

KANSAS MENTAL HEALTH COALITION

.....*Speaking with one voice to meet the critical needs of people with mental illness*

Support Step-Therapy Protections

Position: The Kansas Mental Health Coalition supports SB 304 to establish safety parameters for insurance step therapy policies. Step therapy requirements are also known as “Fail First” pharmacy restrictions – requiring the individual to first “fail” on a number of other medications.

The Problem: Step therapy policies put patients with mental illness at risk and private insurance policies implement them without consistent or predictable patient protections. Many mental health consumers need medication to recover, to alleviate symptoms and to make the illness “manageable”. Access to the full range of FDA approved medications, including those that are new and those most effective promotes successful treatment. Continuity of the medication regime is essential. Finding and maintaining the most effective medications is often the key to a durable recovery that enables children with mental illness to attend school and graduate, enables adults to keep jobs and contribute to their communities, and enables families to stay together.

Research supports exempting mental health drugs from restricted access and identifies potential problems with step-therapy policies.

Research indicates that fail first policies can have devastating consequences when patients with mental illness face rejection of their prescription at the pharmacy counter. When individuals face interruptions or delays in treatment, the consequences include emergency room visits, hospitalizations homelessness, incarceration and even death by suicide. (See an abbreviated list of references attached.)

Why this matters: Navigating the complications of medication restrictions is difficult, and even impossible when changing policies and insurers. Consumers with mental illness often do not have the resources and access to professionals as the average consumer. It is difficult to know whether or not they are entitled to temporary prescriptions or to know if they are supposed to be "grandfathered" when they suddenly find their prescription can't be filled at the pharmacy. Furthermore, individuals who give up on treatment and decompensate rarely maintain private insurance in the long run, and ultimately their care and treatment falls to the public mental health system and state mental health hospitals.

The bottom line: Research shows the potential harm of step therapy policies. Many states have used the science to implement safety restrictions on the use of step therapy, which give consumers equal protections regardless of the insurer. These safety measures are designed to assure the following:

- Prevent abrupt interruptions, especially for patients who have been stable on current medications;
- Prevent requirements to “fail” on medications for long periods of time;
- Prevent requirements to “fail” on medications more than once;
- Require the use of quality research to establish tiered medication options and
- Expedite physician overrides when the step therapy protocol requires medications that are known to put the patient at risk

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The rest of the story about mental health medications

A 2010 study states “mental health-specific inpatient and emergency room utilization and costs increased” from step therapy which “may have the unintended effect of reducing overall antidepressant use and increasing medical use and costs.”¹ Another study found that “managed care policies among patients with psychiatric illness have even been found to shift costs in state budgets to jails.”²

A study of the policies adopted in the Georgia Medicaid program published in 2008³ concluded that while prior authorization 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.” While step therapy saved the state \$19.62 per member per month in atypical antipsychotic expenditures, these savings were “accompanied by a \$31.59 per member per month increase in expenditures for outpatient services.” The authors challenge policymakers who are considering similar policies to “consider carefully the potential for unintended consequences of restricted access to antipsychotic medications.”

A 2010 study concluded that “barriers to medication access may exacerbate the problem of poor adherence and may lead to declines in the health of these vulnerable patients, including higher risks of relapses, hospitalization, and suicide.”⁴

In 2003, Maine instituted a prior authorization and step therapy policy for atypical antipsychotics. Persons affected by prior authorization requirements had a 29 percent greater risk of treatment discontinuity. Due to negative outcomes from adopting this policy including an increase in hospitalizations, the policy was suspended. In an examination of programs in Maine and New Hampshire, a 2009 study found that “the small reduction in pharmacy spending ... 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.”⁵

In a review article on step therapy interventions, the author states that the adoption of step therapy “is quickly outpacing decision makers’ understanding of the clinical, humanistic, and economic value of these programs. Such knowledge is needed to avoid potential unintended consequences such as medication noncompliance.”⁶

The Kaiser Commission on Medicaid and the Uninsured has noted the distinct vulnerability of individuals with mental illness who are on Medicaid and recommends exemptions from restrictions for all psychotherapeutic and anticonvulsive medications.⁷ Psychotropic medications—even those within the same class—have unique properties that result in different effects from one person to another. The National Institute on Mental Health (NIMH) notes that individuals have unique responses to psychiatric medications and need more, not fewer, choices.⁸ NIMH concludes that “a medication that works well for one person with schizophrenia often doesn’t work well for another. Genetic variations are thought to play a key role in this difference in response. While patients search for the right medications, their illnesses may worsen.”

A study by the American Psychiatric Association showed that over half of dual eligible Medicare Part D patients with mental illness had problems accessing needed medications. More than a fifth had medications terminated or interrupted and about one in five were switched to a different medication because the medication on which they were stable was no longer covered or approved.⁹

Harvard University Professor Stephen Soumerai, a leading researcher in this field, stated in 2004: “Given the rapid increase in the use of [prior authorization] policies and other cost-control mechanisms in Medicaid, the relative lack of data on their risks and benefits is cause for concern. It is sobering to realize that if such policies were considered for a clinical study, the possible risks of reduced access to essential medications would likely result in a failure to obtain human-subject approval from most institutional review boards.”¹⁰

¹ Mark, Tami L, Gibson Theresa M., McGuigan, Kimberly and Chu, Bong Chul, “The Effects of Antidepressant Step Therapy Protocols on Pharmaceutical and Medical Utilization and expenditures.” *American Journal of Psychiatry*, 167:10, October 2010.

² Domino et al, *Health Serv Res*, 2007, 42(6 Pt 1):2342-5.

³ Farley, Joel F. et al, “Retrospective Assessment of Medicaid Step-Therapy Prior Authorization Policy for Atypical Antipsychotic Medications,” *Clinical Therapeutics*, Vol. 30, No. 8: 1524-1539, August 2008.

⁴ Lu et al, “Unintended Impacts of a Medicaid Prior Authorization Policy on Access to Medications for Bipolar Illness.” *Medical Care*, Volume 48, Number 1, January 2010

⁵ Zhang et al, “Effects of Prior Authorization on Medication Discontinuation Among Medicaid Beneficiaries With Bipolar Disorder.” *Psychiatric Services*, April 2009 Vol. 60 No. 4

⁶ Motheral, Brenda, “Pharmaceutical Step-Therapy Interventions: A Critical Review of the Literature.” *Journal of Managed Care Pharmacy*, Vol. 17, No. 2 March 2011.

⁷ Kaiser Commission on Medicaid and the Uninsured, “Model Prescription Drug Prior Authorization Process for State Medicaid Programs,” April 2003.

⁸ National Institutes of Health, National Institute of Mental Health, NIMH Perspective on Antipsychotic Reimbursement: Using Results From The CATIE Cost Effectiveness Study, December 2006.

⁹ West, Joyce C., Ph.D., M.P.P., et al, “Medication Access and Continuity: The Experiences of Dual-Eligible Psychiatric Patients During the First 4 Months of the Medicare Prescription Drug Benefit,” *Am J Psychiatry*; 164:789-796, May 2007.

¹⁰ Soumerai, Stephen, *Health Affairs*, 2004: 23:135-46.