



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Atypical Antipsychotics – Oral/Transdermal Page: 1 of 6

Effective Date: 8/30/2024 Last Review Date: 7/2024

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Florida Kids
	<input checked="" type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for oral and transdermal atypical antipsychotic products under the patient's prescription drug benefit.

### Description:

#### **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 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.



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- 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 tablets are indicated for the treatment of adults with schizophrenia.

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.

### 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.

### Latuda

Latuda is indicated for:

- Treatment of adult and adolescent patients age 13 to 17 years with schizophrenia
- Monotherapy treatment of adult and pediatric patients (10 to 17 years) with major depressive episodes associated with Bipolar I disorder (bipolar depression)



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- Adjunctive treatment with lithium or valproate in adult patients with major depressive episodes 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 adjunctive treatment to lithium or valproate
  - Maintenance monotherapy treatment

### Rexulti

Rexulti is indicated for:

- Adjunctive treatment of major depressive disorder (MDD)
- 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

### 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

### Vraylar

Vraylar is indicated for:

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



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- Treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults

**Applicable Drug List:**

aripiprazole  
 aripiprazole orally disintegrating tablet  
 clozapine  
 lurasidone  
 olanzapine  
 paliperidone extended release  
 risperidone  
 quetiapine  
 quetiapine extended release  
 ziprasidone  
 Abilify  
 Abilify Mycite  
 Caplyta  
 Fanapt  
 Invega  
 Latuda  
 Lybalvi  
 Rexulti  
 Saphris  
 Asenapine  
 Secuado  
 Vraylar

**Policy/Guideline:**

Note: requests from behavioral health specialists in the state of New Jersey are not required to meet the authorization criteria.

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

- The request is for continuation of therapy with clinical documentation indicating disease stability or improvement from baseline

**OR**



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- The request is for aripiprazole (Abilify) being prescribed for one of the following: A) treatment of irritability associated with Autistic disorder in a patient 6 to 17 years of age, B) treatment of Tourette's disorder in a patient 6 to 18 years of age

**OR**

- The request is for Rexulti being prescribed for the treatment of agitation associated with dementia due to Alzheimer’s disease

**OR**

- The 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 patient has experienced an inadequate treatment response, intolerance, or contraindication to at least two generic atypical antipsychotics

**OR**

- The patient has a clinical condition or requires a specific dosage form for which there is no generic alternative, or the generic alternatives are not recommended based on published guidelines or clinical literature

**Approval Duration and Quantity Restrictions:**

**Approval:** 12 months; requests from behavioral health specialists will be authorized indefinitely

**Quantity Level Limit:** Reference Formulary for drug specific quantity level limits

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