to the obvious harm this causes these individuals, restricted medication access also incurs high costs to society in the form of both increased Medicaid spending and increased incarceration costs.^{3,14}

One study estimates the total societal costs of formulary restrictions for SMI medications among Medicaid beneficiaries at more than \$1 billion per year.³

FORMULARY CONTROL METHODS AND OUTCOMES

Although various formulary control methods are well-intentioned, they may restrict the SMI population's access to, and the possible benefits of, antipsychotic medications, as described below. Efforts such as step therapies or prior authorizations present particular challenges and may increase administrative burdens for delivering therapies.

FORMULARIES AND INCENTIVE FORMULARIES:

Formularies are lists of medications covered by a specific health plan. Formularies may decrease overall medication spending by encouraging patients and healthcare providers to choose lower-cost drugs, and may also promote competitive pricing of medication. Studies, however, have indicated that formularies can have unintended negative impacts.

One study of Medicaid formulary restrictions found that removing certain higher cost drugs from coverage may adversely affect those who would have most benefitted, leading to deteriorating health status and ultimately, higher nonpharmaceutical spending.¹⁵ They can also have the effect of reversing health gains that prior mental health treatments have made possible.⁶ For example, second generation schizophrenia drugs have been found to control schizophrenia symptoms with fewer side effects as compared to first-generation drugs, leading to an up to 15 percent reduction in relapses.¹⁶

However, formulary restrictions have led doctors to prescribe them less frequently, reducing the use of

atypical antipsychotics by about 5 percent.¹⁷ Formulary restrictions may also increase the probability that a patient resumes the same course of therapy even if it has failed in the past. This likelihood increases by 6.2 percent for atypical antipsychotics if a patient is from a state where formulary restrictions exist.¹⁸

Incentive formularies – tiered lists of medications that offer similar therapies at differing cost – can also lead to negative consequences. When an incentive formulary has been implemented and patients and their physicians determine that a drug either on a higher tier or not on formulary is more effective, costs may shift from the health plan to the patient, increasing the out-of-pocket burden for a population with chronic mental illness.¹⁹

While more information is needed about the full effects that formularies and incentive formularies have on controlling health systems costs, research indicates that because of the specific characteristics of mental disorders and the mental healthcare system, they may not be as effective at controlling costs for psychotropic drugs as they are for other drug classes and may negatively impact mental health treatment.¹⁹

Research Examples: A Florida Medicaid Study found that hospitalization and emergency room visits increased by 20 percent following a policy change re-classifying an atypical antipsychotic as a non-preferred drug. In addition, the study found that any reductions in pharmacy expenditures were largely offset by increased expenditures for hospitalization.²⁰

In another study, patients with problems obtaining clinically indicated and preferred antipsychotics had 17.6 times increased odds of having an adverse event in the past year when compared to those patients without problems obtaining clinically indicated and preferred medications.²¹

PRIOR AUTHORIZATION: Prior authorization can have potential beneficial outcomes. For example, it may lead to a decrease in atypical antipsychotic drug spending² and may help restrict the use of drugs to the disease states for which there is the most clinical evidence for their use. Yet, studies also show that prior authorization can lead to an increase in treatment discontinuities, because an additional step is required that can create a barrier to treatment.² Further, it has been shown to increase the administrative burden for psychiatrists and staff who must obtain this authorization.⁹

National surveys conducted in recent years demonstrate that administrative expenses for providers interacting

with health plans across varying medical conditions on items such as prior authorization and formularies cost the U.S. healthcare system \$23 to \$31 billion each year.²² Prior authorization has also been shown to lead to an increase in expenditures for psychiatric outpatient services, possibly because of the additional administrative burden placed on service providers.⁷

Lastly and most significantly, the challenges posed by prior authorization may lead individuals to discontinue their antipsychotic treatment, which can have significant negative consequences for both the individual and society.²

Research Examples: In a study on the impact of prior authorization requirements, the annual costs of obtaining prior authorization requests, per physician (or full time equivalent physician), ranged from an average of \$2,162 (calculated with U.S. Bureau of Labor Statistics salary data) to an average of \$3,430 (calculated with Salary.com salary data).⁸

STEP THERAPY: Step therapy can have potential beneficial outcomes, including a decrease in overall pharmacy expenditures, by encouraging patients and healthcare providers to choose lower-cost drugs and increasing competitive medication pricing.

However, studies have shown that step therapy restricts clinical decision-making by requiring the use of certain medications first, even if the clinician believes the preferred drugs are less desirable— for example, because of lower tolerability, a complicated dosing regimen, therapeutic noncompliance from adverse side effects, poor treatment outcomes or lack of improvement compared to non-preferred medications.¹⁴

Because step therapy requires patients to first use medications that may be less desirable, it may increase

the likelihood of noncompliance and negative outcomes and hamper continuity of care.²

Research Examples: According to the USC Schaeffer Center, patients with schizophrenia who were required to adhere to step therapy, prior authorizations and quantity limits were more likely to experience hospitalization, had 23% higher inpatient costs, 16% higher total medical costs and worse adherence rates.

Bipolar patients with similar formulary restrictions were more likely to be hospitalized, had 20% higher inpatient costs and 10% higher total costs. Further, formulary restrictions were not associated with statistically significant lower pharmacy expenditures.¹⁴

BACKGROUND ISSUE BRIEF

COST-SHARING: Another approach the health system is using to contain drug costs is to charge patients higher copayments for certain medications or for using certain types of treatment facilities. This strategy can theoretically decrease costs if implemented effectively. However, studies have shown that increasing patient cost sharing can also lead to declines in medication adherence, which in turn can be associated with poorer health outcomes.²³

The impact on the health and financial well-being of poor and chronically ill individuals seems to be particularly evident.²⁴ Studies have also shown even

moderate drug cost sharing reduced the use of essential medications among general low-income and elderly populations, increased hospitalizations and increased the risk of adverse events, such as nursing home admissions.²⁵

It can also pose particular challenges to individuals with serious mental illness, whose average earnings are significantly less than those of individuals without serious mental illness.²⁶ Additionally, this method can negatively affect the quality of care that patients receive because it may influence them to choose a less effective treatment method simply based on cost. This can be particularly true when it comes to the differences among medications that treat most mental illnesses.¹⁹

Research Examples: In a literature review of 160 articles evaluating the relationship between changes in cost sharing and adherence, 85% of articles showed that increasing patient share of medication costs was significantly associated with a decrease in adherence and, consequently, poorer health outcomes.²³

Another literature review found that studies focused on chronically ill patients, including those with schizophrenia, show higher cost sharing for prescription drugs or benefit caps are associated with greater use of inpatient and emergency medical services.^{15,27}

SUMMARY OF IMPACTS OF RESTRICTED ACCESS TO MEDICATIONS

A growing body of evidence indicates that formulary restrictions save little, if any, money on drug spending for SMI and instead contribute to worse patient outcomes and higher overall spending.^{3,14} While these methods may result in lower medication costs, they also may lead to increased spending in other areas such

as emergency care.^{28,6} Restricted access to medication can also lead to increased expenditures on outpatient services, poor adherence to antipsychotics and resulting increase in hospitalizations, more encounters with the criminal justice system, including incarceration, and lost earnings among patients with mental illness.^{3,5,7,14,26}

THE IMPORTANCE OF ACCESS AND CHOICE: Access to and choice of a range of treatment options is essential to the effective treatment of serious mental illness. According to the Medical Directors Council of the National Association of State Mental Health Program Directors, the variability of patient response necessitates the availability of a multitude of treatment options.⁴ Restricting access to medication can also lead to increases in the number of visits to physicians and in hospitalizations.¹³

When both access to and choice of medications are restricted, the consequences include increased use of healthcare resources, increased administrative burdens and costs, and higher risks for SMI patients.^{7,14,29} To achieve the best outcomes, it is important that clinicians have the ability to prescribe the drugs that they believe will be most effective and tolerable for each patient.



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