

Pharmacy Medical Necessity Guidelines: Antipsychotic Medications

Effective: August 1, 2023

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan			Fax Numbers: RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

The approval of generic atypical antipsychotic agents has created an opportunity to improve the cost-effectiveness of treatment and lower prescription costs for patients without compromising efficacy. A logical and evidence-based method must be employed to support and encourage adequate care. A step algorithm provides one such manner by which treatment for bipolar disorder and schizophrenia can be delivered to efficiently improve patient outcomes and control escalating healthcare expenditures.

Drug Name	Generic Name	Utilization Management (UM)
Aripiprazole tablet	aripiprazole	QL
Abilify Maintena, aripiprazole ODT, aripiprazole oral solution	aripiprazole	PA
Abilify MyCite tablet with sensor	aripiprazole	PA; QL
Aristada	aripiprazole lauroxil	PA
Saphris SL tablets	asenapine	PA; QL
Secuado transdermal patch	asenapine	PA
Rexulti	brexpiprazole	PA; QL
Vraylar	cariprazine	PA
Chlorpromazine tablets	chlorpromazine	Covered
Clozapine tablets	clozapine	Covered
Clozapine orally disintegrating tablets	Clozapine	QL
Fluphenazine injection, oral concentrate, elixir, tablets	fluphenazine	Covered
Haloperidol injection, IM solution, oral concentrate, tablets	haloperidol	Covered
Fanapt tablets, titration pack	iloperidone	PA; QL
Loxitane capsules	loxapine	Covered
Caplyta capsules	lumateperone	PA; QL
Latuda tablets	lurasidone	PA; QL
Nuplazid tablets	pimavanserin	PA
Olanzapine intramuscular injection	olanzapine	Covered
Olanzapine ODT, tablets	olanzapine	QL
Zyprexa Relprevv	olanzapine	PA
Lybalvi tablets	Olanzapine/samidorphane	PA; QL
Invega tablets, Sustenna	paliperidone	PA
Perphenazine tablets	perphenazine	Covered
Perseris prefilled suspension	risperidone	PA
Prochlorperazine injection, tablets, suppositories	prochlorperazine	Covered
Quetiapine tablets	quetiapine	QL
Quetiapine extended-release	quetiapine extended-release	PA; QL

Drug Name	Generic Name	Utilization Management (UM)
Risperdal Consta	risperidone	PA
Risperidone ODT, oral solution, tablets	risperidone	QL
Thioridazine tablets	thioridazine	Covered
Thiothixene capsules	thiothixene	Covered
Trifluoperazine tablets	trifluoperazine	Covered
Ziprasidone capsules, Geodon injection	ziprasidone	QL

COVERAGE GUIDELINES

The plan may authorize coverage of an antipsychotic medication requiring prior authorization when all of the following criteria are met:

1. The member is stabilized on the medication
- OR**
2. The member was recently started on the requested medication in an acute care setting, residential setting, or partial hospital setting
- OR**
3. One of the following drug-specific criteria:

Aripiprazole orally disintegrating tablet (ODT) and oral solution

1. Member has a diagnosis of schizophrenia, bipolar disorder, autistic disorder, depression, or Tourette's syndrome
- AND**
2. Member has difficulty swallowing and is therefore unable to administer aripiprazole tablet

Abilify Maintena (aripiprazole)

1. Member tried and failed therapy with or the provider indicates clinical inappropriateness of or non-compliance with at least one oral alternative atypical antipsychotic (e.g., aripiprazole, risperidone, olanzapine)

Abilify MyCite (aripiprazole tablet with sensor)

1. The Member is 18 years of age or older
- AND**
2. The Member has one of the following diagnoses:
 - a) Bipolar disorder
 - b) Schizophrenia
 - c) Major depressive disorder
- AND**
3. Member has a history of poor adherence (<80%) with at least two oral second generation antipsychotics, one of which must be aripiprazole
- AND**
4. Documentation that the low medication adherence with aripiprazole was not related to an inadequate response, intolerance, or adverse effect
- AND**
5. Documentation that the Member has experienced worsening symptoms due to lack of adherence with oral second-generation antipsychotics
- AND**
6. Documentation that the Member has attempted all of the following strategies to improve adherence:
 - a) Use of pillboxes
 - b) Setting reminder alarms
 - c) Coordinating the administration time with that of other daily medications
- AND**
7. Documentation of a comprehensive treatment plan that will incorporate the data from the mobile application/web-based portal to monitor the Member's treatment

Aristada (aripiprazole lauroxil), Aristada Initio

1. The Member tried and failed therapy with or the provider indicates clinical inappropriateness of or non-compliance with at least one oral alternative atypical antipsychotic (e.g., aripiprazole, risperidone, olanzapine)

Caplyta (lumateperone)

1. The Member has a diagnosis of schizophrenia or bipolar disorder
AND
2. The Member tried and failed therapy with or the provider indicates clinical inappropriateness of therapy with at least two alternative generic atypical antipsychotics

Fanapt (iloperidone) or Paliperidone extended-release tablets

1. The Member has a diagnosis of schizophrenia
AND
2. The Member tried and failed therapy with or the provider indicates clinical inappropriateness of therapy with at least two alternative atypical antipsychotic agents, one of which must be risperidone.

Invega Sustenna (paliperidone) injection and Invega Trinza (paliperidone) injection

1. The Member has tried and failed therapy with, or the provider indicates a clinical inappropriateness of or non-compliance with at least one oral alternative atypical antipsychotic (e.g., aripiprazole, risperidone, olanzapine)

Lybalvi (olanzapine/samidorphan) tablet

1. The member has a diagnosis of schizophrenia or bipolar disorder
AND
2. The Member is 18 years of age or older
AND
3. The Member has had an inadequate response or adverse reaction to **two** generic atypical antipsychotics

Nuplazid (pimavanserin)

1. Documented diagnosis of hallucinations and delusions associated with Parkinson’s disease psychosis.
AND
2. The prescribing physician is a neurologist or a psychiatrist
AND
3. Member has tried and failed therapy with or the provider indicates clinical inappropriateness of treatment with quetiapine

Orap (pimozide)

1. The member tried and failed therapy with or the provider indicates clinical inappropriateness of therapy with at least **TWO** alternative antipsychotic agents.

Perseris (risperidone injection)

1. The Member tried and failed therapy with or the provider indicates clinical inappropriateness of or non-compliance with at least one oral alternative atypical antipsychotic (e.g., aripiprazole, risperidone, olanzapine)

Rexulti (brexpiprazole)

1. The Member has a diagnosis of schizophrenia
AND
2. The Member tried and failed therapy with or the provider indicates clinical inappropriateness of therapy with at least two alternative atypical antipsychotic agents, one of which must be aripiprazole
OR
1. The Member has a diagnosis of major depressive disorder
AND
2. The Member had had an inadequate response or intolerance to at least two antidepressant medications from two different therapeutic classes
OR
1. The Member has a diagnosis of dementia due to Alzheimer’s disease **AND** is being treated for agitation

Risperdal Consta (risperidone injection)

1. The Member tried and failed therapy with or the provider indicates clinical inappropriateness of or non-compliance with at least one oral alternative atypical antipsychotic (e.g., aripiprazole, risperidone, olanzapine)

Asenapine, Lurasidone

1. The Member has a diagnosis of bipolar disorder or schizophrenia
AND
2. The Member tried and failed therapy with or the provider indicates clinical inappropriateness of therapy with at least two alternative atypical antipsychotic agents.

Secuado (asenapine patch)

1. The Member has a diagnosis of schizophrenia
AND
2. The Member tried and failed therapy with or the provider indicates clinical inappropriateness of therapy with at least two alternative atypical antipsychotic agents
AND
3. The Member tried and failed therapy with or the provider indicates clinical inappropriateness of therapy with asenapine tablet.

Quetiapine extended-release

1. For the diagnosis of schizophrenia or bipolar disorder
 - a) The Member has a diagnosis of schizophrenia or bipolar disorder
AND
 - b) The Member has an insufficient response or adverse effects to a trial with quetiapine immediate-release (IR), or the provider indicates the Member is at increased risk for adverse clinical outcome with the use of quetiapine IR
2. For the diagnosis of depression,
 - a) The Member has a diagnosis of depression
AND
 - b) Documentation quetiapine extended-release will be used as adjunctive therapy in conjunction with an antidepressant medication
AND
 - c) The Member tried and failed therapy with at least three antidepressant medications, or the provider indicates clinical inappropriateness of therapy with alternative antidepressant medications

Vraylar (cariprazine)

1. The Member has a diagnosis of bipolar disorder or schizophrenia
AND
2. The Member tried and failed therapy with or the provider indicates clinical inappropriateness of therapy with at least two alternative atypical antipsychotic agents.

OR

1. The Member has a diagnosis of major depressive disorder
AND
2. The Member has tried and failed therapy with at least two generic antidepressants or the provider indicates clinical inappropriateness of therapy with all antidepressants

Zyprexa Relprevv (olanzapine injection)

1. The Member tried and failed therapy with or the provider indicates clinical inappropriateness of treatment with at least two atypical antipsychotics, one of which must be oral olanzapine.

LIMITATIONS

1. The following quantity limitations apply:

Aripiprazole tablet, orally disintegrating tablet	1 tablet per day
Aripiprazole oral solution	25 mL per day
Caplyta (lumateperone)	1 capsule per day
Fanapt (iloperidone)	2 tablets per day
Invega (paliperidone)	1 tablet per day

Latuda (lurasidone)	1 tablet per day
Lybalvi (olanzapine/samidorphan)	1 tablet per day
Nuplazid (pimavanserin) 10 mg, 17 mg tablets	2 tablets per day
Nuplazid (pimavanserin) 34 mg tablets	1 tablet per day
Rexulti (brexpiprazole)	1 tablet per day
Saphris (asenapine)	2 tablets per day
Secuado (asenapine)	1 patch per day
Seroquel XR (quetiapine) 50 mg, 300 mg, 400 mg	2 tablets per day
Seroquel XR (quetiapine) 150 mg, 200 mg	1 tablet per day

2. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.
3. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception, but will be considered on an individual basis for prior authorization.

CODES

None

REFERENCES

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9. Invega (paliperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2022.
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18. Nuplazid (pimavanserin) [prescribing information]. San Diego, CA: ACADIA Pharmaceuticals, Inc; November 2020.
19. Pimozide [prescribing information]. Chestnut Ridge, NY: Par Pharmaceutical; March 2017.
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21. Rexulti (brexpiprazole) [prescribing information]. Rockville, MD: Otsuka Pharmaceuticals; May 2023.
22. Risperdal Consta (risperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; February 2021.

23. Saphris (asenapine) [prescribing information]. Madison, NJ: Allergan USA; October 2021.
24. Secuado (asenaprine) [prescribing information]. Miami, FL: Noven Therapeutics, LLC; November 2022.
25. Seroquel XR (quetiapine extended-release) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2022.
26. Vraylar (cariprazine) [prescribing information]. Madison, NJ: Allergan USA; December 2022.
27. Zyprexa Relprevv (olanzapine) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; February 2021.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. April 11, 2023: Effective May 1, 2023, updated Vraylar criteria to include new indication of major depressive disorder. Updated Rexulti criteria for major depression to remove requirement that member step through two antipsychotics.
2. July 11, 2023: Effective August 1, 2023, updated Rexulti criteria to include expanded indication of treatment of agitation associated with dementia due to Alzheimer's disease.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

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