

<b>Policy Name:</b>	<b>Reblozyl (luspatercept)</b>	<b>Policy #:</b>	<b>2733P</b>
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## Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Reblozyl.

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Reblozyl under the specialty medical benefit when the following criteria has been met.

## Criteria

### 1. Coverage Criteria for Anemia due to Beta-Thalassemia

- 1.1 Documented diagnosis of anemia due to beta thalassemia
- 1.2 Age 18 years or older
- 1.3 Prescribed by or in consultation with a hematologist (blood doctor)
- 1.4 Documentation that the patient has had at least 6 red blood cell units transfused within the past 24 weeks

### 2. Coverage Criteria for Anemia due to Myelodysplastic Syndrome

- 2.1 Documented diagnosis of anemia due to myelodysplastic syndrome with ring sideroblasts or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis
- 2.2 Documentation that the patient has had at least 2 red blood cell units transfused over the past 8 weeks if patient is NOT erythropoiesis-stimulating agent-naïve
- 2.3 Age 18 years or older
- 2.4 Prescribed by or in consultation with a hematologist (blood doctor)
- 2.5 Documentation of very low to intermediate risk disease as defined by one of the following tools:
  - Revised International Prognostic Scoring System (IPSS-R): Very low, low, intermediate (score of 0 to less than or equal to 4.5)
  - International Prognostic Scoring System (IPSS): Low/Intermediate-1 (Score 0 to 1)
  - WHO-Based Prognostic Scoring System (WPSS): Very low, low, intermediate (Score of 0 to 2)
- 2.6 Hemoglobin level less than (<) 10g/dL

### 3. Exclusion Criteria

- 3.1 Hemoglobin (sickle) S/beta thalassemia or alpha thalassemia (e.g. Hemoglobin H)
- 3.2 Use as a substitute for red blood cell transfusion in patients who require immediate correction of anemia

### 4. Approval Period

- 4.1 Initial Approval: 12 months
- 4.2 Reapproval: 12 months with documentation that the member's disease has stabilized and not progressed (member has experienced a clinically meaningful decrease in transfusion burden)

## CPT Codes

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## HCPCS Codes

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## References

1. Reblozyl (luspatercept) [prescribing information]. Summit, NJ: Celgene Corporation; May 2024.
2. Cappellini MD, Viprakasit V, Taher AT, et al. A Phase 3 Trial of Luspatercept in Patients with Transfusion-

Dependent  $\beta$ -Thalassemia. N Engl J Med 2020; 382:1219.

3. Cappellini MD., Farmakis D., Porter J, et al. 2021 Thalassaemia International Federation Guidelines for the Management of Transfusion-dependent Thalassemia. Hemasphere. 2022 Jul 29;6(8):e732.
4. Fenaux P, Haase D, Santini V, et al; ESMO Guidelines Committee. Myelodysplastic syndromes: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2021 Feb;32(2):142-156.
5. Platzbecker U, Della Porta MG, Santini V, et al. Efficacy and safety of luspatercept versus epoetin alfa in erythropoiesis-stimulating agent-naive, transfusion-dependent, lower-risk myelodysplastic syndromes (COMMANDS): interim analysis of a phase 3, open-label, randomised controlled trial. Lancet. 2023 Jul 29;402(10399):373-385.

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