Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Asparaginase Products

Effective: October 14, 2025

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

Erwinaze (asparaginase *Erwinia Chrysanthemi*) is an asparagine specific enzyme indicated as a component of a multi-agent chemotherapeutic regimen indicated for the treatment of patients with acute lymphoblastic leukemia (ALL) who have developed hypersensitivity to *E-coli* derived asparaginase.

Rylaze (asparaginase *Erwinia Chrysanthemi [recombinant]-rywn*) is an asparagine specific enzyme indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of ALL and lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month or older who have developed hypersensitivity to *E. coli*-derived asparaginase.

Clinical Guideline Coverage Criteria

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

1. Documented of **one (1)** of the following:
    a. For Erwinaze, a diagnosis of acute lymphoblastic leukemia
    b. For Rylaze, a diagnosis of acute lymphoblastic leukemia or lymphoblastic lymphoma

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation the patient has developed hypersensitivity to E. coli-derived asparaginase

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description

References

1. Erwinase (asparaginase Erwinia Chrysanthemi) [prescribing information]. Langhorne, PA: EUSA Pharma (USA), Inc. 2011 Nov.
2. Rylaze (asparaginase Erwinia Chrysanthemi [recombinant]-rywn) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; 2025 July.

Approval And Revision History

November 14, 2023: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- October 8, 2024: No changes (eff 10/8/24)
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- October 14, 2025: No changes (eff 10/14/25)
- January 1st, 2026: Administrative update: Removed codes: J9019 and J9020 due to code discontinuation, effective 1/1/26.

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.