

Specialty Guideline Management

Reblozyl

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Reblozyl	luspatercept-aamt

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Indicated for:

- Treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions
- Treatment of anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions
- Treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 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)

Compendial Use

Myelofibrosis-associated anemia⁵

Limitations of Use

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

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Anemia with beta thalassemia

Initial requests:

- Pretreatment or pretransfusion hemoglobin (Hgb) level
- Either of the following:
 - Hemoglobin electrophoresis or high-performance liquid chromatography (HPLC) results OR molecular genetic testing results, or
 - Chart notes or medical record documentation stating diagnosis of beta thalassemia (β -thalassemia) or hemoglobin E/ β -thalassemia was previously confirmed

Anemia of myelodysplastic syndrome or myelodysplastic/myeloproliferative neoplasm

Initial requests:

Pretreatment or pretransfusion hemoglobin (Hgb) level

Exclusions¹

Anemia with beta thalassemia

Coverage will not be provided for members with hemoglobin S/ β -thalassemia or alpha-thalassemia.

Coverage Criteria

Anemia with beta thalassemia^{1-4,7-9}

Authorization of 16 weeks may be granted for treatment of anemia with beta thalassemia in members 18 years of age or older when all of the following criteria are met:

- The member has symptomatic anemia evidenced by a pretreatment or pretransfusion Hgb level less than or equal to 11 grams per deciliter (g/dL).
- The member has a diagnosis of beta thalassemia (β -thalassemia) or hemoglobin E/ β -thalassemia (β -thalassemia with mutation and/or multiplication of alpha globin is allowed) confirmed by one of the following:
 - Hemoglobin electrophoresis or high-performance liquid chromatography (HPLC)
 - Molecular genetic testing
- The member required at least 6 red blood cell (RBC) units to be transfused in the previous 24 weeks.

Note: If a red blood cell (RBC) transfusion occurred prior to dosing, the pretransfusion hemoglobin (Hgb) level must be considered for dosing purposes.

Anemia of myelodysplastic syndrome or myelodysplastic/myeloproliferative neoplasm^{1,5,6}

Authorization of 24 weeks may be granted for treatment of anemia of myelodysplastic syndrome or myelodysplastic/myeloproliferative neoplasm in members 18 years of age or older when all of the following criteria are met:

- The member has either of the following:
 - Very low- to intermediate-risk myelodysplastic syndrome
 - Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
- The member has symptomatic anemia evidenced by a pretreatment or pretransfusion Hgb level less than or equal to 11 g/dL.
- The member has been receiving regular red blood cell (RBC) transfusions as defined by greater than or equal to 2 units per 8 weeks.

Myelofibrosis-associated anemia⁵

Authorization of 12 months may be granted for the treatment of myelofibrosis-associated anemia.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting authorization for an indication listed in the coverage criteria section when both of the following criteria are met:

- The member has achieved or maintained a reduction in red blood cell transfusion burden.
- The member has not experienced an unacceptable toxicity from Reblozyl.

References

1. Reblozyl [package insert]. Summit, NJ: Celgene Corporation, a Bristol-Myers Squibb Company; May 2024.
2. Capellini MD, Viprakasit V, Taher AT, et al. A phase 3 trial of luspatercept in patients with transfusion-dependent β -thalassemia. *N Engl J Med*. 2020;382(13):1219-31.
3. Benz EJ, Angelucci E. Diagnosis of thalassemia (adults and children). In: UpToDate, Timauer, JS (Ed), UpToDate, Waltham, MA, 2023. URL: www.uptodate.com. Accessed February 4, 2025.
4. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. <http://www.nccn.org>. February 4, 2025.
5. Fenaux P, Platzbecker U, Mufti GJ, et.al. Luspatercept in patients with lower-risk myelodysplastic syndromes. *N Engl J Med*. 2020;382:140-51.
6. Farmakis D, Porter J, Taher A, Cappellini MD, Angastiniotis M, Eleftheriou A. 2021 Thalassaemia International Federation guidelines for the management of transfusion-dependent thalassemia. *Hemasphere*. 2022;6(8):e732.