

Patent expirations for blockbuster antipsychotic meds could save billions

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Medicaid is expected to save billions of dollars a year as patents for several blockbuster antipsychotic medications expire and use of generic versions of these drugs increases, according to a new study by researchers at the University of Maryland School of Medicine. These savings may provide relief from the high costs of these medications and allow policymakers to lift restrictions on patients' access, the researchers argue.

The study forecast that annual Medicaid payments for antipsychotic medicines will decrease by nearly \$1.8 billion (or nearly 50 percent) by 2016 and by \$2.8 billion (or 76 percent) by 2019. The forecasting models were developed by the authors, Eric Slade, PhD, an associate professor in the Department of Psychiatry and Linda Simoni-Wastila, BSPharm, MSPH, PhD, a professor at the University of Maryland School of Pharmacy. The study, the first to look at these possible cost savings, was published in the July issue of the journal *Psychiatric Services*.

The researchers predicted changes in overall Medicaid spending for antipsychotics between 2011 and 2019. In 2011, Medicaid spent more than \$3.6 billion on second-generation antipsychotics. Five branded medications—aripiprazole, quetiapine, olanzapine, ziprasidone, and paliperidone—accounted for \$3.3 billion or 90 percent of this spending. Medicaid is the major payer for antipsychotic medications in the U.S., accounting for between 70 percent and 80 percent of all antipsychotic prescriptions.



"Mental health medications are among the most prescribed drugs in Medicaid, and many of these medications have recently become available as generics or soon will be," said Dr. Slade, who is an economist. "Our predictions suggest that this change will result in a substantial financial windfall to states and to the federal government."

Antipsychotics are the mainstay of treatment for psychotic illnesses such as schizophrenia and bipolar disorder. In the 1990s, a new category of antipsychotic medications, known as "second generation antipsychotics," was introduced. These new medications promised fewer side effects, but they were also more expensive. Between 1999 and 2005, annual antipsychotic expenditures per Medicaid beneficiary more than doubled. By 2009, antipsychotics accounted for nearly 15 percent of all Medicaid expenditures for medications.

During the 1990's and 2000's, concerns about rising antipsychotic expenditures in Medicaid led many states to impose restrictions on the use of second-generation antipsychotics. Common Medicaid restrictions include requirements that a physician obtain prior authorization before writing a prescription, limits on the total number of prescriptions a patient can fill per month, and requirements to prescribe certain antipsychotics before trying others. Dr. Slade notes that as antipsychotic spending decreases, some of these limits may no longer be necessary.

"These findings have the potential to improve the lives of people suffering from schizophrenia and other mental disorders," said Bankole A. Johnson, MD, DSc, MB, ChB, chairman of the UM SOM psychiatry department. "As someone who treats patients I see firsthand how these diseases can cause suffering, and I hope this study can help alleviate some of that pain."

Patent protection for nearly all second generation antipsychotic medications, which include aripiprazole, asenapine, clozapine,



iloperidone, lurasidone, olanzapine, paliperidone, quetiapine and ziprasidone, has expired or will expire within the next few years. Using data on antipsychotic prescriptions and spending in Medicaid, the researchers developed estimates of the savings to the Medicaid program from use of one drug, risperidone, during the years 2008 to 2011. Risperidone, one of the first second-generation drugs, became available generically in 2008. They then used these estimates to forecast savings for all antipsychotic medications.

"This study offers important information for policymakers as they navigate the difficulties of balancing fiscal responsibility with patients' needs," said Dean E. Albert Reece, MD, PhD, MBA, who is also the vice president for Medical Affairs, University of Maryland, and the John Z. and Akiko K. Bowers Distinguished Professor and Dean of the School of Medicine. "Dr. Slade's work is a great example of how the school is using data to make discoveries about health and health policy that have the potential to make a difference for patients."

Dean Reece and the Dean of the School of Pharmacy, Natalie D. Eddington, PhD, FCP, FAAPS, also praised the cooperation between UM SOM and the School of Pharmacy, saying that such cross-school integration often yields fruitful results. "This work by Dr. Slade and Dr. Simoni-Wastila shows how faculty from different disciplines, in different schools, can work together to bring their knowledge to bear on important questions, with novel, and useful, results," said Dean Eddington.

Provided by University of Maryland

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