Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Rytelo™ (imetelstat)

Effective: January 1, 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

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☒ 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

Myelodysplastic syndrome (MDS) refers to a group of cancers that keep blood stem cells from maturing into health blood cells. Systemic consequences include anemia, bleeding, increased risk of infection, and increased risk of transformation to acute leukemias. Treatment options for MDS fall into different categories based on risk and prognosis. Supportive care should be used in all patients with MDS and include transfusion with packed red blood cells and platelets, erythropoiesis-stimulating agents (ESAs) and antibiotics. The other treatment categories are broken down into low- (noncurative, symptomatic treatments) and high-intensity (may reduce risk of death) therapies. Additionally, certain subtypes of MDS may also be treated with specific pharmacologist agents.

Rytelo (imetelstat) is the first oligonucleotide human telomerase inhibitor approved by the Food and Drug Administration (FDA).

Approval of Rytelo is based on the Phase 3 IMerge, placebo-controlled trial where 178 patients with transfusion dependent, IPSS low- or intermediate-1 risk MDS that is relapsed /refractory to ESA treatment were randomized to receive Rytelo or placebo until disease progression or unacceptable toxicity. The proportions of patients receiving Rytelo who achieved red blood cell transfusion independence for at least 8 (39.8% vs 15.0%) and 24 (28.0% vs 3.3%) consecutive weeks were higher compared to placebo, respectively.

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 ESAs.

Clinical Guideline Coverage Criteria

The plan may authorization 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

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

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. Rytelo (imetelstat) [prescribing information]. Bloomington, IN: Catalent Indiana, LLC.; June 2024.
2. American Cancer Society. Myelodysplastic syndromes. Accessed October 2024.
3. Platzbecker U, 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;403(10423):249-260.

Approval And Revision History

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

December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/25)

Subsequent endorsement date(s) and changes made:

- Administrative update: November 2024: Added J code J0870, effective 1/1/25.

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines 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.