STEP THERAPY CRITERIA

DRUG CLASS	**ATYPICAL ANTIPSYCHOTICS – ORAL/TRANSDERMAL (BRAND PRODUCTS ONLY)**
BRAND NAME (generic)	
	ABILIFY (ORAL TABLET) (BRAND ONLY) (aripiprazole)
	ABILIFY MYCITE (BRAND ONLY) (aripiprazole)
	CAPLYTA (BRAND ONLY) (lumateperone)
	FANAPT (BRAND ONLY) (iloperidone)
	GEODON (ORAL CAPSULE) (BRAND ONLY) (ziprasidone)
	INVEGA (ORAL TABLET) (BRAND ONLY) (paliperidone)
	LATUDA (BRAND ONLY) (lurasidone hydrochloride)
	LYBALVI (BRAND ONLY) (olanzapine and samidorphan)
	OPIPZA (BRAND ONLY) (aripiprazole)
	REXULTI (BRAND ONLY) (brexpiprazole)
	RISPERDAL (ORAL TABLET & ORAL SOLUTION ONLY) (BRAND ONLY) (risperidone)
	SAPHRIS (BRAND ONLY) (asenapine)
	SECUADO (BRAND ONLY) (asenapine transdermal)

SEROQUEL, SEROQUEL XR (BRAND ONLY)
(quetiapine)

VRAYLAR (BRAND ONLY)
(cariprazine)

ZYPREXA (ORAL TABLET & ODT ONLY) (BRAND ONLY)
(olanzapine)

Status: CVS Caremark® Criteria
Type: Initial Step Therapy; Post Step Therapy Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Abilify

Abilify (aripiprazole) Oral Tablets 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 Mycite

Abilify Mycite, a drug-device combination product comprised of aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor intended to track drug ingestion, is indicated for the:

- Treatment of adults with schizophrenia
- Treatment of bipolar I disorder
    - Acute treatment of adults with manic and mixed episodes as monotherapy and as adjunct to lithium or valproate
    - Maintenance treatment of adults as monotherapy and as adjunct to lithium or valproate
- Adjunctive treatment of adults with Major Depressive Disorder

Limitations of Use

- The ability of the Abilify Mycite to improve patient compliance or modify aripiprazole dosage has not been established.
- The use of Abilify Mycite to track drug ingestion in "real-time" or during an emergency is not recommended because detection may be delayed or not occur.

Caplyta

Caplyta is indicated for the treatment of:

- Schizophrenia in adults.
- Depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate.

Fanapt

Fanapt is indicated for:

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

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. 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 in adults.

Bipolar I Disorder (Acute Mixed or Manic Episodes and Maintenance Treatment as an Adjunct to Lithium or Valproate)
- Geodon is indicated as monotherapy for the acute treatment of adults with manic or mixed episodes associated with bipolar I disorder.
- Geodon is indicated as an adjunct to lithium or valproate for the maintenance treatment of bipolar I disorder in adults.

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 (13 to 17 years) with schizophrenia.
- Monotherapy treatment of adult and pediatric patients (10 to 17 years) with major depressive episode associated with bipolar I disorder (bipolar depression).
- Adjunctive treatment with lithium or valproate in adult patients with major depressive episode associated with bipolar I disorder (bipolar depression).

Lybalvi
Lybalvi is indicated for the treatment of:
- Schizophrenia in adults
- Bipolar I disorder in adults
  - Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate
  - Maintenance monotherapy treatment

Opipza
Opipza is indicated for the:
- treatment of schizophrenia in patients ages 13 years and older
- adjunctive treatment of major depressive disorder (MDD) in adults
- treatment of irritability associated with autistic disorder in pediatric patients 6 years and older
- treatment of Tourette’s disorder in pediatric patients 6 years and older

Rexulti
Rexulti is indicated for:
- Adjunctive treatment of major depressive disorder (MDD) in adults.
- Treatment of schizophrenia in adults and pediatric patients ages 13 years and older
- Treatment of agitation associated with dementia due to Alzheimer's disease

Limitations of Use:
Rexulti is not indicated as an as needed ("prn") treatment for agitation associated with dementia due to Alzheimer's disease.

Risperdal
Schizophrenia
Risperdal (risperidone) is indicated for the treatment of schizophrenia. Efficacy was established in 4 short-term trials in adults, 2 short-term trials in adolescents (ages 13 to 17 years), and one long-term maintenance trial in adults.

Bipolar Mania
Monotherapy
Risperdal is indicated for the treatment of acute manic or mixed episodes associated with Bipolar I Disorder. Efficacy was established in 2 short-term trials in adults and one short-term trial in children and adolescents (ages 10 to 17 years).

Adjunctive Therapy
Risperdal adjunctive therapy with lithium or valproate is indicated for the treatment of acute manic or mixed episodes associated with Bipolar I Disorder. Efficacy was established in one short-term trial in adults.

Irritability Associated with Autistic Disorder
Risperdal is indicated for the treatment of irritability associated with autistic disorder, including symptoms of aggression towards others, deliberate self-injuriousness, temper tantrums, and quickly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years).

Saphris
Saphris is indicated for:
- Schizophrenia in adults
- Bipolar I disorder
  - Acute monotherapy of manic or mixed episodes, in adults and pediatric patients 10 to 17 years of age
  - Adjunctive treatment to lithium or valproate in adults
  - Maintenance monotherapy treatment in adults

Secuado
Secuado is indicated for the treatment of adults with schizophrenia.

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 episodes 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 in adults
- Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults

- Treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults
- Adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults

Zyprexa

Schizophrenia

Oral Zyprexa is indicated for the treatment of schizophrenia. Efficacy was established in three clinical trials in adult patients with schizophrenia: two 6-week trials and one maintenance trial. In adolescent patients with schizophrenia (ages 13-17), efficacy was established in one 6-week trial.

When deciding among the alternative treatments available for adolescents, clinicians should consider the increased potential (in adolescents as compared with adults) for weight gain and dyslipidemia. Clinicians should consider the potential long-term risks when prescribing to adolescents, and in many cases this may lead them to consider prescribing other drugs first in adolescents.

Bipolar I Disorder (Manic or Mixed Episodes)

Monotherapy

Oral Zyprexa is indicated for the acute treatment of manic or mixed episodes associated with bipolar I disorder and maintenance treatment of bipolar I disorder. Efficacy was established in three clinical trials in adult patients with manic or mixed episodes of bipolar I disorder: two 3- to 4-week trials and one monotherapy maintenance trial. In adolescent patients with manic or mixed episodes associated with bipolar I disorder (ages 13-17), efficacy was established in one 3-week trial.

When deciding among the alternative treatments available for adolescents, clinicians should consider the increased potential (in adolescents as compared with adults) for weight gain and dyslipidemia. Clinicians should consider the potential long-term risks when prescribing to adolescents, and in many cases this may lead them to consider prescribing other drugs first in adolescents.

Adjunctive Therapy to Lithium or Valproate

Oral Zyprexa is indicated for the treatment of manic or mixed episodes associated with bipolar I disorder as an adjunct to lithium or valproate. Efficacy was established in two 6-week clinical trials in adults. The effectiveness of adjunctive therapy for longer-term use has not been systematically evaluated in controlled 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, pediatric 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 should be part of a total treatment program that often includes psychological, educational and social interventions.

Zyprexa and Fluoxetine in Combination: Depressive Episodes Associated with Bipolar I Disorder

Oral Zyprexa and fluoxetine in combination is indicated for the treatment of depressive episodes associated with bipolar I disorder, based on clinical studies. When using Zyprexa and fluoxetine in combination, refer to the Clinical Studies section of the package insert for Symbyax.

Zyprexa monotherapy is not indicated for the treatment of depressive episodes associated with bipolar I disorder.

Zyprexa and Fluoxetine in Combination: Treatment Resistant Depression

Oral Zyprexa and fluoxetine in combination is indicated for the treatment of treatment resistant depression (major depressive disorder in patients who do not respond to 2 separate trials of different antidepressants of adequate dose and duration in the current episode), based on clinical studies in adult patients. When using Zyprexa and fluoxetine in combination, refer to the Clinical Studies section of the package insert for Symbyax.

Zyprexa monotherapy is not indicated for the treatment of treatment resistant depression.

INITIAL STEP THERAPY*

**Include Rx and OTC products unless otherwise stated.*

If the patient has filled a prescription for at least a 30-day supply of generic aripiprazole, asenapine, lurasidone, olanzapine, paliperidone, quetiapine, quetiapine extended-release, risperidone, 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

Authorization may be granted for the requested drug when ONE the following criteria is met:

- The patient has experienced an inadequate treatment response, after a trial of at least 30 days, to ONE of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, paliperidone, quetiapine, quetiapine extended-release, risperidone, ziprasidone
- The patient has an intolerance or a contraindication that would prohibit a 30-day trial of ONE of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, paliperidone, quetiapine, quetiapine extended-release, risperidone, ziprasidone
- The 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

CONTINUATION OF THERAPY

Authorization may be granted for the requested drug when the following criteria is met:

- The patient is currently taking the requested drug with evidence of improvement

DURATION OF APPROVAL (DOA)

- 657-D: DOA: 36 months

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