Pharmacy Medical Necessity Guidelines: Antipsychotic Medications

Effective: July 20, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ 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; QL
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

Drug Name	Generic Name	Utilization Management (UM)
Caplyta capsules	lumateperone	PA;QL
Latuda tablets	lurasidone	PA; QL
Nuplazid tablets	pimavanserin	PA
Olanzapine intramuscular injection	olanzapine	Covered
Olanzapine ODT, tablets	olanzapine	QL
Invega tablets, Sustenna	paliperidone	PA; QL
Perphenazine tablets	perphenazine	Covered
Perseris prefilled suspension	risperidone	PA; QL
Prochlorperazine injection, tablets, suppositories	prochlorperazine	Covered
Quetiapine tablets	quetiapine	QL
Quetiapine extended-release	quetiapine extended-release	PA; QL
Risperdal Consta	risperidone	PA, QL
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
Zyprexa Relprevv	olanzapine	PA, QL

COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred antipsychotic medication for Members 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, or other psychotic disorder

AND

2. Member has difficulty swallowing and is therefore unable to administer aripiprazole tablet

Abilify Maintena (aripiprazole)

1. Documented diagnosis of bipolar disorder, schizophrenia, or other psychotic disorder

AND

2. 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

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 aripriprazole

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. Documented 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.

Caplyta (lumateperone)

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 three alternative generic atypical antipsychotics

Fanapt (iloperidone) or Invega (paliperidone) extended-release tablets

1. 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 concern with the use of oral paliperidone and with injectable risperidone

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 is at least 18 years of age with 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 oral atypical antipsychotics, one of which must be risperidone

AND

3. The Member tried and failed therapy with or the provider indicates clinical inappropriateness of therapy with Risperdal Consta

Rexulti (brexpiprazole)

1. 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

AND

2. **For the diagnosis of depression:** The Member had had an inadequate response or intolerance to at least two antidepressant medications from two different therapeutic classes

Risperdal Consta (risperidone injection)

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

Saphris (asenapine), Secuado (asenapine patch), Latuda (lurasidone), Vraylar (cariprazine)

1. The Member tried and failed therapy with or the provider indicates clinical inappropriateness of therapy with at least two alternative atypical antipsychotic agents.

AND

2. **Secuado only:** 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 is at least 13 years of age with a diagnosis of schizophrenia or at least 10 years of age with a diagnosis of 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

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	30 tablets per 30 days
Aripiprazole oral solution	750 mLs per 30 days
Abilify Maintena (aripiprazole)	1 vial per 28 days
Caplyta (lumateperone)	30 capsules per 30 days
Fanapt (iloperidone)	60 tablets per 30 days
Invega (paliperidone)	30 tablets per 30 days
Invega Sustenna (paliperidone)	1 vial per 30 days; 2 vials for 1st 30 days
Latuda (lurasidone)	30 tablets per 30 days
Nuplazid (pimavanserin) 10 mg, 17 mg tablets	60 tablets per 30 days
Nuplazid (pimavanserin) 34 mg tablets	30 tablets per 30 days
Perseris (risperidone) prefilled suspension syringe	1 syringe per 30 days
Rexulti (brexpiprazole)	30 tablets per 30 days
Risperdal Consta (risperidone)	2 injections per 28 days
Saphris (asenapine)	60 tablets per 30 days
Seroquel XR (quetiapine) 50 mg, 300 mg, 400 mg	60 tablets per 30 days

Seroquel XR (quetiapine) 150 mg, 200 mg	30 tablets per 30 days
Zyprexa Relprevv 210 mg, 200 mg	2 vials per 28 days
Zyprexa Relprevv 405 mg	1 vial per 28 days

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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2. Abilify Maintena (aripiprazole) [prescribing information]. Rockville, MD: Otsuka Pharmaceuticals; January 2020.
3. Abilify Mycite (aripiprazole tablets with sensor) [prescribing information]. Rockville, MD: Otsuka Pharmaceuticals; February 2020.
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9. Invega (paliperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; January 2019.
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17. Orap (pimozide) [prescribing information]. Sellersville, PA: Gate Pharmaceuticals; August 2011.
18. Perseris (risperidone) [prescribing information]. North Chesterfield, VA: Indivior, Inc; December 2019.
19. Rexulti (brexpiprazole) [prescribing information]. Tokyo, Japan: Otsuka Pharmaceuticals; February 2018.
20. Saphris (asenapine) [prescribing information]. Irvine, CA: Allergan USA; February 2017.
21. Secuado (asenaprine) [prescribing information]. Miami, FL: Noven Therapeutics, LLC; October 2019.
22. Seroquel XR (quetiapine extended-release) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2020.
23. Vraylar (cariprazine) [prescribing information]. Madison, NJ: Allergan USA; May 2019.

APPROVAL HISTORY

June 9, 2015: Reviewed by Pharmacy & Therapeutics Committee; consolidated individual guidelines; added criteria for children less than 6 years of age; modified duration approval to 2 years.

Subsequent endorsement date(s) and changes made:

1. October 6, 2015: Modified duration approval to life of plan; added criteria for Orap and for Rexulti.
2. January 1, 2016: Administrative change to rebranded template; incorporated table inclusive of all medications on the Tufts Health Together Preferred Drug List.
3. June 14, 2016: Added Aristada and Vraylar to the guideline. Removed limitation #2 "Quantities that exceed the quantity limit will be reviewed according to the Drugs w/ Quantity Limitations criteria."
4. July 12, 2016: Added Nuplazid to the guideline with prior authorization criteria.
5. August 9, 2016: Updated approval criteria for children less than 6 years of age.
6. February 14, 2017: Updated approval criteria for children less than 6 years of age.
7. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Removed Pediatric Behavioral Medication Initiative criteria. Added criteria for Risperdal Consta and Zyprexa Relprevv. Added trial with quetiapine to Nuplazid criteria.
8. September 18, 2018: Effective 9/24/18, removed immediate release aripiprazole injection due to product discontinuation. Added Aristada Initio to the MNG. Effective 1/1/19, removed off-label criteria for quetiapine extended-release.
9. October 16, 2018: Effective 10/22/18, updated aripiprazole criteria to include Tourette's syndrome diagnosis. Effective 1/1/19, removed off-label criteria for aripiprazole. Administrative update to template.
10. November 13, 2018: Added Nuplazid 34 mg tablets to the criteria. Added quantity limits for Nuplazid.
11. December 11, 2018: Added criteria and quantity limit for Perseris. Updated the minimum age criteria for quetiapine extended-release for the treatment of bipolar and schizophrenia.
12. February 12, 2019: Effective 3/1/2019, updated MNG to indicate aripiprazole tablets are covered. Added quantity limit information for aripiprazole oral solution. Administrative update to remove aripiprazole IM solution from Overview section. Effective 7/1/2019, updated criteria for aripiprazole orally disintegrating tablet, oral solution, and Abilify Maintena.
13. March 12, 2019: Added criteria for Abilify MyCite (aripriprazole tablets with sensor).
14. March 10, 2020: Effective 4/1/2020, added Secuado (asenapine) to the MNG and updated the depression criteria for quetiapine xr to remove age requirement and depression features. Effective 7/1/2020, updated Rexulti criteria.
15. April 14, 2020: Effective 4/20/2020, added Caplyta criteria and quantity limit to the MNG.
16. July 14, 2020: Administrative update, added language concerning samples to the limitations section of the MNG.

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.

Provider Services