Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Medical Benefit Drugs
Rykindo® (risperidone)

Effective: April 1, 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 (a 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

Food and Drug Administration - Approved Indications

Rykindo (risperidone) is an atypical antipsychotic indicated for the treatment of schizophrenia in adults and as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Rykindo for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of **one (1)** of the following
    a. Autism spectrum disorders
    b. Bipolar disorder
    c. Major depressive disorder
    d. Schizophrenia/schizoaffective disorder
    e. Tourette syndrome
    f. Other psychiatric or neurologic condition requiring treatment with an antipsychotic (e.g., post-traumatic stress disorder)

AND

2. Documented inadequate response, adverse reaction, or contraindication to **ALL** of the following:
    a. Risperdal Consta
    b. Uzedy

AND

3. Documentation the requested quantity is less than or equal to 2 injections per 28 days

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2801	Injection, risperidone (rykindo), 0.5 mg

References:

1. Rykindo® [package insert]. Yantai, Shandong Province (China): Shandong Luye Pharmaceutical Co., Ltd.; 2023 June.
2. Keepers GA, et al. The American Psychiatric Association Practice Guideline for the Treatment of Patients With Schizophrenia. Am J Psychiatry. 2020 Sep 1;177(9):868-872. doi: 10.1176/appi.ajp.2020.177901. PMID: 32867516.
3. Psychosis and schizophrenia in adults: prevention and management. London: National Institute for Health and Care Excellence (NICE); March 2014.
4. Clinical Practice Guideline for Management of Bipolar Disorder in Adults. VA/DoD clinical practice guideline for management of bipolar disorder in adults. Washington (DC): Department of Veterans Affairs, Department of Defense; 2023
5. National Institute for Health and Clinical Excellence. Bipolar disorder: the assessment and management of bipolar disorder in adults, children and adolescents, in primary and secondary care. National clinical practice guideline number 185 [monograph on the internet]. London (UK): National Institute for Health Care Excellence; 2020.
6. Risperdal Consta® [package insert]. Titusville(NJ):Janssen Pharmaceuticals, Inc.; 2021 Feb.

Approval and Revision History

December 12, 2023: Reviewed by the Pharmacy & Therapeutics Committee.
Subsequent endorsement date(s) and changes made:

- April 1, 2024: Administrative Update: Added J Code J2801 to Medical Necessity Guideline.
- December 9, 2025: Administrative update to remove Harvard Pilgrim Stride from guideline. No additional changes.
- March 10, 2026: Effective 4/1/26, removed Perseris from required trial alternatives due to discontinuation from the manufacturer.

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.