SmartHealth Ascension

Luspatercept

(Reblozyl®) J0896 (0.25mg)

Covered with prior authorization

Reblozyl® (luspatercept) may be authorized when the following criteria are met:

Beta-Thalassemia:
Individual meets ALL of the following criteria:

- Individual is 18 years of age or older; **AND**
- Individual requires regular red blood cell transfusions; **AND**
- The medication is being prescribed by or in consultation with a hematologist

Myelodysplastic Syndrome or Myelodysplastic/Myeloproliferative Neoplasm:
Individual meets ALL of the following criteria:

- Individual is 18 years of age or older; **AND**
- Treatment of anemia with a documented diagnosis of **EITHER** of the following
  - Myelodysplastic syndromes with ring sideroblasts (MDS-RS)
  - Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis associated anemia (MDS/MPN-RS-T); **AND**
- Individual has very low- to intermediate-risk myelodysplastic syndrome (determined by the Revised International Prognostic Scoring System [IPSS-R score less than or equal to 5.0; **AND**
- Individual does not have a confirmed mutation with deletion 5q (del 5q); **AND**
- Individual currently requires blood transfusions, defined as at least two red blood cell units over the previous 8 weeks; **AND**
  - Individual meets **ONE** of the following:
    - Individual has had an inadequate response to a trial of an erythropoiesis stimulating agent (ESA) for at least 6 weeks, unless intolerant
    - Serum erythropoietin level is greater than 500 mU/L; **AND**
- Pretreatment hemoglobin level is < 10.0 g/dL; **AND**
- Luspatercept (Reblozyl) will not be used in combination with an erythropoiesis stimulating agent (ESA); **AND**
- The medication is being prescribed by or in consultation with a hematologist or oncologist.

Exclusion criteria:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.

- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial approval duration:

- **Beta-Thalassemia: up to 4 months**
- **MDS-RS or MDS/MPN-RS-T: up to 6 months**

Reauthorization approval duration:

- **Beta-Thalassemia: up to 12 months**
- **MDS-RS or MDS/MPN-RS-T: up to 12 months**

Reauthorization Criteria:
Reblozyl® (luspatercept) is considered medically necessary for continued use when initial criteria are met **AND** there is documentation of beneficial response including the following:

- According to the prescriber, the individual has experienced a clinically meaningful decrease in transfusion burden.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Reblozyl® is an erythroid maturation agent indicated for the following conditions:

- Beta-thalassemia, for treatment of adults with anemia who require regular red blood cell (RBC) transfusions.
- Myelodysplastic syndromes with ring sideroblasts (MDS-RS) or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) associated anemia, for those failing an erythropoiesis stimulating agent and requiring two or more RBC units over 8 weeks in adult patients with very low- to intermediate-risk disease.

References:

1. Cappellini MD, Cohen A, Porter J, et al. Guidelines for the Management of Transfusion Dependent Thalassaemia (TDT) [Internet]. 3rd edition. Nicosia (CY): Thalassaemia International Federation; 2014. Available at: https://www.ncbi.nlm.nih.gov/books/NBK269382/.
2. National Organization for Rare Disorders (NORD). Beta thalassemia. Available at: https://rarediseases.org/rare-diseases/thalassemia-major//.
3. Reblozyl [prescribing information]. Summit; NJ and Cambridge, MA: Celgene/Acceleron; 2020.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.