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Three key antipsychotics lose patent protection

November 16, 2011 by Brian Albright

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State Medicaid programs, patients to save as major atypical meds “go generic”



Pharmaceuticals are one of the fast growing cost centers in most state Medicaid programs, and antipsychotic medications are among the most expensive drugs prescribed to Medicaid recipients. There may be some relief on the way for straining state Medicaid budgets, as several major atypical antipsychotics become

available in generic form.

Already, Zyprexa (olanzapine), has lost its patent protection and in March 2012, both Seroquel IR (quetiapine), and Geodon (ziprasidone) will go off-patent. As generic versions of these drugs enter the market (see sidebar), prices could fall anywhere from 20 to 50 percent or more over the next several years. That could mean big savings not only for Medicaid agencies, but also for patients whose out-of-pocket costs for purchases and co-pays could fall substantially.

"You could see significant savings," says Joe Parks, MD, chair of the NASMHPD Medical Directors Council and chief clinical officer for the Missouri Department of Mental Health. "Psychotropic medications are about a third of most Medicaid pharmacy budgets, so we're talking about big dollars."

Insurers participating in Medicaid Part D plans could also potentially receive a windfall. Reimbursement rates are adjusted retrospectively, meaning they would trail the drop in drug prices, allowing insurers to keep the difference during the first year the prices drop.

Perhaps the only organizations that are not looking forward to 2012 are the pharmaceutical companies that developed these soon-to-be-generic medications. Research firm Decision Resources (Waltham, Mass.) predicts a significant decline in the size of the market for atypical antipsychotics as more generics enter and fewer potential blockbuster medications are introduced.

In the markets covered by their research (the U.S., France, Germany, Italy, Spain, Japan, and the UK), the bipolar disorder drug market is expected to drop from \$6.5 billion in 2010 to just \$4 billion in 2020 (See Figure: Global Market Share). In the United States, the market will drop from \$5.8 billion to \$3.1 billion during that period. Atypical antipsychotics accounted for \$5.3 billion of the total bipolar drug sales in 2010, with Seroquel, Abilify, and Zyprexa leading the market.

More formulary options

Although it could be a while before prices drop (specific generic manufacturers typically get six months of exclusive distribution rights), the introduction of new generics will likely impact managed care formularies and preferred drug lists. In the past, there were only two generic atypicals available (risperidone and clozapine).

"Generics really do present a cost-effective opportunity to treat psychotic patients," says Karen Rhea, MD, Chief Medical Officer at Centerstone in Nashville. "I'm also very interested in seeing the uninsured population have access to atypicals. In Tennessee, many of our state hospital patients are being discharged on older antipsychotics, and this will present an opportunity for that particular population."

Atypical antipsychotics have a range of efficacy for schizophrenia, mania, and bipolar depression, as well as differing levels of common side effects (like weight gain, sedation, and links to cardiac disease and diabetes).

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Having a mix of generics available will make it easier to tailor individual treatment at a lower cost.

"We will have a good balance of choices," says George Oestreich, Pharm.D, MPA, principal at Missouri-based consultancy G.L.O. and Associates. Oestreich was formerly the Deputy Division Director for clinical Services at MO HealthNet, the Missouri Medicaid agency. "The ideal situation is you have one that is a low sedative, one that has a relatively low weight-gain profile, and one that would have a general low metabolic disease process initiating propensity. We're getting pretty close to that with these generics."

Generics move to the front of the line

One potential downside is that with less expensive options available, patients may have to jump through more hoops to receive the best medication for their treatment.

"There is a concern that we would have less access to a wider range of atypicals when there are more generic versions available," Rhea says. "In Tennessee we have a significant number of branded atypicals in our preferred list. For other drugs, there are step therapies, so you have to have a failure, intolerance, or contraindication of two preferred agents before you get to the non-preferred drug."

Once these new generics are widely available, their use will likely balloon fairly quickly. One major atypical antipsychotic, Risperdal (risperidone), went generic in 2008, and it provides a good case study of what could occur in the market over the next two years.

Once Risperdal lost its patent protection, generic penetration in the atypicals market went from three percent in 2008 to more than 25 percent by the end of 2009, according to research published in the journal *Psychiatry* last year. "When you look at state formularies and the managed care approach, they went crazy to include generic risperidone," says William Glazer, MD, president of Glazer Medical Solutions in Key West, Fla. "It went right to the front of the line in formularies."

Because of the risks inherent in treating patients with these agents, most programs provide a significant amount of leeway for prescribers, since several studies have shown that denying access to expensive antipsychotics can increase other medical treatments (including emergency mental health treatment and hospitalization) down the road.

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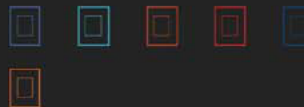


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