

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	NA	X	X	X	NA	NA	X

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## Antipsychotic Medications Age and Step Therapy

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

***\*Indiana Medicaid – see State Specific Mandates below***

***\*Maryland Medicaid – see State Specific Mandates below***

***\*Virginia Medicaid – see State Specific Mandates below***

***\*Washington Medicaid – see State Specific Mandates below***

Atypical Antipsychotics	Notes
Abilify Mycite (aripiprazole with sensor) MSB Abilify Aripiprazole tablets Aripiprazole oral disintegrating tablets Aripiprazole solution	Non-Preferred Use MSB criteria Preferred Non-Preferred Non-Preferred
clozapine tablets MSB Clozaril	Preferred Use MSB criteria
Fanapt (iloperidone) tablets Fanapt (iloperidone) Titration Pack	Non-Preferred
FazaClo (clozapine) oral disintegrating tablets	Non-Preferred
MSB Geodon capsules Ziprasidone capsules	Use MSB Criteria Preferred
MSB Invega tablets Paliperidone ER tablets	Use MSB criteria Preferred
Latuda (lurasidone) tablets	Non-Preferred
MSB Risperdal tablets, oral solution MSB Risperdal M-tabs oral disintegrating tablets Risperidone oral tablets Risperidone solution Risperdal oral disintegrating tablets	Use MSB criteria Use MSB criteria Preferred Preferred Non-Preferred
Saphris (asenapine) sublingual tablets	Non-Preferred

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MSB Seroquel tablets Quetiapine tablets Seroquel XR (quetiapine XR) tablets	Use MSB criteria Preferred Non-Preferred
Symbyax (olanzapine and fluoxetine)	Non-Preferred
Versacloz (clozapine) oral suspension	Non-Preferred
Vraylar (cariprazine)	Non-Preferred
MSB Zyprexa tablets Olanzapine tablets MSB Zyprexa Zydis oral disintegrating tablets Olanzapine oral disintegrating tablets	Use MSB criteria Preferred Use MSB criteria Non-Preferred
<b>Traditional Antipsychotics</b>	<b>Notes</b>
MSB Orap tablets Pimozide tablets	Use MSB Criteria Non-Preferred
perphenazine tablets	Preferred
Stelazine (trifluoperazine) tablets	Preferred
Navane (thiothixene) capsules	Preferred
Loxapine capsules	Preferred
Adasuve inhalation powder	Non-Preferred (Subject to Age Edit Only)
Prolixin/Permitil (fluphenazine hydrochloride) tablets, elixir, liquid concentrate	Preferred
Fluphenazine decanoate injection	Preferred
MSB Haldol injection Haloperidol tablets, liquid concentrate, injection	Use MSB criteria Preferred
Thorazine (chlorpromazine) tablets (excludes injectables)	Preferred

## **APPROVAL CRITERIA**

## **MULTI-SOURCE BRAND**

Requests for the following antipsychotic medications:

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- MSB Abilify
- MSB Clozaril
- MSB Geodon capsules
- MSB Invega tablets
- MSB Orap tablets
- MSB Risperdal tablets, oral solution
- MSB Risperdal M-tabs oral disintegrating tablets
- MSB Seroquel tablets
- MSB Zyprexa tablets
- MSB Zyprexa Zydis oral disintegrating tablets
- MSB Haldol injection

may be approved when Multi-Source Brand criteria (see specific Multi-Source Brand criteria) **AND** age limits listed below, are met.

### **STEP THERAPY APPROVAL CRITERIA**

Requests for the following *non-preferred oral atypical* antipsychotics medications:

- aripiprazole ODT/solution
- risperidone ODT
- risperidone oral syringe
- Abilify Mycite (aripiprazole with sensor)
- Fanapt (iloperidone)
- Latuda (lurasidone)
- Saphris (asenapine)
- Seroquel XR (brand and generic)
- Symbyax (brand and generic)
- Vraylar (cariprazine)

may be approved when the following criteria **AND** age limits listed below, are met:

I. Individual has been maintained on a stable dose of the requested medication;

**OR**

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- II. Individual has had a trial of and inadequate response or intolerance to **one** preferred generic oral atypical antipsychotic;

Preferred generic oral atypical antipsychotics: aripiprazole tablet, olanzapine, paliperidone, quetiapine, risperidone tablet/solution, ziprasidone

**OR**

- III. The preferred generics are not FDA approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and the non-preferred agent does;

**OR**

- IV. The request is for quetiapine ER and I. or II. or III above are met; **OR**  
 A. Individual has a diagnosis of Major Depressive Disorder; **AND**  
 B. Individual must use concomitant antidepressant therapy;

**OR**

- V. The request is for Latuda and I. or II. or III above are met; **OR**  
 A. Individual is age 10-17 with a diagnosis of bipolar depression; **OR**  
 B. Individual has significant cardiovascular risk factors (such as high risk for QTc prolongation);  
**OR**  
 C. Individual is at high risk for complications related to weight gain;

**OR**

- VI. The requested agent is Abilify Mycite and the prescriber has confirmed clinical necessity to track drug ingestion;

**PRIOR AUTHORIZATION - AGE APPROVAL CRITERIA**

Requests for antipsychotic agents in the pediatric population (age 17 and under) may be approved when the following criteria are met:

- I. Individual has been maintained on a stable dose of the requested medication;

**OR**

- II. Prescriber is a Psychiatrist, Neurologist or Developmental/Behavioral Pediatrician; **OR**

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III. Prescriber has consulted with a Psychiatrist, Neurologist or Developmental/Behavioral Pediatrician;

**OR**

IV. Prescriber does not have timely access to a Psychiatrist, Neurologist of Developmental/Behavioral Pediatrician; **AND**

V. The individual meets the following criteria (Note: If all other conditions below are met, allow 3 month supply to provide time to consult with a specialist):

A. Individual is 5 years of age or older;

**AND**

B. Medication being requested is Risperdal (risperidone) tablets or solution;

**OR**

C. Individual is 6 years of age or older;

**AND**

D. Medication being requested is one of the following:

1. Abilify (aripiprazole) oral – not Abilify Mycite formulation; **OR**
2. Trifluoperazine;

**OR**

E. Individual is 10 years of age or older;

**AND**

F. Medication being requested is one of the following:

1. Symbyax (olanzapine and fluoxetine); **OR**
2. Seroquel (quetiapine); **OR**
3. Seroquel XR (quetiapine XR); **OR**
4. Saphris (asenapine); **OR**
5. Latuda (lurasidone)

**OR**

G. Individual is 12 years of age or older;

**AND**

H. Medication being requested is one of the following:

1. Invega (paliperidone) oral; **OR**
2. Orap (pimozide); **OR**
3. Perphenazine; **OR**
4. Thiothixene; **OR**
5. Fluphenazine decanoate injection;

**OR**

I. Individual is 13 years of age or older;

**AND**

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J. Medication being requested is one of the following:

1. Zyprexa (olanzapine) oral;

**AND**

VI. Individual has a psychiatric diagnosis that is amenable to treatment with an antipsychotic agent, including, but not limited to the following:

- A. Schizophrenia; **OR**
- B. Bipolar disorder [Seroquel (quetiapine), Risperdal (risperidone), Zyprexa (olanzapine), Geodon (ziprasidone), Seroquel XR (quetiapine), Abilify (aripiprazole), Saphris (asenapine), Latuda (lurasidone), Vraylar (cariprazine), chlorpromazine]; **OR**
- C. Irritability associated with autism [Risperdal (risperidone), Abilify (aripiprazole) – not Abilify Mycite formulation]; **OR**
- D. Severe behavioral problems including explosive hyperexcitability which cannot be accounted for by immediate provocation (chlorpromazine, haloperidol);

**AND**

VII. One of the following:

- A. Individual has utilized non-drug treatment measures, such as psychosocial intervention/care, in the previous 12 months; **OR**
- B. Individual has had an acute inpatient visit for a diagnosis of schizophrenia, bipolar disorder or other psychotic disorder in the previous 12 months; **OR**
- C. Individual has had at least 2 visits in outpatient, intensive outpatient, or partial hospitalization setting for a diagnosis of schizophrenia, bipolar disorder or other psychotic disorder in the previous 12 months;

**AND**

VIII. Prescriber is regularly monitoring for metabolic side effects (such as, obtaining blood glucose or Hemoglobin A1C (HbA1c), total cholesterol or LDL-C, reviewing BMI changes);

**AND**

IX. Prescriber is regularly monitoring for neurological side effects [such as, evaluation of movement disorders using tools including Abnormal Involuntary Movement Scale (AIMS) and the Neurological Rating Scale (NRS)];

**OR**

- X. Individual is requesting an antipsychotic agent to treat the following diagnoses:
  - A. Nausea and vomiting (chlorpromazine, perphenazine, prochlorperazine); **OR**
  - B. Tourette's Disorder/tic disorder [Orap (pimozide), Abilify (aripiprazole) – not Abilify Mycite formulation, haloperidol]; **OR**

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C. Pre-surgical apprehension (chlorpromazine);

**AND**


XI. No therapeutic alternative exists or therapeutic alternatives were ineffective.

State Specific Mandates		
Virginia Medicaid	10/1/15	<p style="text-align: center;"><b><u>Virginia Medicaid:</u></b></p> <p>Individuals 17 years of age and younger will require prior authorization for all antipsychotic agents, aligning with Virginia Medicaid FFS program requirements.</p> <ol style="list-style-type: none"> <li>I. Starting 10/1/15, members utilizing all antipsychotics <b><u>except the following</u></b> will follow the criteria outlined here: chlorpromazine, haloperidol (tablets or liquid), Risperdal (risperidone) tablets or solution, trifluoperazine.</li> <li>II. Starting 11/1/15, <b><u>all</u></b> members will follow the criteria outlined here.</li> </ol> <p>Per DMAS: Effective March 1, 2015, the Department of Medical Assistance Services (DMAS) will expand its typical and atypical antipsychotic service authorization (SA) requirement (also known as a PA or prior authorization) to any member under the age of eighteen (18) enrolled in Virginia Medicaid's fee-for-service program. The SA requirement for members under the age of eighteen (18) are as follows:</p> <ol style="list-style-type: none"> <li>I. The drug must be prescribed by a psychiatrist or neurologist or the prescriber must supply proof of a psychiatric consultation AND,</li> <li>II. the member must have an appropriate diagnosis, as indicated on the attached SA form AND,</li> </ol>

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		<p>III. the member must be participating in a behavioral management program AND,</p> <p>IV. Written, informed consent for the medication must be obtained from the parent or guardian.</p> <p>SAs will be given for six (6) months, after which a new SA will need to be obtained. If the SA criteria listed above are not met, a thirty (30) day emergency fill will be allowed and the SA request will be reviewed by a board certified Child and Adolescent Psychiatrist. Failure to complete the SA process and meet the clinical criteria during this thirty (30) day period will result in the denial of subsequent pharmacy claims for the drug. Service authorization does not guarantee payment for the drug; payment is contingent upon passing all edits contained within the claims payment process, the individual's continued Medicaid eligibility, the provider's continued Medicaid eligibility, and the ongoing medical necessity for the drug.</p> <div style="text-align: center;">  <p>Microsoft Word 97 - 2003 Document</p> </div> <p>SA criteria document:</p> <p>In addition, use of preferred atypical antipsychotic agents prior to a non-preferred atypical antipsychotic will still be required.</p> <p>The preferred oral atypical antipsychotic agents are as follows: risperidone, olanzapine, quetiapine fumarate, ziprasidone, aripiprazole tablets, paliperidone. Trial and failure of one of these products is required prior to use of a non-preferred atypical antipsychotic unless the following applies:</p> <p>I. Latuda is requested and individual is diagnosed with bipolar disorder along with significant cardiovascular risk factors (such as a high risk of QTc prolongation) or is at high risk for complications related to weight gain.</p>
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CRX-ALL-0325-19



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Applicable	X	X	NA	NA	X	NA	X	NA	X	X	X	NA	NA	X

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		<p><b>Requests for individuals 18 and over will follow criteria outlined below:</b></p> <p><b><u>All antipsychotic agents are approved for use in individuals 18 and older.</u></b> However, use of preferred atypical antipsychotic agents prior to a non-preferred atypical antipsychotic will still be required. The preferred oral atypical antipsychotic agents are as follows: risperidone, olanzapine, quetiapine fumarate, ziprasidone, aripiprazole tablets, paliperidone. Trial and failure of one of these products is required prior to use of a non-preferred oral atypical antipsychotic unless the following applies:</p> <ol style="list-style-type: none"> <li>I. Latuda is requested and individual is diagnosed with bipolar disorder along with significant cardiovascular risk factors (such as a high risk of QTc prolongation) or is at high risk for complications related to weight gain.</li> <li>II.</li> </ol>
Indiana Medicaid	8/15/15	<ol style="list-style-type: none"> <li>1. Invega Trinza – change effective 8/15/2015               <ol style="list-style-type: none"> <li>a. Invega Trinza will be allowed after the individual has been stabilized on at least 4 months of therapy on Invega Sustenna.</li> <li>b. If there is not a 4 month prescription history of Invega Sustenna, the medication request will need to be evaluated.</li> <li>c. 90 days' supply will be authorized; limit of 4 injections per year.</li> </ol> </li> </ol>
	10/1/15	<ol style="list-style-type: none"> <li>1. Beginning 10/1/2015, only individuals 18 and over may receive long-acting injectable antipsychotic agents.               <ol style="list-style-type: none"> <li>a. For children under 18, PA requests will be denied; oral medications should be utilized.</li> <li>b. Exception: Children of adult size (16 and 17 years old only) may obtain a prescription for long-acting injectable antipsychotic agents for a diagnosis of schizophrenia ONLY.</li> </ol> </li> </ol>

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	4/1/16	<p>2. Beginning 04/15/2016, only individuals 18 and over may receive the following oral antipsychotic agents: clozapine, Fanapt, Loxapine, Vraylar, Perphenazine, fluphenazine, Rexulti, ziprasidone.</p> <p>a. Exception: Children of adult size (16 and 17 years old only) may obtain a prescription for the above listed antipsychotic agents for a diagnosis of schizophrenia ONLY.</p>
Maryland Medicaid		Maryland behavioral health is state carve out
Washington Medicaid		<ul style="list-style-type: none"> <li>Amerigroup will follow the Washington Health Care PDL for Coverage</li> <li>Provide indefinite coverage for all members regardless of formulary status ONLY IF PREVIOUSLY PRESCRIBED</li> </ul>

**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: May 30, 2017.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

National Committee for Quality Assurance (NCQA). The Healthcare Effectiveness Data and Information Set (HEDIS), 2017, volume 2. Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics (APP).

National Committee for Quality Assurance (NCQA). The Healthcare Effectiveness Data and Information Set (HEDIS), 2017, volume 2. Metabolic Monitoring for Children and Adolescents on Antipsychotics (APM).

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