Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Rytelo™ (imetelstat)

Effective: January 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

Rytelo (imetelstat) is an oligonucleotide telomerase inhibitor indicated for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESAs).

Clinical Guideline Coverage Criteria

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

Initial Authorization Criteria

1. Documented diagnosis of myelodysplastic syndrome

AND

2. Documentation of very low- to intermediate-risk disease

AND

3. Documentation the patient has required **four (4)** or more red blood cell units over an **eight (8)** week timeframe

AND

4. Documentation of **one (1)** of the following:
   a. The patient has had no response to erythropoiesis-stimulating agents
   b. The patient is ineligible to treatment with erythropoiesis-stimulating agents

AND

5. Patient is at least 18 years of age or older

AND

6. Prescribed by or in consultation with a hematologist or oncologist

Reauthorization Criteria

1. Documented diagnosis of very low- to intermediate-risk myelodysplastic syndromes

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with a hematologist or oncologist

AND

4. Documentation that the Member has experienced a therapeutic response as defined by the provider indicating a decrease in the need for red blood cell transfusions

Limitations

- Initial approval of Rytelo will be limited to six (6) months. Reauthorization of Rytelo will be provided in 12-month intervals.
- Members new to the plan and stable on Rytelo should be reviewed against Reauthorization criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0870	INJECTION, IMETELSTAT, 1 MG

References

1. Platzbecker U, Santini V, Fenaux P, et al. Imetelstat in patients with lower-risk myelodysplastic syndromes who have relapsed or are refractory to erythropoiesis-stimulating agents (IMerge): a multinational, randomised, double-blind, placebo-controlled, phase 3 trial. Lancet. 2024 Jan 20; 403 (10423): 249 – 60
2. National Comprehensive Cancer Network. Myelodysplastic syndromes (Version 2.2024). 2024 May 22. Available at: https://www.nccn.org. Accessed on September 12 2024.
3. Rytelo (imetelstat) [prescribing information]. Bloomington, IN: Catalent Indiana, LCC.; June 2024.

Approval And Revision History

October 8, 2024: Reviewed by the Pharmacy & Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- Administrative update: November 2024: Added J code J0870, effective 1/1/25.
- December 2025: Evote, no changes (effective 1/1/26)

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.