CareFirst Family of health care plans

CVS caremark™

STEP THERAPY CRITERIA

DRUG CLASS PRODUCTS)	**ATYPICAL ANTIPSYCHOTICS (BRAND ONLY**
BRAND NAME (BRAND ONLY)	**ABILIFY (ORAL TABLET & ORAL SOLUTION ONLY)**
(generic)	**(aripiprazole)**
	FANAPT (BRAND ONLY) (iloperidone)
	GEODON (BRAND ONLY) (ziprasidone)
	INVEGA (ORAL TABLET) (BRAND ONLY) (paliperidone)
	LATUDA (BRAND ONLY) (lurasidone hydrochloride)
	REXULTI (BRAND ONLY) (brexpiprazole)
	SAPHRIS (BRAND ONLY) (asenapine)
	SEROQUEL, SEROQUEL XR (BRAND ONLY) (quetiapine)
	VRAYLAR (BRAND ONLY) (cariprazine)

Status: CVS Caremark Criteria
Type: Initial Step Therapy; Post Step Therapy Prior Authorization ***Ref # 657-D***

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

Fanapt
Fanapt tablets are indicated for the treatment of schizophrenia in adults. When deciding among the alternative treatments available for this condition, the prescriber should consider the finding that Fanapt is associated with prolongation of the QTc interval. Prolongation of the QTc interval is associated in some other drugs with the ability to cause torsade de pointes-type arrhythmia, a potentially fatal polymorphic ventricular tachycardia which can result in sudden death. In many cases this would lead to the conclusion that other drugs should be tried first. Whether Fanapt will cause torsade de pointes or increase the rate of sudden death is not yet known. Patients must be titrated to an effective dose of Fanapt. Thus, control of symptoms may be delayed during the first 1 to 2 weeks of treatment compared to some other antipsychotic drugs that do not require a similar titration. Prescribers should be mindful of this delay when selecting an antipsychotic drug for the treatment of schizophrenia.

Geodon
Geodon is indicated for the treatment of schizophrenia, as monotherapy for the acute treatment of bipolar manic or mixed episodes, and as an adjunct to lithium or valproate for the maintenance treatment of bipolar disorder. Geodon intramuscular is indicated for acute agitation in schizophrenic patients. When deciding among the alternative treatments available for the condition needing treatment, the prescriber should consider the finding of ziprasidone's greater capacity to prolong the QT/QTc interval compared to several other antipsychotic drugs. Prolongation of the QTc interval is associated in some other drugs with the ability to cause torsade de pointes-type arrhythmia, a potentially fatal polymorphic ventricular tachycardia, and sudden death. In many cases this would lead to the conclusion that other drugs should be tried first. Whether ziprasidone will cause torsade de pointes or increase the rate of sudden death is not yet known.
Schizophrenia
Geodon is indicated for the treatment of schizophrenia. The efficacy of oral ziprasidone was established in four short-term (4-week and 6-week) controlled trials of adult schizophrenic inpatients and in one maintenance trial of stable adult schizophrenic inpatients.
Bipolar I Disorder
Geodon is indicated as monotherapy for the acute treatment of manic or mixed episodes associated with bipolar I disorder. Efficacy was established in two 3-week monotherapy studies in adult patients.
Geodon is indicated as an adjunct to lithium or valproate for the maintenance treatment of bipolar I disorder. Efficacy was established in a maintenance trial in adult patients. The efficacy of Geodon as monotherapy for the maintenance treatment of bipolar I disorder has not been systematically evaluated in controlled clinical trials.
Acute Treatment of Agitation in Schizophrenia
Geodon intramuscular is indicated for the treatment of acute agitation in schizophrenic patients for whom treatment with ziprasidone is appropriate and who need intramuscular antipsychotic medication for rapid control of agitation. The efficacy of intramuscular ziprasidone for acute agitation in schizophrenia was established in single day controlled trials of agitated schizophrenic inpatients. "Psychomotor agitation" is defined in DSM-IV as "excessive motor activity associated with a feeling of inner tension." Schizophrenic patients experiencing agitation often manifest behaviors that interfere with their diagnosis and care, e.g., threatening behaviors, escalating or urgently distressing behavior, or self-exhausting behavior, leading clinicians to the use of intramuscular antipsychotic medications to achieve immediate control of the agitation.
Since there is no experience regarding the safety of administering ziprasidone intramuscular to schizophrenic patients already taking oral ziprasidone, the practice of co-administration is not recommended.
Ziprasidone intramuscular is intended for intramuscular use only and should not be administered intravenously.

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 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.

Latuda

Latuda is indicated for:

- Treatment of adult and adolescent patients age 13 to 17 years with schizophrenia
- Monotherapy treatment of adult patients with major depressive episodes associated with bipolar I disorder (bipolar depression)
- Adjunctive treatment with lithium or valproate in adult patients with major depressive episodes associated with bipolar I disorder (bipolar depression)

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.

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. The efficacy of Latuda in the treatment of mania associated with bipolar disorder has not been established.

Rexulti

Rexulti is indicated for:

- Adjunctive treatment of major depressive disorder (MDD)
- Treatment of schizophrenia

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
- Maintenance monotherapy treatment in Bipolar I disorder

Seroquel

Schizophrenia

Seroquel is indicated for the treatment of schizophrenia. The efficacy of Seroquel in schizophrenia was established in three 6-week trials in adults and one 6–week trial in adolescents (13–17 years). The effectiveness of Seroquel for the maintenance treatment of schizophrenia has not been systematically evaluated in controlled clinical trials.

Bipolar Disorder

Seroquel is indicated for the acute treatment of manic episodes associated with bipolar I disorder, both as monotherapy and as an adjunct to lithium or divalproex. Efficacy was established in two 12-week monotherapy trials in adults, in one 3-week adjunctive trial in adults, and in one 3-week monotherapy trial in pediatric patients (10-17 years).

Seroquel is indicated as monotherapy for the acute treatment of depressive episodes associated with bipolar disorder. Efficacy was established in two 8-week monotherapy trials in adult patients with bipolar I and bipolar II disorder.
Seroquel is indicated for the maintenance treatment of bipolar I disorder, as an adjunct to lithium or divalproex. Efficacy was established in two maintenance trials in adults. The effectiveness of Seroquel as monotherapy for the maintenance treatment of bipolar disorder has not been systematically evaluated in controlled clinical trials.
Special Considerations in Treating Pediatric Schizophrenia and Bipolar I Disorder
Pediatric schizophrenia and bipolar I disorder are serious mental disorders, however, diagnosis can be challenging. For pediatric schizophrenia, symptom profiles can be variable, and for bipolar I disorder, patients may have variable patterns of periodicity of manic or mixed symptoms. It is recommended that medication therapy for pediatric schizophrenia and bipolar I disorder be initiated only after a thorough diagnostic evaluation has been performed and careful consideration given to the risks associated with medication treatment. Medication treatment for both pediatric schizophrenia and bipolar I disorder is indicated as part of a total treatment program that often includes psychological, educational and social interventions.

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. Efficacy was supported by three 6-week trials in adults with schizophrenia and one 6-week trial in adolescents with schizophrenia (13-17 years) 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 . Efficacy was supported by two 12-week monotherapy trials and one 3-week adjunctive trial in adults with manic epsidoes associated with bipolar I disorder as well as one 3-week monotherapy trial in children and adolescents (10-17 years) 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 and supported by 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 I disorder has not been systematically evaluated in controlled clinical trials.
Adjunctive 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.
Special Considerations in Treating Pediatric Schizophrenia and Bipolar I Disorder
Pediatric schizophrenia and bipolar I disorder are serious mental disorders, however, diagnosis can be challenging. For pediatric schizophrenia, symptom profiles can be variable, and for bipolar I disorder, patients may have variable patterns of periodicity of manic or mixed symptoms. It is recommended that medication therapy for pediatric schizophrenia and bipolar I disorder be initiated only after a thorough diagnostic evaluation has been performed and careful consideration given to the risks associated with medication treatment. Medication treatment for both pediatric schizophrenia and bipolar I disorder is indicated as part of a total treatment program that often includes psychological, educational and social interventions.

Vraylar
Vraylar is indicated for:

- Treatment of schizophrenia
- Acute treatment of manic or mixed episodes associated with bipolar I disorder

INITIAL STEP THERAPY

If the patient has filled a prescription for a 30 day supply of aripiprazole, olanzapine, paliperidone, risperidone, quetiapine (regular or extended release), or ziprasidone within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- Patient is currently taking the prescribed medication with evidence of improvement.
  OR
- Patient has experienced an inadequate treatment response to aripiprazole, olanzapine, paliperidone, risperidone (any dosage form), quetiapine (regular or extended release), or ziprasidone after a trial of at least 30 days.
  OR
- Patient has an intolerance, drug interaction, or contraindication to aripiprazole, olanzapine, paliperidone, risperidone (any dosage form), quetiapine (regular or extended release), or ziprasidone that would prohibit a 30 day trial.
  OR
- 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.

REFERENCES

1. Abilify [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; February 2017.
2. Fanapt [package insert]. Washington, DC: Vanda Pharmaceuticals; February 2017.
3. Geodon [package insert]. New York, NY: Pfizer/Roerig; August 2015.
4. Invega [package insert]. Titusville, NJ: Ortho-Mc-Neil-Janssen Pharmaceuticals, Inc.; February 2017.
5. Latuda [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; February 2017.
6. Rexulti [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; February 2017.
7. Saphris [package insert]. Irvine, CA: Allergan USA Inc.; February 2017.
8. Seroquel [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2017.
9. Seroquel XR [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2017.
10. Vraylar [package insert]. Irvine, CA: Allergan USA, Inc.; February 2017.
11. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed May 2017.
12. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed May 2017.
13. American Psychiatric Association. Practice guideline for the treatment of patients with schizophrenia. *Am J Psychiatry*. 2004; 161: (Suppl) 1-56. http://www.psychiatryonline.com (accessed May 2017).
14. Dixon, L., Perkins, D. et.al. Guideline Watch (September 2009): Practice Guideline for the Treatment of Patients with Schizophrenia. American Psychiatric Association. Accessed May 2017.
15. Leucht S, Corves C, Arbter D, Engel RR, Li C, Davis JM: Second-generation versus first-generation antipsychotic drugs for schizophrenia: a meta-analysis. Lancet 2009; 373:31–41.