## PRIOR AUTHORIZATION CRITERIA

<table>
<thead>
<tr>
<th>DRUG CLASS</th>
<th>ATYPICAL ANTIPSYCHOTICS</th>
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</thead>
<tbody>
<tr>
<td>BRAND NAME (generic)</td>
<td>ABILIFY (aripiprazole)</td>
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<td>ABILIFY MAINTENA (aripiprazole injection)</td>
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<td>FANAPT (iloperidone)</td>
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<td>INVEGA (paliperidone)</td>
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<td>INVEGA SUSTENNA (paliperidone injection)</td>
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<td>LATUDA (lurasidone)</td>
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<td>REXULTI (brexpiprazole)</td>
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<td>RISPERDAL CONSTA (risperidone injection)</td>
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<td>SAPHRIS (asenapine)</td>
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<td>SEROQUEL XR (quetiapine)</td>
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<td>VRAYLAR (cariprazine)</td>
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**Status:** CVS Caremark Criteria  
**Type:** Initial Prior Authorization

## POLICY

**FDA APPROVED INDICATIONS**  
Abilify  
Abilify Oral Tablets and Oral Solution are indicated for the treatment of:  
- Schizophrenia  
- Acute Treatment of Manic and Mixed Episodes associated with Bipolar I Disorder  
- Adjunctive Treatment of Major Depressive Disorder  
- Irritability Associated with Autistic Disorder
• Treatment of Tourette’s Disorder

Abilify Maintena
Abilify Maintena (aripiprazole) is indicated for the treatment of schizophrenia. Efficacy was demonstrated in a placebo-controlled, randomized-withdrawal maintenance trial in patients with schizophrenia and additional support for efficacy was derived from oral aripiprazole trials.

Fanapt
Fanapt tablets are indicated for the treatment of adults with schizophrenia. Efficacy was established in two short-term (4- and 6-week) placebo- and active-controlled studies of adult patients with schizophrenia.

Invega
Schizophrenia
Invega (paliperidone) Extended-Release Tablets are indicated for the treatment of schizophrenia. The efficacy of Invega in schizophrenia was established in three 6-week trials in adults and one 6-week trial in adolescents, as well as one maintenance trial in adults.

Schizoaffective Disorder
Invega (paliperidone) Extended-Release Tablets are indicated for the treatment of schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers and/or antidepressant therapy. The efficacy of Invega in schizoaffective disorder was established in two 6-week trials in adults.

Invega Sustenna
Invega Sustenna (paliperidone palmitate) is indicated for the treatment of schizophrenia. Efficacy was established in four short-term studies and one longer-term study in adults.

Latuda
Schizophrenia
Latuda is indicated for the treatment of patients with schizophrenia. The efficacy of Latuda in schizophrenia was established in five 6-week controlled studies of adult patients with schizophrenia. The effectiveness of Latuda for longer-term use, that is, for more than 6 weeks, has not been established in controlled studies. Therefore, the physician who elects to use Latuda for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

Depressive Episodes Associated with Bipolar I Disorder
Monotherapy: Latuda is indicated as monotherapy for the treatment of patients with major depressive episodes associated with bipolar I disorder (bipolar depression). The efficacy of Latuda was established in a 6-week monotherapy study in adult patients with bipolar depression.

Adjunctive Therapy with Lithium or Valproate: Latuda is indicated as adjunctive therapy with either lithium or valproate for the treatment of patients with major depressive episodes associated with bipolar I disorder (bipolar depression). The efficacy of Latuda as adjunctive therapy was established in a 6-week study in adult patients with bipolar depression who were treated with lithium or valproate.

Rexulti
Rexulti is indicated for:
- Adjunctive treatment of major depressive disorder (MDD)
- Treatment of schizophrenia

Major Depressive Disorder
Rexulti is indicated for adjunctive treatment of MDD. The efficacy of Rexulti was established in two six-week trials in adults.

Schizophrenia
Rexulti is indicated for treatment of schizophrenia. The efficacy of Rexulti was established in two six-week trials in adults.

Risperdal Consta
Schizophrenia
Risperdal Consta (risperidone) is indicated for the treatment of schizophrenia.

Bipolar Disorder
Risperdal Consta is indicated as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of Bipolar I Disorder.
Saphris
Saphris is indicated for:
- Schizophrenia
- Acute treatment of manic or mixed episodes associated with Bipolar I disorder as monotherapy or adjunctive treatment to lithium or valproate

Schizophrenia
Saphris is indicated for the treatment of schizophrenia. The efficacy of Saphris was established in two 6-week trials and one maintenance trial in adults.

Bipolar Disorder
Monotherapy: Saphris is indicated for the acute treatment of manic or mixed episodes associated with bipolar I disorder. Efficacy was established in two 3-week monotherapy trials in adults.
Adjunctive Therapy: Saphris is indicated as adjunctive therapy with either lithium or valproate for the acute treatment of manic or mixed episodes associated with bipolar I disorder. Efficacy was established in one 3-week adjunctive trial in adults.

Seroquel XR
Schizophrenia
Seroquel XR is indicated for the treatment of schizophrenia. The efficacy of Seroquel XR in schizophrenia was established in one 6-week and one maintenance trial in adults with schizophrenia as well by extrapolation from three 6-week trials in adults with schizophrenia treated with Seroquel.

Bipolar Disorder
Seroquel XR is indicated for the acute treatment of manic or mixed episodes associated with bipolar I disorder, both as monotherapy and as an adjunct to lithium or divalproex. The efficacy of Seroquel XR in manic or mixed episodes of bipolar I disorder was established in one 3-week trial in adults with manic or mixed episodes associated with bipolar I disorder as well by extrapolation from two 12-week monotherapy and one 3-week adjunctive trial in adults with manic episodes associated with bipolar I disorder treated with Seroquel.
Seroquel XR is indicated for the acute treatment of depressive episodes associated with bipolar disorder. The efficacy of Seroquel XR was established in one 8-week trial in adults with bipolar I or II disorder as well as extrapolation from two 8-week trials in adults with bipolar I or II disorder treated with Seroquel.
Seroquel XR is indicated for the maintenance treatment of bipolar I disorder, as an adjunct to lithium or divalproex. Efficacy was extrapolated from two maintenance trials in adults with bipolar I disorder treated with Seroquel. The effectiveness of monotherapy for the maintenance treatment of bipolar disorder has not been systematically evaluated in controlled clinical trials.

Adjuventive Treatment of Major Depressive Disorder (MDD)
Seroquel XR is indicated for use as adjunctive therapy to antidepressants for the treatment of MDD. The efficacy of Seroquel XR as adjunctive therapy to antidepressants in MDD was established in two 6-week trials in adults with MDD who had an inadequate response to antidepressant treatment.

Vraylar
Treatment of schizophrenia.
The efficacy of Vraylar for the treatment of schizophrenia was established in three, 6-week, randomized, double-blind, placebo-controlled trials.

Acute treatment of manic or mixed episodes associated with bipolar I disorder.
The efficacy of Vraylar in the acute treatment of bipolar mania was established in three, 3-week placebo-controlled trials.

COVERAGE CRITERIA
Atypical antipsychotics will be covered with prior authorization when the following criteria are met:
- Patient is using the requested drug for an FDA-Approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines).
  AND
  - The request is for oral forms of Abilify or Rexulti AND the patient unable to take generic risperidone OR olanzapine due to inadequate treatment response, intolerance, or contraindication
  OR
  - The patient unable to take at least two generic atypical antipsychotics due to inadequate treatment response, intolerance, or contraindication
OR
  o Patient has a clinical condition for which there is no generic alternative or the generic alternatives are not recommended based on published guidelines or clinical literature.

OR
  o The patient requires use of a specific dosage form that is not available in the generic alternatives (examples: suspension, solution, injection).

REFERENCES