

The Need to Preserve Access: Risperdal® and Atypical Antipsychotic Medications

“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.” The National Institute of Mental Health, Jan 2008¹

Atypical Antipsychotic Medications

“Antipsychotics” are a broad class of medications widely used in the treatment of schizophrenia and bipolar disorder. This class includes the “atypical” antipsychotics, which are largely unrelated medications with unique mechanisms of action. These biochemical differences result in important differences in side effects, drug interactions, and different effectiveness for individuals.

For many people, atypical antipsychotics play an important role in their recovery by offering relief from the most debilitating symptoms of mental illness.

Risperdal®

Risperdal® (risperidone) will become available in generic form in June 2008—the first of the newer atypical antipsychotics. For some individuals, this may result in greater affordability.

With pressures to contain costs, state Medicaid agencies may attempt to encourage or require individuals who are on Risperdal® to switch to a generic form. This raises concerns, however, in light of growing reports of serious adverse reactions to some generics, including an FDA news bulletin on a generic form of Wellbutrin XL.²

◆ **NAMI believes that the decision to switch to risperidone should be made by the individual consumer and his or her doctor.**

Some states may also consider proposing troubling policies and preferred drug list changes that restrict access to other atypical antipsychotics as a means to promote greater use of generic versions of Risperdal®.

While some individuals may do well on risperidone, others may not. Because responses to antipsychotics are difficult to predict, persons with mental illnesses

must often try several medications before finding the right treatment match.

Finding the right medication is critical because failure to respond to or tolerate a medication may lead to costly and devastating relapses. A psychotic or manic episode can result in lasting cognitive impairment, emergency department visits, hospitalization—or even homelessness, incarceration, or suicide. Ten percent of individuals with schizophrenia die by suicide. This makes the need to find the right medication for an individual more compelling.

Additionally, many people with schizophrenia do not believe that they are ill, which often reduces their medication adherence. This problem, known as anosognosia, makes medication decisions for this illness more sensitive than for other conditions.

As a result, policies that encourage switching or therapeutic substitution or that impose fail-first and step therapy requirements raise serious health concerns.

Switching

Switching consumers who are doing well on another antipsychotic to risperidone threatens continuity of care and will result in high health costs and poor outcomes.

Nearly half of dual-eligible Medicare Part D patients who were stable but switched to a different psychiatric medication because of plan coverage experienced significant adverse events: 35 percent had an emergency room visit and 15.5 percent were hospitalized.³ The human and medical cost is profound.

◆ **NAMI opposes switching consumers who are stable on another antipsychotic to risperidone.**





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Therapeutic Substitution

Therapeutic substitution programs are designed to encourage pharmacists to switch a consumer from one drug to another that is in the same class, typically to a less expensive medication.

Because the class of antipsychotics is predominantly made up of chemically dissimilar drugs, therapeutic substitution would most often result in receiving a medication with a different active ingredient and different mechanism of action—and different side effects.

Since individuals vary in their responses to an anti-psychotic, typically have other co-occurring conditions, and often live with anosognosia, therapeutic substitution places consumers at considerable health and safety risk and jeopardizes appropriate medication decisions made between a patient and his or her doctor.

- ◆ **NAMI opposes therapeutic substitution of psychiatric medications.**

Fail-First or Step Therapy

Fail-first and step therapy policies require individuals to try, and even fail, on a preferred medication before they are allowed to take a non-preferred medication that may work better for them.

State agencies may seek to impose these policies to promote greater use of a less costly generic, risperidone.

Unlike many medications, side effects of anti-psychotic medications can be extremely serious. These side effects, along with patient characteristics such as presenting symptoms, family history, and comorbid conditions, require multiple options for persons with mental illness.

Given the high stakes involved for persons living with mental illness, fail-first and step therapy policies pose substantial risks. States that choose these policies will be conducting experiments with unknown outcomes on an extremely vulnerable population.

- ◆ **NAMI opposes fail-first and step therapy policies that require individuals to fail on a preferred medication before allowing another medication.**

Summary

Medication tolerance and continuation is often key to successfully treating serious mental illness. Policies that promote access to and continuation of psychiatric medications provide high health value for both individuals and the programs that serve them.

Unique Consumer Characteristics Indicate Need for Shared Physician-Patient Decision Making

- ✓ **Consumer is vulnerable or sensitive to increases in the hormone prolactin.**
Elevations in prolactin can result in sexual side effects and breast enlargement and milk production in both males and females.
- ✓ **Consumer has difficulty sleeping or is experiencing excessive agitation.**
Other atypicals typically produce more sedation than risperidone.
- ✓ **Consumer is on one or more medications that interact with risperidone.**
Certain antidepressants and other medications affect blood levels of risperidone, affecting effectiveness.
- ✓ **Consumer has a history of responsiveness to another atypical antipsychotic or non-responsiveness to risperidone.**
The National Institute of Mental Health reports that genetic variations of the RGS4 gene influence responses to various antipsychotic medications, noting that a medication that works well for one person with schizophrenia often doesn't work well for another.⁴
- ✓ **Consumer is reluctant or unwilling to take risperidone.**
A medication cannot be effective if the consumer does not take it. To maximize good outcomes, consumer input must be valued in clinical decision making. In addition, some individuals with serious mental illness do not believe that they are ill and may discontinue or refuse to take medications. Therefore, if they are willing to take a particular medication in a class, it is critical that it is available to them and to their doctor without restrictions.

1 National Institutes of Health, National Institute of Mental Health, "Ethnicity Predicts How Gene Variations Affect Response to Schizophrenia Medications," *Science Update*, January 2, 2008.

2 FDA News Drug Daily Bulletin, "Generic Wellbutrin Called into Question," October 22, 2007, Vol. 4 No. 207.

3 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.

4 National Institutes of Health, National Institute of Mental Health, "Ethnicity Predicts How Gene Variations Affect Response to Schizophrenia Medications," *Science Update*, January 2, 2008.