

Pharmacy Policy Bulletin

Category: Managed Rx Coverage
Number: J-307
Subject: Atypical Antipsychotics
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NOTE: *This version of the policy is effective 9/1/2010, the previous version is effective up to 8/31/20. Please click version 002 of J-307 below for more details.*

Policy Applies to: *Commercial Plans.*

Agents addressed in this policy: Abilify (aripiprazole), Symbyax (olanzapine & fluoxetine), Seroquel XR (quetiapine)

Background:

Antipsychotics are used to treat a myriad of mental health conditions. There are two categories of antipsychotics, first generation or typical antipsychotics and second generation or atypical antipsychotics. Typical antipsychotics (e.g, chlorpromazine) exhibit a high incidence of adverse reactions such as extrapyramidal signs (EPS) and tardive dyskinesia at clinically effective doses. Atypical antipsychotics (e.g. quetiapine, risperidone, olanzapine) may exhibit adverse reactions mentioned above but the incidence is much less often.

It is important that both classes of drugs are utilized in appropriate patient populations. The US Food and Drug Administration has required manufacturers of all antipsychotic drugs to add a boxed warning to the drugs' prescribing information about the risk of mortality in elderly patients treated for dementia-related psychosis.

Abilify (aripiprazole) is an atypical antipsychotic that is approved for the treatment of schizophrenia, bipolar mania, and as adjunctive treatment of major depressive disorder (MDD). The mechanism of action is unknown but it has been proposed that aripiprazole acts as a partial agonist against D2 and 5-HT1A receptors and antagonist activity at 5-HT2A receptors.

Symbyax combines an atypical antipsychotic (olanzapine) with a selective serotonin reuptake inhibitor (fluoxetine) into one dosage form and is indicated for the acute treatment of depressive episodes associated with Bipolar I Disorder in adults and for the acute treatment of treatment-resistant depression, defined as Major Depressive Disorder in adults who do not respond to 2 separate trials of different antidepressants of adequate dose and duration in the current episode.

Seroquel XR is a dibenzothiazepine antipsychotic agent that is approved for the management of bipolar disorder, schizophrenia and as adjunctive treatment for major depressive disorder in adults who do not respond to an antidepressant alone over a duration of 6 weeks.

Approval Criteria: When a benefit, coverage for Abilify, Symbyax or Seroquel XR will be approved when one of the following criteria

are met:

1. The member as at least one (1) paid claim from the following categories within the past 12 months: a) mood stabilizers (e.g. Lithium) OR b) antipsychotics (e.g. Haldol, Risperidone, Seroquel etc) **OR**
2. The member has a least one paid claim for two (2) different antidepressants (e.g. SNRI, SSRI, TCA) including an active claim for 1 antidepressant within the past 12 months. **OR**
3. The member has a previous claim for Abilify, Symbyax or Seroquel XR within the last 180 days.

Members who meet criteria as outlined above will receive automatic authorization at the point of service without documentation of additional information. Claims will adjudicate automatically online.

For members who do not meet the criteria above, the dispensing pharmacist will be prompted that a prior authorization is required.

Prior authorization requests will be approved if members meet the following criteria:

1. Abilify, Symbyax or Seroquel XR is being prescribed as adjunctive treatment of major depressive disorder in adults (> 18 years old) **AND**
2. The member has tried and failed at least 1 other agent used for treatment of major depressive disorder **OR**
3. The member has a diagnosis of schizophrenia **OR**
4. The member has a diagnosis of bipolar disorder **OR**
5. The member has a diagnosis of autism spectrum disorder.

Coverage of these specific drug products for disease states outside of those listed above should be denied based on the lack of clinical data to support their effectiveness and safety in such conditions.

For members with a closed (Select) formulary, Abilify (aripiprazole), Symbyax (olanzapine/fluoxetine) and Seroquel XR (quetiapine) will only be approved if the member has tried and failed at least two (2) other formulary alternatives in addition to meeting the criteria outlined within this policy.

Duration of Authorization:

If approved, authorization should be granted for up to one year.

References:

1. Abilify [package insert]. Research Triangle Park, NC: GlaxoSmithKline; November 2008.
2. Symbyax [package insert]. Indianapolis, IN: Eli Lilly and Company; March 2009.
3. Seroquel XR [package insert]. Wilmington, DE: AstraZeneca; December 2009
4. Marcus RN, McQuade RD, Carson WH, et al. The efficacy and safety of aripiprazole as adjunctive therapy in major depressive disorder: a second multicenter, randomized, double-blind, placebo controlled study. J Clin Psychopharmacol. 2008 Apr; 28(2): 156-65.
5. American Psychiatric Association. Practice Guidelines for the treatment of patients with schizophrenia. 2nd ed. Arlington (VA): American Psychiatric Association; Available at: http://www.guideline.gov/summary.aspx?doc_id=3302
6. U.S. Food and Drug Administration. Information for Healthcare Professionals Antipsychotics. Available at: http://www.fad.gov/cder/drug/InfoSheets/HCP/antipsychotics_convential.htm
7. Berman RM, Marcus RN, Swanink R et al. The efficacy and safety of aripiprazole as adjunctive therapy in major depressive disorder: a multicenter randomized double- blind, placebo- controlled study. J Clin Psychiatry. 2007 Jun; 68(6): 843-53.

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[\[Version 002 of J-307\]](#)

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