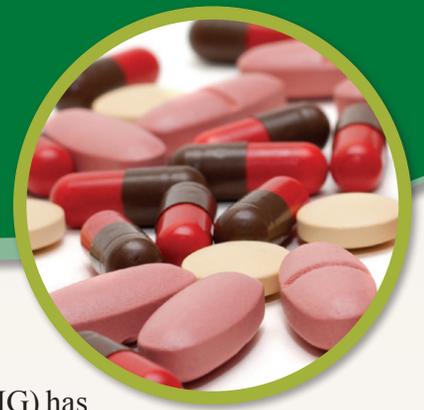


Atypical Antipsychotic Medications: Use in Adults



The Centers for Medicare & Medicaid Services (CMS) Medicaid Integrity Group (MIG) has identified issues with the utilization of the atypical antipsychotic drug therapy class. The U.S. Food and Drug Administration (FDA) approves product labeling for prescription drugs. The MIG has identified that some providers may have prescribed atypical antipsychotics outside of FDA-approved product labeling for indication, age, dosage, or duration of therapy. Therefore, CMS's goal is to improve quality of care and enhance patient safety by educating providers on the proper use of atypical antipsychotics in adults.

This fact sheet summarizes for providers the current FDA-approved product labeling for the use of atypical antipsychotic medications in adults. After reading this document, the provider should be able to accurately:

- Describe the FDA-approved indications for the use of atypical antipsychotics in adult patients;
- Formulate treatment regimens that comply with FDA-approved product labeling; and
- Describe the adverse reactions and risks associated with atypical antipsychotic therapy in adult patients.

FDA-Approved Indications for Atypical Antipsychotic Medications in Adults

Atypical antipsychotics, or second-generation antipsychotics (SGAs), are dopamine receptor antagonists that may also antagonize norepinephrine and serotonin (5-HT) receptors to varying degrees. The FDA-approved adult indications for atypical antipsychotics are summarized in Table 1. The FDA-approved adult indications and dosages for atypical antipsychotics are provided in the document “Atypical Antipsychotics: U.S. Food and Drug Administration-Approved Indications and Dosages for Use in Adults.”



Table 1. FDA-Approved Adult Indications for Atypical Antipsychotics

Indications	Atypical Antipsychotics
bipolar I disorder	aripiprazole,[1] asenapine,[2] olanzapine,[3] quetiapine,[4] quetiapine extended-release (XR),[5] risperidone,[6] ziprasidone[7]
schizophrenia	aripiprazole, asenapine, clozapine,[8, 9] iloperidone,[10] lurasidone,[11] olanzapine, paliperidone,[12] quetiapine, quetiapine XR, risperidone, ziprasidone
schizoaffective disorder	clozapine, paliperidone
major depressive disorder (MDD), adjunct	aripiprazole, olanzapine, quetiapine XR

Treatment Guidelines for the Use of Atypical Antipsychotics in Adults

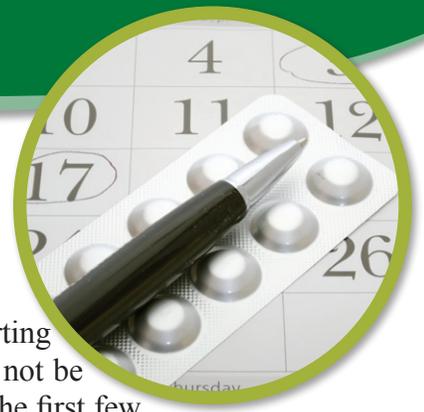
The Agency for Healthcare Research and Quality (AHRQ) hosts a database of treatment guidelines. Please search “atypical antipsychotics,” or any of the conditions for which an atypical antipsychotic is an indicated treatment, in the AHRQ’s National Guideline Clearinghouse at <http://www.guideline.gov> for information on the available treatment guidelines. Links to some of the guidelines that provide information on the use of atypical antipsychotics in adults are provided in Table 2.

Table 2. Treatment Guidelines for the Use of Atypical Antipsychotics in Adults

Sponsoring Organization	Title of Guideline	Link to Guideline
American Psychiatric Association	Practice guideline for the treatment of patients with schizophrenia. Second edition.	http://www.guideline.gov/content.aspx?id=5217
Department of Veterans Affairs, Department of Defense	VA/DoD clinical practice guideline for management of bipolar disorder in adults.	http://www.guideline.gov/content.aspx?id=16314

The Schizophrenia Patient Outcomes Research Team (PORT) has published treatment recommendations for the use of atypical antipsychotics by patients with schizophrenia. Information on the PORT recommendations can be found at <http://www.ahrq.gov/clinic/schzrec.htm> on the AHRQ website.[13]





Time to Symptom Improvement with an Atypical Antipsychotic

Many patients will experience relief of some symptoms within a few days of starting treatment with an atypical antipsychotic, but the full effects of the medication may not be seen for up to six weeks. Agitation and hallucinations are typically relieved during the first few days of treatment, but it may take weeks for delusions to subside. Every patient responds differently to antipsychotic therapy, so it may take several trials of different antipsychotic medications to find the one that works best.[14] The titration schedule of the medication may also influence the length of time it takes to see symptom improvement: a medication that takes two weeks to reach the recommended dose may require a longer trial than a medication that takes less than a week to reach the recommended dose.

If a patient does not achieve the desired clinical response, the dose of the atypical antipsychotic may need to be increased or the medication may need to be changed to a different antipsychotic medication. Treatment guidelines can provide guidance when a change in therapy is warranted. Factors for switching medication therapy include:

- Lack of efficacy;
- Lack of improvement in negative symptoms;
- Presence of extrapyramidal side effects (EPS) or adverse reactions impacting adherence to therapy; and
- Cost of therapy.

If a patient does not achieve the desired clinical response, patient adherence to therapy should be assessed prior to increasing dosage, switching to a different antipsychotic, or prescribing an additional medication. If the patient has had trouble complying with treatment in the past, a long-acting injectable medication may be the best option. The patient should still be evaluated for symptom improvement during the effective duration of the long-acting injectable medication to assess its efficacy.

Off-Label Use of Atypical Antipsychotics in Adults

An AHRQ report titled “Efficacy and Comparative Effectiveness of Off-Label Use of Atypical Antipsychotics” was published in 2007.[15] In September 2011, the AHRQ released an update titled “Off-Label Use of Atypical Antipsychotics: An Update.”[16] After the 2007 report was published, studies for off-label indications were published and previous off-label indications were approved by the FDA. Safety and efficacy were evaluated, and a summary of the findings for each off-label indication is provided in the 2011 update. Links to the 2007 report and the 2011 update are available at <http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=778&PCem=EN> on the AHRQ website.

ACRONYMS

5-HT	serotonin
AHRQ	Agency for Healthcare Research and Quality
ANC	absolute neutrophil count
APA	American Psychiatric Association
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CMS	Centers for Medicare & Medicaid Services
DoD	Department of Defense
EPS	extrapyramidal side effects
FDA	U.S. Food and Drug Administration
MDD	major depressive disorder
MIG	Medicaid Integrity Group
NCHS	National Center for Health Statistics
NIH	National Institutes of Health
OTC	over the counter
PORT	Patient Outcomes Research Team
SGA	second-generation antipsychotic
VA	Department of Veterans Affairs
WBC	white blood cell

Adverse Reactions and Risks of the Use of Atypical Antipsychotics in Adults

Patients should be made aware of the risks of taking an atypical antipsychotic prior to initiating therapy. Because atypical antipsychotic medications are associated with significant weight gain and metabolic changes, a baseline weight, blood glucose level, and lipid panel should be established and then monitored.[17] Other common adverse reactions are:

- Drowsiness;
- Orthostatic hypotension;
- Tachycardia;
- Menstrual problems;
- Blurred vision;
- Sun sensitivity; and
- Skin rash.[18]

Risk of Suicidality

The atypical antipsychotics aripiprazole, olanzapine, quetiapine, and quetiapine XR are FDA approved for the treatment of depression episodes in bipolar I disorder or as adjunctive treatment for MDD. Antidepressant medications have been shown to increase the risk of suicidal thinking and behavior. In a pooled-analysis of short-term, placebo-controlled trials of nine antidepressant medications, patients taking an antidepressant had twice the risk of suicidality in the first few months of treatment than those taking placebo. The long-term risk is unknown. As a result of this analysis, a boxed warning was added to all antidepressant medications since the risk was not confined to one class of antidepressants.[19]

The boxed warning for aripiprazole, quetiapine, and olanzapine (when used in combination with fluoxetine) states:[20]

SUICIDALITY AND ANTIDEPRESSANT DRUGS

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of [Insert established name] or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber.

The FDA requires that a Medication Guide be provided with each prescription for aripiprazole, olanzapine, quetiapine, and quetiapine XR to alert patients to the risk of suicidal thinking and behavior. Each Medication Guide includes information on precautions that may be taken. Links to the required Medication Guides can be found at <http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> on the FDA website.

Use in Elderly Patients with Dementia

In 2005, the FDA issued a public health advisory to alert consumers and providers that atypical antipsychotics have been associated with increased mortality when used to treat behavioral disorders in elderly patients with dementia. The advisory states: “Of a total of seventeen placebo controlled trials performed with olanzapine (Zyprexa®), aripiprazole (Abilify®), risperidone (Risperdal®), or quetiapine (Seroquel®) in elderly demented patients with behavioral disorders, fifteen showed numerical increases in mortality in the drug-treated group compared to the placebo-treated patients. These studies enrolled a total of 5,106 patients, and several analyses have demonstrated an approximately 1.6 to 1.7 fold increase in mortality in these studies. Examination of the specific causes of these deaths revealed that most were either due to heart related events (e.g., heart failure, sudden death) or infections (mostly pneumonia).”[21] None of the atypical antipsychotic medications are FDA approved for this indication. A “Boxed Warning” has been added to product labeling to describe this increased risk of mortality and to note that atypical antipsychotics are not approved for this indication.[22]

The boxed warning for all atypical antipsychotic medications, including clozapine, states:[23]

**WARNINGS: INCREASED MORTALITY IN ELDERLY PATIENTS WITH
DEMENTIA-RELATED PSYCHOSIS**

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. [Established medication name] is not approved for the treatment of patients with dementia-related psychosis.

Risk of Serious Allergic Reactions with Asenapine

On September 1, 2011, the FDA published a Drug Safety Communication to alert the public to the risk of serious allergic reactions with asenapine. The allergic reactions are Type I hypersensitivity reactions that may include anaphylaxis, angioedema, difficulty breathing, hypotension, rash, swollen tongue, tachycardia, or wheezing. Patients should be counseled on the signs and symptoms of an allergic reaction, and should be instructed to seek immediate medical attention if signs or symptoms occur.[24]

Post-Injection Delirium and Sedation with Olanzapine Pamoate Injection

Olanzapine pamoate injection is a long-acting atypical antipsychotic. It has been associated with delirium and sedation, typically seen in a patient with an olanzapine overdose. Because of the severity of this potential adverse reaction, olanzapine pamoate injection may only be given in a registered healthcare facility, is only available through a restricted distribution program, and may not be dispensed directly to the patient.

The boxed warning for olanzapine pamoate injection states:[25]

WARNING: POST-INJECTION DELIRIUM/SEDATION SYNDROME

Post-Injection Delirium/Sedation Syndrome—Adverse events with signs and symptoms consistent with olanzapine overdose, in particular, sedation (including coma) and/or delirium, have been reported following injections of ZYPREXA RELPREVV. ZYPREXA RELPREVV must be administered in a registered healthcare facility with ready access to emergency response services. After each injection, patients must be observed at the healthcare facility by a healthcare professional for at least 3 hours. Because of this risk, ZYPREXA RELPREVV is available only through a restricted distribution program called ZYPREXA RELPREVV Patient Care Program and requires prescriber, healthcare facility, patient, and pharmacy enrollment [see Dosage and Administration (2.1), Warnings and Precautions (5.1, 5.2), Overdosage (10.2), and Patient Counseling Information (17.2)].

Clozapine Warnings

Clozapine has been associated with agranulocytosis, seizures, myocarditis, and orthostatic hypotension. It has also been linked to respiratory arrest and cardiac arrest in patients taking benzodiazepines or other psychotropic drugs. The FDA-required boxed warnings for clozapine address these serious adverse reactions.[26, 27]

The boxed warning for all clozapine products states:[28]

BOXED WARNING

1. Agranulocytosis

Because of a significant risk of agranulocytosis, a potentially life-threatening adverse event, CLOZARIL® (clozapine) should be reserved for use in (1) the treatment of severely ill patients with schizophrenia who fail to show an acceptable response to adequate courses of standard antipsychotic drug treatment, or (2) for reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder who are judged to be at risk of reexperiencing suicidal behavior.

Patients being treated with clozapine must have a baseline white blood cell (WBC) count and absolute neutrophil count (ANC) before initiation of treatment as well as regular WBC counts and ANCs during treatment and for at least 4 weeks after discontinuation of treatment (see WARNINGS).

Clozapine is available only through a distribution system that ensures monitoring of WBC count and ANC according to the schedule described below prior to delivery of the next supply of medication (see WARNINGS).

2. Seizures

Seizures have been associated with the use of clozapine. Dose appears to be an important predictor of seizure, with a greater likelihood at higher clozapine doses. Caution should be used when administering clozapine to patients having a history of seizures or other predisposing factors. Patients should be advised not to engage in any activity where sudden loss of consciousness could cause serious risk to themselves or others. (see WARNINGS.)

3. Myocarditis

Analyses of postmarketing safety databases suggest that clozapine is associated with an increased risk of fatal myocarditis, especially during, but not limited to, the first month of therapy. In patients in whom myocarditis is suspected, clozapine treatment should be promptly discontinued. (see WARNINGS.)

4. Other Adverse Cardiovascular and Respiratory Effects

Orthostatic hypotension, with or without syncope, can occur with clozapine treatment. Rarely, collapse can be profound and be accompanied by respiratory and/or cardiac arrest. Orthostatic hypotension is more likely to occur during initial titration in association with rapid dose escalation. In patients who have had even a brief interval off clozapine, i.e., 2 or more days since the last dose, treatment should be started with 12.5 mg once or twice daily. (See WARNINGS and DOSAGE AND ADMINISTRATION.)

Since collapse, respiratory arrest and cardiac arrest during initial treatment has occurred in patients who were being administered benzodiazepines or other psychotropic drugs, caution is advised when clozapine is initiated in patients taking a benzodiazepine or any other psychotropic drug. (see WARNINGS.)

Due to the increased risk of agranulocytosis in a patient treated with clozapine, manufacturers of clozapine are required by the FDA to maintain a clozapine registry to monitor a patient’s white blood cell (WBC) count and absolute neutrophil count (ANC) throughout the course of treatment with clozapine. Novartis, the manufacturer of Clozaril®, is also responsible for maintaining a “non-rechallenge database” for patients who should not be rechallenged with clozapine due to the increased health risks associated with the medication. Manufacturers of generic clozapine must cross-reference a patient’s name against the non-rechallenge database and must provide information about a patient who should be added to this database.[29] Links to the clozapine registries are provided in Table 3.

Table 3. Links to Clozapine Registries

Medication	Manufacturer	Link to Registry
Clozaril®	Novartis International AG	http://www.clozaril.com/hcp/tools/pdf/tsr_kit.pdf
FazaClo®	AzurPharma, Ltd.	https://www.fazacloregistry.com
clozapine	Caraco Pharmaceutical Laboratories, Ltd.	https://www.caracoclozapine.com
clozapine	Mylan Pharmaceuticals Inc.	http://www.mylan-clozapine.com
clozapine	Teva Pharmaceuticals USA	http://www.clozapineregistry.com

Resources

Please visit <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-State/By-State.html> for links to State Medicaid program websites.

The Center for Drug Evaluation and Research (CDER) hosts a website providing health professionals with current information on over-the-counter (OTC) and prescription drugs. Visit <http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals> to access drug-related databases, information on drug recalls and alerts, current information on new and generic drug approvals, and information on drug safety and availability.

Section 1927(g)(1)(B) of the Social Security Act identifies the predetermined standards that the State’s drug use review program must use to assess data on drug use. Visit http://www.ssa.gov/OP_Home/ssact/title19/1927.htm for information on the compendia.

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- 5 Seroquel XR® (quetiapine extended-release) prescribing information. (2010, December). Retrieved April 14, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022047s025lbl.pdf
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