



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name:	Atypical Antipsychotics – Oral/Transdermal	Page:	1 of 6
Effective Date:	2/13/2025	Last Review Date:	1/2025
Applies to:	<input checked="" type="checkbox"/> Illinois	<input checked="" type="checkbox"/> Florida Kids	<input checked="" type="checkbox"/> Pennsylvania Kids

### 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.
- 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.



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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)
- 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



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### **Opipza**

Opipza is indicated for:

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

### **Applicable Drug List:**

aripiprazole  
aripiprazole orally disintegrating tablet  
clozapine



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lurasidone  
olanzapine  
paliperidone extended release  
risperidone  
quetiapine  
quetiapine extended release  
ziprasidone  
Abilify  
Abilify Mycite  
Caplyta  
Fanapt  
Invega  
Latuda  
Lybalvi  
Opipza  
Rexulti  
Saphris  
Asenapine  
Secuado  
Vraylar

**Policy/Guideline:**

**Coverage Criteria:**

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

- The requested drug is being prescribed for ONE of the following: treatment of irritability associated with autistic disorder in a patient 6 to 17 years of age, treatment of Tourette's disorder in a patient 6 to 18 years of age AND the following criteria is met:
  - The request is for Abilify (aripiprazole) or Opipza (aripiprazole)
- The requested drug is being prescribed for the treatment of agitation associated with dementia due to Alzheimer's disease AND the following criteria is met:
  - The request is for Rexulti (brexpiprazole)
- The requested drug is being prescribed for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines) AND ONE of the following criteria is met:
  - The patient has experienced an inadequate treatment response, intolerance, or contraindication to at least TWO generic atypical antipsychotics (Documentation is required for approval).



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- 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

### **Continuation of Therapy**

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

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

### **Approval Duration and Quantity Restrictions:**

**Approval:** 12 months

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

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