

KANSAS MENTAL HEALTH COALITION

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

Medicaid Medication Management and Step-Therapy

Position: The Kansas Legislature should support K.S.A. 39-7,121(c), which prohibits the use of step therapy restrictions for Medicaid prescriptions. The Coalition opposes efforts to overturn the current statute by allowing step-therapy or fail-first policies to be applied to prescriptions recommended by a patient's physician.

The Problem: Fail first policies harm people with mental illness when medication restrictions delay or interrupt important mental health treatment. Research supports exempting mental health drugs from restricted access and identifies potential problems with step-therapy policies. Step therapy policies require a patient to try a less expensive medication, chosen by an insurance company or management program, and "fail" on it before they can be prescribed a restricted medication chosen by their doctor. Numerous studies have shown that preventing access to specific medications which have been proven to be helpful to individual patients will harm Medicaid subscribers with mental illness. When individuals face interruptions or delays in treatment, the consequences include emergency room visits, hospitalizations homelessness, incarceration and even death by suicide.

In 2002, the Kansas Legislature exempted "medications including atypical anti-psychotic medications, conventional anti-psychotic medications and other(s)...used for the treatment of severe mental illness," from a Medicaid preferred formulary and prior authorization (K.S.A. 39-7,121(b)). In 2015, the Kansas Legislature removed that exemption, while creating a Mental Health Medication Advisory Committee to create prior authorization policies and assure that medications were being prescribed safely and effectively across all three Medicaid managed care contractors. The step therapy protection remained in statute. The initial meetings of the MHMAC have lacked transparency and offered no opportunity for meaningful input. Important planning to develop processes for medication approval that do not require excessive administrative interruptions for professionals and prevent instances where patients face rejection of their prescription at the pharmacy must be completed.

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Why this matters: Many mental health consumers, like others with chronic diseases, need medication to recover, to alleviate symptoms and make the illness "manageable." Access to the full range of FDA approved medications, including those that are new and often most effective, promotes successful treatment. We know that the right medication or combination of medications for an individual can mean the difference between recovery and living successfully with a mental illness or experiencing devastating decompensation. Finding the right combination of medications and therapies can take years.

The bottom line: KMHC opposes step therapy policies for mental health medications. We will continue to work with state officials to evaluate and implement policies that enhance patient safety and create efficiency without jeopardizing patient access to medications. Until the Mental Health Medication Advisory Committee for Medicaid has proven its ability to implement successful prior authorization policies based on safe and effective prescribing, the Coalition cannot endorse the consideration of step therapy policies which focus only on drug costs.

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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.” The Georgia Department of Human Resources also found in their review that there was no significant increase in cost from going to open access from a restricted formulary in their state hospital facilities.

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.