

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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Name: Atypical Antipsych Oral/Transdermal		otics –	Page:	2 of 6
Effective Da	ate: 8/30/2024		Last Review Date:	7/2024
Applies to:	⊠Illinois □New Jersey ⊠Pennsylvania Kids	□Florida □Maryland □Virginia	⊠Florida Kids □Michigan □Kentucky PRMD	

• 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

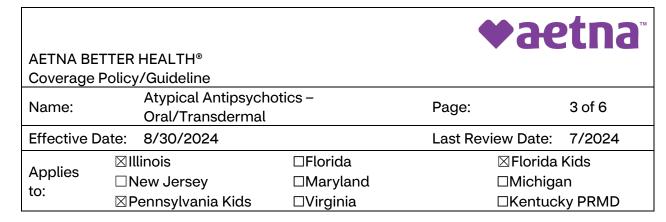
Invega (paliperidone) Extended-Release Tablets are indicated for the treatment of schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers and/or antidepressant therapy.

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)



• 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
 - o 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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Coverage Policy/Guideline							
Name: Atypical Antipsychol Oral/Transdermal			otics –	Page:	4 of 6		
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Applies to:	⊠Illinois		□Florida	🛛 Florida Kids			
	□Ne	w Jersey	□Maryland	□M	□Michigan		
	⊠Pe	nnsylvania Kids	□Virginia	□K	□Kentucky PRMD		
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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

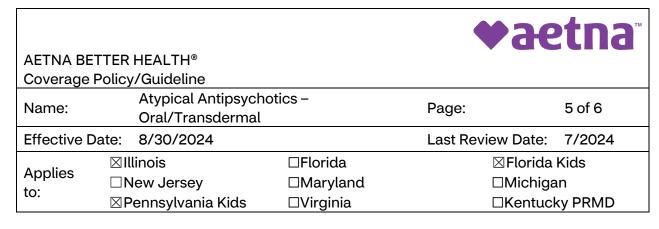
Policy/Guideline:

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

• 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



• 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

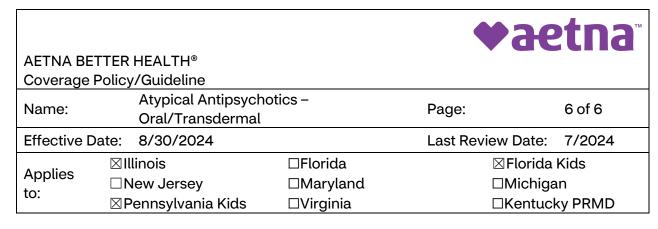
Approval Duration and Quantity Restrictions:

Approval: 12 months

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

References:

- 1. Abilify [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; November 2022.
- 2. Abilify Mycite [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; February 2023.
- 3. Caplyta [package insert]. New York, NY: Intra-Cellular Therapies, Inc.; June 2023.
- 4. Fanapt [package insert]. Washington, D.C.: Vanda Pharmaceuticals Inc.; February 2017.
- 5. Invega [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2022.
- 6. Latuda [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; May 2022.
- 7. Lybalvi [package insert]. Waltham, MA: Alkermes, Inc.; September 2023.
- 8. Rexulti [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; May 2023.
- 9. Saphris [package insert]. Madison, NJ: Allergan USA, Inc.; October 2021.
- 10. Secuado [package insert]. Miami, Florida: Noven Therapeutics, LLC; December 2023.
- 11. Vraylar [package insert]. Madison, NJ: Allergan USA, Inc.; December 2022.
- 12. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed January 08, 2024.
- 13. Lexicomp Online, Lexi-Drugs Online Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed January 08, 2024.
- 14. Micromedex[®] (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 01/08/2024).
- 15. Keepers GA, Fochtmann LJ, Anzia JM, et al. The American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia. Third Edition. Washington, DC: American Psychiatric Association; 2021. Available at:



https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890424841. Accessed January 08, 2024.

 Gelenberg AJ, Freeman MP, Markowitz JC, et al. American Psychiatric Association (APA) Practice Guideline for the Treatment of Patients with Major Depressive Disorder, Third Edition. October 2010. Available at:

https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Accessed January 08, 2024.

17. Hirschfeld RM, Bowden CL, Gitlin MJ, et al. American Psychiatric Association (APA) Practice Guideline for the Treatment of Patients with Bipolar Disorder. Second Edition. Washington DC: American Psychiatric Association; 2002. Available at:

https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf . Accessed January 08, 2024.