Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Reblozyl® (luspatercept-aamt)

Effective: March 10, 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

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

Reblozyl (luspatercept-aamt) is an erythroid maturation agent indicated for the treatment of:

- **Beta Thalassemia**
  Anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions
- **Myelodysplastic Syndromes Associated Anemia**
  Anemia without previous erythropoiesis stimulating agent (ESA) use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes who may require regular red blood cell (RBC) transfusions
- **Myelodysplastic syndromes with ring sideroblasts (MDS-RS) or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts (MDS/MPN-RST) and thrombocytosis associated anemia**
  Anemia failing an erythropoiesis stimulating agent (ESA) and requiring two (2) or more red blood cell units over eight (8) weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T).

Reblozyl is not indicated for use as a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia.

Clinical Guideline Coverage Criteria

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

Beta Thalassemia

Initial Authorization Criteria

1. Documented diagnosis of beta thalassemia

AND

2. Prescribed by or in consultation with a hematologist

AND

3. Documentation the patient requires regular red blood cell transfusions as defined by a minimum of **six (6)** red blood cell units in a 24-week period and no transfusion-free period greater than 35 days during that period

AND

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

Reauthorization Criteria

1. Documented diagnosis of beta thalassemia

AND

2. Prescribed by or in consultation with a hematologist

AND

3. Documentation of a reduction in transfusion requirements from pretreatment baseline of at least **two (2)** units packed red blood cells

AND

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

Myelodysplastic Syndromes

Initial Authorization Criteria

1. Documented diagnosis of **one (1)** of the following:
    a. Myelodysplastic syndrome
    b. Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis

AND

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

AND

3. Documentation the patient has required **two (2)** or more red blood cell units over an **eight (8)** week timeframe

AND

4. If the patient has myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis, documentation of **one (1)** of the following:
    a. Inadequate response to an erythropoiesis stimulating agent
    b. Clinical inappropriateness to treatment with an erythropoiesis stimulating agent

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

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0896	Injection, luspatercept-aamt, 0.25 mg

References

1. Angelucci E. A new medical therapy for anemia in thalassemia. Blood. 2019;133(12):1267.
2. Cappellini MD, Cohen A, Porter J, et al. Guidelines for the management of transfusion dependent thalassemia, 3rd edition. 2014 [Accessed January 2020]. Available on the Internet. URL: https://thalassaemia.org.cy/publications/tif-publications/guidelines-for-the-management-of- transfusion-dependent-thalassaemia-3rd-edition-2014/.
3. Estey EH. Prognosis of the myelodysplastic syndromes in adults. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on April 28, 2020).
4. Edward J Benz, Jr, MD Emanuele Angelucci, MD. Management of thalassemia. In: UpToDate. Waltham, MA. (Accessed on March 24, 2022).
5. Estey EH. Treatment of lower-risk myelodysplastic syndromes (MDS). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on March 24, 2022).
6. Fenaux P, Platzbecker U, Mufti GJ, et al. Luspatercept in patients with lower -risk myelodysplastic syndromes. N Engl J Med. 2020;382:140-51.
7. Reblozyl (luspatercept-aamt) [prescribing information]. South San Francisco, CA: Genentech, Inc.; May 2024.

Approval And Revision History

May 17, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)

June 13, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees effective January 1, 2023
- Administrative update: April 2023 added Medical Benefit Drugs to title, updated MATogether and RITogether fax numbers to 617-673-0939
- May 17, 2023: Annual review, no change, effective July 1, 2023.
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- February 13, 2024: Minor wording updates. Administrative update to check off Harvard Pilgrim Health Care Commercial business line. Added coverage criteria for the supplemental indication of myelodysplastic syndromes associated anemia to the Medical Necessity Guideline (effective 3/1/2024).
- March 11, 2025: No changes. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template (eff 3/11/25).
- March 10, 2026: No changes. Administrative update to remove Carelink from guideline template.

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.