Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drug

Antipsychotic Medications

Effective: May 12, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☐ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (dual-eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

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.

Brand Name	Generic Name	Utilization Management
Fluphenazine injection	fluphenazine	Covered
Geodon injection	ziprasidone	Covered
Haloperidol injection	haloperidol	Covered
Olanzapine injection	olanzapine	Covered
Prochlorperazine injection	prochlorperazine	Covered
Abilify Asimtufii	aripiprazole	Prior authorization
Abilify Maintena	aripiprazole	Prior authorization
Aristada	aripiprazole lauroxil	Prior authorization
Aristada Initio	aripiprazole lauroxil	Prior authorization
Erzofri	paliperidone	Prior authorization
Invega Sustenna	paliperidone	Prior authorization
Invega Hafayera	paliperidone	Prior authorization
Invega Trinza	paliperidone	Prior authorization
Perseris	risperidone	Prior authorization
Risperdal Consta	risperidone	Prior authorization
Rykindo	risperidone	Prior authorization

Uzedy	risperidone	Prior authorization
Zyprexa Relprevv	olanzapine	Prior authorization

Clinical Guideline Coverage Criteria

The plan may authorize coverage of an antipsychotic medication requiring prior authorization 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:

Abilify Asimtufii, Abilify Maintena, Aristada, Aristada Initio

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

Erzofri, Invega Hafyera, Invega Sustenna, Invega Trinza

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

Perseris, Risperdal Consta, Rykindo, Uzedy

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

Zyprexa Relprevv

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

Limitations

- 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

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
C9152	Injection, aripiprazole, (Abilify Asimtufii), 1 mg
C9158	Injection, risperidone, (Uzedy), 1 mg
J0401	Injection, aripiprazole, extended-release 1 mg (Ability Maintena)
J1943	Injection, aripiprazole lauroxil (Aristada initio), 1 mg
J1944	Injection, aripiprazole lauroxil, (Aristada), 1 mg
J2358	Injection, olanzapine, long-acting, 1 mg (Zyprexa Relprevv)
J2426	Injection, paliperidone palmitate extended release, 1 mg (Invega Sustenna)
J2427	Injection, paliperidone palmitate extended release (Invega Hafyera or Invega Trinza), 1 mg
J2794	Injection, risperidone (Risperdal Consta), 0.5 mg
J2798	Injection, risperidone, (Perseris), 0.5 mg
J2801	Injection, risperidone (Rykindo), 0.5 mg
J2428	Injection, paliperidone palmitate extended release (erzofri), 1 mg

References

1. Abilify Asimtufii (aripiprazole) [prescribing information]. Kanda-Tsukasamachi, Chiyoda-ku, Tokyo: Otsuka Pharmaceuticals Co. Ltd.; April 2023.
2. Abilify Maintena (aripiprazole) [prescribing information]. Rockville, MD: Otsuka Pharmaceuticals; June 2020.

3. 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.
4. Aristada (aripiprazole lauroxil) [prescribing information]. Waltham, MA: Alkermes, Inc.; March 2021.
5. Aristada Initio (aripiprazole lauroxil extended-release) [prescribing information]. Waltham, MA; Alkermes, Inc.; March 2021.
6. Erzofri (paliperidone) [prescribing information]. Shijiazhuang, Hebei Province, China: Luye Innomind Pharma Shijiazhuang Co., Ltd,; December 2024
7. Invega Hafyera (paliperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; August 2021.
8. Invega Sustenna (paliperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; February 2021.
9. Invega Trinza (paliperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; February 2021.
10. Kay SR, Fiszbein A, Opler LA. The positive and negative syndrome scale (PANSS) for schizophrenia. Schizophr Bull. 1987;13(2):261-76.
11. 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.
12. 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.
13. Perseris (risperidone) [prescribing information]. North Chesterfield, VA: Indivior, Inc; December 2019.
14. Risperdal Consta (risperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; February 2021.
15. Rykindo (risperidone) [prescribing information]. Yantai, Shandong Province, China: Shandong Luye Pharmaceutical Co., Ltd.; May 2023.
16. Uzedy (risperidone) [prescribing information]. Parsippany, NJ: Teva Neuroscience, Inc.; April 2023.
17. Zyprexa Relprevv (olanzapine) [prescribing information]. Indianapolis, IN: Lilly, USA, LCC; October 2019.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T).

- September 21, 2022, year: Reviewed by the Medical Policy Approval Committee (MPAC).
- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees effective January 1, 2023
- Administrative update: June 2023 added Medical Benefit Drugs to title and updated MATogether and RITogether fax numbers to 617-673-0939
- Coding update per HCPCS level II quarterly release. Effective July 1, 2023, the following HCPCS codes have been added: J2427
- September 12, 2023: Removed S0166 and J3486 to mirror covered status. Added Abilify Asimtufii and Uzedy to the Medical Necessity Guideline. Removed the Limitation Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria. Added documentation of non-compliance with an alternative approvable rationale. Minor wording updates to clarify coverage and make policy more concise (effective October 1, 2023).
- November 14, 2023: Effective December 1, 2023, added Rykindo to the Medical Necessity Guideline.
- April 1, 2024: Administrative Update: Added J Code J2801 to Medical Necessity Guideline.
- February 11, 2025: Effective March 1, 2025, added Erzofri to the Medical Necessity Guideline. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template
- March 11, 2025: Administrative Update: Added J Code: J2428. Effective 4/1/25
- May 12, 2026: No changes.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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