Pharmacy Medical Necessity Guidelines: Atypical 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 plan is implementing a step therapy program for brand name atypical antipsychotics to encourage the first-line use of generic agents. 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 by managed care organizations in order to support and encourage adequate care. A step therapy 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.

COVERAGE GUIDELINES

Note: Prescriptions that meet the initial step therapy requirements will adjudicate **automatically** at the point of service. If the Member does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit PA requests to the plan using the Universal Pharmacy Medical Review Request Form for Members who do not meet the step therapy criteria at the point of service.

Members who are currently (within 180 days prior to the effective date) filling prescriptions for an atypical antipsychotic drug affected by this policy under the prescription benefit administered by the plan will be able to continue treatment on such existing drug regimen.

For Members who are new Members of the plan without prior claims history, physicians must provide documentation of prior use of a Step-1, Step-2, or Step-3 atypical antipsychotic drug to continue treatment on such existing drug regimen.

Refer to the table below for formularies and medications subject to this policy:

Drug	Tufts Health Plan Large Group Plans	Tufts Health Plan Small Group and Individual Plans
Step-1		
clozapine	Covered	Covered
risperidone		
risperidone ODT		
olanzapine		
quetiapine		
ziprasidone		
Step-2		

Drug	Tufts Health Plan Large Group Plans	Tufts Health Plan Small Group and Individual Plans
aripiprazole tablets*	Requires prior use of a drug on Step-1, Step-2 or Step-3	Requires prior use of a drug on Step-1, Step-2 or Step-3
aripiprazole ODT*		
olanzapine ODT		
olanzapine / fluoxetine		
paliperidone		
quetiapine extended-release*		
Step-3		
Caplyta	Requires prior use of a drug on Step-2 or Step-3	Requires prior use of a drug on Step-2 or Step-3
Latuda®*		
Rexulti™		
Secuado® transdermal patch		
Versacloz® suspension		
Vraylar™		
Abilify®*, Abilify oral solution®*		Not covered
Clozaril®		
Geodon®		
Risperdal®		
Risperdal® M-Tab®		
Seroquel XR®*		
Symbyax®		
Zyprexa®		
Zyprexa Zydis®		
Seroquel®	Not covered	

* See below for special coverage considerations.

Automated Step Therapy Coverage Criteria
The following stepped approach applies to coverage of the Step-2 and Step-3 medications by the plan:

Step 1: Medications on Step-1 are covered without prior authorization.

Step 2: The plan may cover medications on Step-2 if the following criteria are met:
- The Member has had a trial of a Step-1, Step-2 or Step-3 medication within the previous 180 days as evidenced by a paid claim under the prescription benefit administered by the plan.

Step 3: The plan may cover medications on Step-3 if the following criteria are met:
- The Member has had a trial of a Step-2 or Step-3 medication within the previous 180 days as evidenced by a paid claim under the prescription benefit administered by the plan.

Coverage Criteria for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale
The following stepped approach applies to atypical antipsychotic medications covered by the plan:

Step 2: The plan may cover Step-2 medications if the following criteria are met:
1. The Member has had a trial of a Step-1, Step-2 or Step-3 medication as evidenced by physician documented use.

OR

2. The Member has a physician documented contraindication or intolerance to all Step-1 medications

Step 3: The plan may cover Step-3 medications if the following criteria are met:
1. The Member has had a trial of a Step-2 or Step-3 medication as evidenced by physician documented use.

OR

2. The Member has a physician documented contraindication or intolerance to all Step-1 and Step -2 medications

Note: The plan may cover medications on Step-2 or Step-3 if a Member has received one of the **non-covered** medications, listed below in the limitation section, as evidenced by physician documented use.

Abilify MyCite (Note – Abilify MyCite is not on Step Therapy criteria)
Abilify MyCite may be covered if ALL of the following criteria are met and a Prior Authorization request to Tufts Health Plan is submitted:

1. Member is 18 years of age or older

AND

2. Member has one of the following diagnoses: bipolar disorder, schizophrenia, 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 of treatment failure with or intolerance to a long acting injectable aripiprazole formulation, or documentation of clinical rationale that a long acting injectable aripiprazole formulation is not medically appropriate for this Member

AND

5. Documentation that the low medication adherence rate with aripriprazole was not related to an inadequate response, intolerance, or adverse effect

AND

6. Documentation that the member has experienced worsening symptoms due to lack of adherence with oral second-generation antipsychotics

AND

7. 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

8. Documentation of a comprehensive treatment plan that will incorporate the data from the mobile application/web-based portal to monitor the member's treatment

Aripiprazole
Aripiprazole may be covered as an **adjunct to an antidepressant for Major Depressive Disorder** if **ALL** of the following criteria are met and a PA request to Tufts Health Plan is submitted:

1. Documented diagnosis of Major Depressive Disorder

AND

2. The Member is currently taking an antidepressant as evidenced by a paid claim under the prescription benefit administered by the plan or by physician documented use

If the request is for the brand Abilify (aripiprazole), in addition the criteria for generic aripiprazole:

1. Documentation of one of the following:
    a. Documentation from the requesting physician that the Member had an allergy to an ingredient in the generic aripiprazole that is not contained in the brand-name product

    OR

    b. Documentation from the requesting physician and clinical justification that a change to the generic would result in instability of the medical condition

    OR

    c. The request for the brand-name product is due to a drug shortage

Latuda (lurasidone)
Latuda (lurasidone) may be covered for **Bipolar Depression** if **ALL** of the following criteria are met and a PA request to Tufts Health Plan is submitted:

1. Documented diagnosis of Bipolar Depression

Quetiapine extended-release
Quetiapine extended-release may be covered as an **adjunct to an antidepressant for Major Depressive Disorder** if **ALL** of the following criteria are met and a PA request to Tufts Health Plan is submitted:

1. Documented diagnosis of Major Depressive Disorder

AND

2. The Member is currently taking an antidepressant as evidenced by a paid claim under the prescription benefit administered by the plan or by physician documented use

If the request is for the brand Seroquel XR (quetiapine extended-release), in addition the criteria for generic quetiapine extended-release:

1. Documentation of one of the following:
    a. Documentation from the requesting physician that the Member had an allergy to an ingredient in the generic quetiapine extended-release that is not contained in the brand name product

    OR

    b. Documentation from the requesting physician and clinical justification that a change to the generic would result in instability of the medical condition

    OR

    c. The request for the brand-name product is due to a drug shortage.

Rexulti

Rexulti (Brexpiprazole) may be covered as an **adjunct to an antidepressant for Major Depressive Disorder** if **ALL** of the following criteria are met and a PA request to Tufts Health Plan is submitted:

1. Documented diagnosis of Major Depressive Disorder

AND

2. The Member is currently taking an antidepressant as evidenced by a paid claim under the prescription benefit administered by the plan or by physician documented use

AND

3. One of the following:
    a. Documentation of treatment failure with or intolerance to, or the provider indicates clinical inappropriateness of therapy with, aripiprazole and quetiapine

    OR

    b. The member was recently started on Rexulti in an acute care setting, residential setting, or partial hospital setting

Vraylar (cariprazine)

Vraylar (cariprazine) may be covered for **Bipolar Depression** if **ALL** of the following criteria are met and a PA request to Tufts Health Plan is submitted:

1. Documented diagnosis of Bipolar Depression

LIMITATIONS

1. Medications on Step-2 and Step-3 are not covered unless the above step therapy criteria are met.
2. The plan does not authorize coverage of noncovered medications through this step therapy program. Refer to the Pharmacy Medical Necessity Guidelines for Noncovered Drugs with Suggested Alternatives and submit a formulary exception request to Tufts Health Plan, as indicated.
3. The plan does not cover the following medications on all Commercial formularies: Fanapt, Invega, Seroquel, and Saphris. Refer to the Pharmacy Medical Necessity Guidelines for Noncovered Drugs with Suggested Alternatives.
4. The plan does not cover the following medications on the MA/RI/NH EHB formularies: Abilify, Clozaril, Fanapt, Geodon, Invega, Risperdal, Risperdal M-Tab, Saphris, Seroquel, Seroquel XR, Symbyax, Zyprexa, and Zyprexa Zydis. Refer to the Pharmacy Medical Necessity Guidelines for Noncovered Drugs with Suggested Alternatives.
5. Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.
6. The following quantity limitations apply:

Abilify (aripiprazole) tablets	up to 90 tablets per 90 days
Abilify Discmelt (aripiprazole oral disintegrating tablets)	up to 180 tablets per 90 days
Abilify (aripiprazole) oral solution	up to 6 bottles per 90 days
Abilify MyCite (aripiprazole) tablets	Up to 90 tablets per 90 days
Latuda (lurasidone) 20 mg, 40 mg, 60 mg and 120 mg	up to 90 tablets per 90 days
Latuda (lurasidone) 80 mg	up to 180 tablets per 90 days
Rexulti (brexpiprazole)	Up to 90 tablets per 90 days

CODES

None

REFERENCES

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3. Caplyta prescribing information. New York, NY: Intra-Cellular Therapies, Inc.; 2019 December.
4. Clozaril (clozapine) [prescribing information]. Rosemont, PA: HLS Therapeutics, Inc.; 2017 February.
5. Drug Facts and Comparisons. Facts & Comparisons® eAnswers [online]. 2010. Available from Wolters Kluwer Health, Inc. Accessed 2016 May 17.
6. Kay SR, Fiszbein A, Opler LA. The positive and negative syndrome scale (PANSS) for schizophrenia. *Schizophr Bull*. 1987;13(2):261-76.
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8. Latuda (lurasidone) [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; 2018 March.
9. 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.
10. Seroquel XR (quetiapine extended-release) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2017 February.
11. Secuado (asenapine film, extended release) [prescribing information]. Japan Saga Tosu: Hisamitsu Pharmaceutical Co. Inc.; October 2019.
12. Versacloz (clozapine) [prescribing information]. Tampa, FL: TruPharma, LLC; 2018 January.
13. Vraylar (cariprazine) [prescribing information]. Madison, NJ: Allergan USA, Inc.; 2019 May.

APPROVAL HISTORY

September 13, 2011: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- January 10, 2012: Added Risperdal M-Tab to Step-3 of the Medical Necessity Guidelines.
- April 10, 2012: Moved Geodon to Step-3 for COMM MA/RI and not covered for the GFF, and added ziprasidone to Step-2. Moved Seroquel 100, 200, 300 & 400 mg to Step-3, and added quetiapine 100, 200, 300 & 400 mg to Step-2.
- June 12, 2012: Administrative update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs. Clarified step criteria to reflect that Step-3 drugs are prerequisites for drugs on Step-2.
- August 14, 2012: Added generic olanzapine / fluoxetine (generic of Symbyax) to Step-2 of the step therapy. Clarified that Geodon, Risperdal, Risperdal M-Tab, Seroquel, Zyprexa, Zyprexa Zydis and Symbyax are not covered on the Generic Focused Formulary. Added the non-covered atypical antipsychotic drugs Fanapt, Invega, Latuda and Saphris to the limitations section. Added note that non-covered products (Fanapt, Invega, Latuda and Saphris) may qualify as prerequisites for Step-2 or Step-3 medications. Added use of samples or vouchers/coupons for brand name medications limitation.
- February 12, 2013: Added Abilify Discmelt and Abilify Oral Solution to Step-3 of the Medical Necessity Guidelines. Added the following quantity limits for Abilify Discmelt 60 tablets per 30 days and for Abilify oral solution 2 bottles per 30 days.
- June 11, 2013: Removed "Physician" from the criteria for documenting diagnosis.
- October 8, 2013: Administrative update: Removed requirement of 30-day trial and replaced with just a previous trial of the medication.
- April 1, 2014: Administrative update: Removed language pertaining to the Generic Focused Formulary and added EHB MA/RI Formulary.
- June 10, 2014: Removed the language requiring previous use of Step-1, Step-2, or Step-3 medications within the last 2 years.
- January 13, 2015: (Effective January 19, 2015) Added Latuda to Step-3 of the medical necessity guidelines and added criteria for use in Bipolar depression. Updated the limitations with the quantity limits for Latuda and clarified the quantity limits allow up to a 90 day supply.

- March 10, 2015: For effective date April 1, 2015 – Moved Geodon, Risperdal, Risperdal M-tab, Seroquel, Symbyax, Zyprexa, and Zyprexa Zydis to not covered for the MA/RI EHB formularies.
- June 9, 2015: Added aripiprazole tablets and ODT to step-2 of the Medical Necessity Guidelines.
- August 11, 2015: Moved quetiapine 100, 200, 300, and 400 mg tablets and olanzapine tablets to step-1 of the Medical Necessity Guidelines
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- February 9, 2016: Added paliperidone to Step-2 of the Medical Necessity Guidelines. Also updated table to move Abilify products to Not Covered for Small Group and Individual formularies and add Seroquel XR to Step-3.
- June 14, 2016: Added Vraylar to the Step Therapy program at Step-3. Added Rexulti to the list of non-covered medications.
- July 12, 2016: Added Nuplazid to the guideline with prior authorization criteria.
- January 10, 2017: Moved Seroquel XR to Not Covered for Small Group and Individual formularies and added quetiapine extended-release to the Medical Necessity Guideline at Step-2 for all formularies.
- February 14, 2017: Moved ziprasidone from a step-2 to a step-1 medication.
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template. Removed criteria for Seroquel (quetiapine) 25 mg and 50 mg; Effective July 1, 2017 – move Seroquel to not covered for the large group formularies.
- December 12, 2017: Administrative update, removed Nuplazid from the MNG.
- December 11, 2018: Updated step therapy criteria to require trial with applicable step-1, 2, or 3 medications or the member has a physician documented contraindication or intolerance to all lower step medications.
- March 12, 2019: Added Abilify MyCite to the Medical Necessity Guidelines, with prior authorization criteria and quantity limitations. Effective 7/1/2019, added Rexulti to the Step Therapy Criteria and quantity limitations and added criteria for Rexulti for use as an adjunctive therapy for major depressive disorders.
- August 13, 2019: Updated coverage criteria for Vraylar, based on new indication for treatment of bipolar depression.
- September 10, 2019: Effective January 1, 2020 added clozapine to list of step-1 medications and added Versacloz suspension to the list of step-3 medications for all Commercial lines of business. Added Clozaril to the list of step-3 medications for Commercial Large Group plans. Cozaril tablets continue to be non-covered for Commercial Small Group and Exchange plans.
- March 10, 2020: Added Secuado to step 3 of the step therapy program.
- April 14, 2020: Added Caplyta to step therapy criteria on Step-3.
- July 14, 2020: Removed sample exclusion language from coverage criteria and updated sample limitation to the following: Samples, free goods, or similar offerings of the requested medication do not quality for an established clinical response or exception but will be considered on an individual basis for prior authorization.

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.