Luspatercept-aamt (Reblozyl®)	Place of Service Hospital Administration Home Infusion Administration Office Administration Outpatient Facility Infusion Administration Infusion Center Administration HCPCS: **J0896** per 0.25 mg

Condition listed in policy (*see criteria for details*)

- Myelodysplastic syndromes associated anemia
- Myelofibrosis-associated anemia
- Transfusion-dependent beta thalassemia

AHFS therapeutic class: Hematopoietic Agent

Mechanism of action: Erythroid maturation agent

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Reblozyl® (luspatercept-aamt) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Transfusion-dependent beta thalassemia

1. Age 18 years or older, **AND**
2. Provider attestation that patient is transfusion-dependent, **AND**
3. Either of the following:
    a. Patient has not received prior therapy with Zynteglo, or
    b. Patient had inadequate response with Zynteglo

Covered Doses

Up to 1.25 mg/kg SC every 3 weeks

Coverage Period

Initial: 6 months

Reauthorization: 6 months if meets below criteria

1. Physician attestation that patient has experienced a reduction in transfusion burden [at least 2 red blood cell (RBC) units in the past 24 weeks], and
2. Either of the following:
    a. Patient has not received prior therapy with Zynteglo, or
    b. Patient had inadequate response with Zynteglo

ICD-10:

D56.1, D56.5

Myelodysplastic syndromes associated anemia

1. Disease is lower risk (IPSS-R very low, low, intermediate, IPSS low/intermediate-1, WPSS very low, low, intermediate), **AND**
2. Provider attestation that patient is transfusion dependent (i.e., requiring 2 or more red blood cell units over 8 weeks)

Covered Doses

Up to 1.75 mg/kg SC every 3 weeks

Coverage Period

Initial: 6 months

Reauthorization: indefinite if meets below criteria

- Physician attestation that patient has experienced a reduction in transfusion burden [at least 2 red blood cell (RBC) units in the past 24 weeks]

ICD-10:

C93.10, D46.0, D46.1, D46.20, D46.21, D46.4, D46.9, D46.A, D46.B, D46.Z

Myelofibrosis-associated anemia

1. Being used with ruxolitinib if there is the presence of symptomatic splenomegaly and/or constitutional symptoms, **AND**
2. Provider attestation that patient is transfusion dependent (i.e., requiring 2 or more red blood cell units over 8 weeks)

Covered Doses

Up to 1.75 mg/kg SC every 3 weeks

Coverage Period
Initial: 6 months

Reauthorization: indefinite if meets below criteria
- Physician attestation that patient has experienced a reduction in transfusion burden [at least 2 red blood cell (RBC) units in the past 24 weeks]

ICD-10:
C94.40-C94.42, C94.6, D47.1, D47.4, D75.81

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for Reblozyl® (luspatercept-aamt) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)
Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information
How supplied:
- 25 mg (single-dose vial)
- 75 mg (single-dose vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network. Myelodysplastic Syndromes (Version 3.2023). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Myeloproliferative Neoplasms (Version 1.2024). Available at http://www.nccn.org.
- Reblozyl® (luspatercept-aamt) [Prescribing Information]. Summit, NJ: Celgene Corporation; 8/2023.

(7) Policy Update
Date of last review: 1Q2024
Date of next review: 1Q2025
Changes from previous policy version:
- New indication in Section (2): Added coverage for myelofibrosis-associated anemia

  Rationale: NCCN2A support