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.

The goal of the MassHealth Pediatric Behavioral Health Medication Initiative (PBHMI) is to encourage safe prescribing of behavioral health medication regimens to members less than 18 years of age. As part of the PBHMI, a prior authorization is required for pediatric members less than 6 years of age who are being prescribed any antipsychotic, regardless as to whether or not the antipsychotic is preferred on the Plan's formulary.

Drug Name	Generic Name	For members < 6 years of age	For members ≥ 6 years of age
Aripiprazole tablet	aripiprazole	PA; QL	QL
Abilify Maintena, aripiprazole ODT, aripiprazole oral solution	aripiprazole	PA; QL	PA; QL
Ablify MyCite tablet with sensor	aripiprazole	PA; QL	PA; QL
Aristada, Aristada Initio	aripiprazole lauroxil	PA	Covered
Saphris SL tablets	asenapine	PA; QL	PA; QL
Secuado transdermal patch	asenapine	PA	PA
Rexulti	brexpiprazole	PA; QL	PA; QL
Vraylar	cariprazine	PA	PA
Chlorpromazine tablets	chlorpromazine	PA	Covered
Clozapine tablets, Versacloz susp, Fazaclo ODT	clozapine	PA	Covered
Fluphenazine inj, oral conc, elixir,tablets	fluphenazine	PA	Covered
Haloperidol inj, IM soln, oral conc, tablets	haloperidol	PA	Covered

Drug Name	Generic Name	For members < 6 years of age	For members ≥ 6 years of age
Fanapt tabs, titration pack	iloperidone	PA; QL	PA; QL
Loxitane capsules	loxapine	PA	Covered
Caplyta capsules	lumateperone	PA;QL	PA;QL
Latuda tablets	lurasidone	PA; QL	PA; QL
Nuplazid tablets	pimavanserin	PA	PA
Olanzapine im inj	olanzapine	PA	Covered
Olanzapine ODT, tablets, Zyprexa Relprevv	olanzapine	PA; QL	QL
Invega tablets, Sustenna	paliperidone	PA; QL	PA; QL
Perphenazine tablets	perphenazine	PA	Covered
Prochlorperazine inj, tablets, sup	prochlorperazine	PA	Covered
Quetiapine tablets	quetiapine	PA; QL	QL
Seroquel xr	quetiapine extended-release	PA; QL	PA; QL
Perseris prefilled suspension	risperidone	PA; QL	PA; QL
Risperidone Consta, ODT, oral soln, tabs	risperidone	PA; QL	QL
Thioridazine tablets	thioridazine	PA	Covered
Thiothixene capsules	thiothixene	PA	Covered
Trifluoperazine tablets	trifluoperazine	PA	Covered
Ziprasidone capsules, Geodon inj	ziprasidone	PA; QL	QL

COVERAGE GUIDELINES

In addition to medication-specific prior authorization criteria, the Plan may authorize coverage of a preferred or non-preferred antipsychotic medication for Members less than 6 years of age when the following criteria are met:

For Members less than 6 years of age:

1. Member has one of the following:
    a. Recent psychiatric hospitalization (within the last three months)

    OR

    b. History of severe risk of harm to self or others

    OR

2. All of the following criteria are met:
    a. Complete medication treatment plan, including name, dose, and frequency of all current behavioral health medications, associated target symptom(s), and behavioral health diagnoses

    AND

    b. A comprehensive behavioral health treatment plan (i.e., non-pharmacological interventions) is in place

    AND

    c. The prescriber is a specialist (e.g., child psychiatry, pediatric neurology, or developmental/behavioral pediatrics) or a consult is provided

    AND

    d. One of the following:
        i. Member is in acute stage of treatment (initiation of antipsychotic treatment likely with subsequent dose adjustment to maximize response and minimize side effects)

        OR

        ii. All of the following:
            1. Member is in maintenance stage of treatment (response to antipsychotic treatment with goal of remission or recovery)

            AND

            2. Regimen is effective, therapy benefits outweigh risks, and appropriate monitoring is in place

            AND

            3. If member has been on the antipsychotic regimen for the past 12 months, clinical rationale for extended therapy including at least one of the

following: previous efforts to reduce/simplify the antipsychotic regimen in the past 12 months resulted in symptom exacerbation; or family/caregiver does not support the antipsychotic regimen change at this time due to risk of exacerbations; or other significant barrier for antipsychotic therapy discontinuation

OR

iii. All of the following:
   1. Member is in discontinuation stage of treatment (clinically indicated that the antipsychotic regimen can likely be successfully tapered)

AND

   2. Cross-titration/taper of antipsychotic therapy

For all members:

The plan may authorize coverage of a non-preferred antipsychotic medication when all of the following criteria are met (for children less than 6 years of age, the age-specific criteria also apply in addition to the medication-specific criteria listed below):

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

1. Clinical rationale for use of requested agent instead of Aristada® (aripiprazole lauroxil)*

*A diagnosis of bipolar I disorder is not a sufficient rationale to bypass a trial with Aristada®

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

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

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

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

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

3. For an off-label behavioral health diagnosis
   a) The Member is at least 18 years of age with an off-label behavioral health diagnosis

AND

   b) The Member tried and failed therapy with two alternative atypical antipsychotic agents, one of which must be quetiapine IR, or the provider indicates clinical inappropriateness of therapy with the use of alternative agents

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
Abilify MyCite (aripiprazole tablet with sensor)	30 tablets per 30 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
Rexulti (brexpiprazole)	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
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

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

1. Abilify (aripiprazole) [prescribing information]. Rockville, MD: Otsuka Pharmaceuticals; February 2020.
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.
4. American Diabetes Association, American Psychiatric Association, American Association of Clinical Endocrinologists, et al. Consensus development of conference on antipsychotic drugs and obesity and diabetes. *Diabetes Care*. 2004 Feb;65(2):267-72.
5. Aristada (aripiprazole lauroxil) [prescribing information]. Waltham, MA: Alkermes, Inc.; August 2019.
6. Aristada Initio (aripiprazole lauroxil extended-release) [prescribing information]. Waltham, MA; Alkermes, Inc.; August 2019.
7. Caplyta (lumateperone) [prescribing information]. New York, NY: Intra-Cellular Therapies, Inc; December 2019.

8. Fanapt (iloperidone) [prescribing information]. Washington, D.C.: Vanda Pharmaceuticals Inc.; February 2017.
9. Invega (paliperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; January 2019.
10. Invega Sustenna (paliperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; January 2019.
11. Invega Trinza (paliperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; January 2019.
12. Kay SR, Fiszbein A, Opler LA. The positive and negative syndrome scale (PANSS) for schizophrenia. *Schizophr Bull*. 1987;13(2):261-76.
13. Kelleher JP, Centorrino F, Albert MJ, et al. Advances in atypical antipsychotics for the treatment of schizophrenia: new formulations and new agents. *CNS Drugs*. 2002;16(4):249-61.
14. Latuda (lurasidone) [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; December 2019.
15. Lehman AF, Lieberman JA, Dixon LB, et al. Practice guidelines for the treatment of patients with schizophrenia, second edition. *Am J Psychiatry*. 2004 Feb;161(2 Suppl):1-56.
16. Nuplazid (pimavanserin) [prescribing information]. San Diego, CA: ACADIA Pharmaceuticals, Inc; May 2019.
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, Adding Tufts Health RITogether to the template.
8. February 16, 2018: Removed approval criteria for Aristada from the guideline, as it is now covered. Updated criteria for Abilify Maintena to require a trial and failure with Aristada. Removed immediate release aripiprazole injection from guideline due to product discontinuation.
9. September 18, 2018: Added Aristada Initio to the MNG as covered for Members 6 years of age and older.
10. October 16, 2018: Administrative update to template. Effective 10/22/18, updated aripiprazole criteria to include Tourette's Syndrome diagnosis.
11. November 13, 2018: Effective 11/19/18, added Nuplazid 34 mg tablets to the criteria. Added quantity limits for Nuplazid.
12. December 11, 2018: Added criteria for Perseris (risperidone) injection. Updated the minimum age criteria for quetiapine extended-release for the treatment of schizophrenia and bipolar disorder.
13. February 12, 2019: Effective 3/1/2019, updated MNG to indicate aripriprazole tablets are covered (PBHMI restrictions apply). Updated criteria for Abilify Maintena. Added quantity limit information for aripiprazole oral solution. Effective 7/1/2019, updated criteria for aripiprazole orally disintegrating tablet and aripiprazole oral solution.
14. March 12, 2019: Added criteria for Abilify MyCite (aripriprazole tablets with sensor).

15. 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.
16. April 14, 2020: Effective 4/20/2020, added Caplyta criteria and quantity limit to the MNG.
17. 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. They are used in conjunction with a member's benefit document and in coordination with the member's physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan members or to certain delegated service arrangements. Unless otherwise noted in the member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink^{SM} members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.