CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Reblozyl (luspatercept-aamt)
BILLING CODE	J0896
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Reblozyl, approved by the FDA in 2019, is an erythroid maturation agent indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions. It acts as a ligand trap to block inhibitors of late-stage erythropoiesis.
Beta-thalassemia is a rare blood disorder caused by mutations in the beta-globin (HBB) gene which lead to absent (β^0) or reduced (β^+) production of functional adult hemoglobin (HbA), impeding RBC development and survival (ineffective erythropoiesis) to result in microcytic anemia, iron overload, and other complications. The most severely affected patients have lifelong dependency on RBC transfusions and require iron chelation.
In the phase 3 BELIEVE trial, the primary outcome measure was achievement of transfusion burden reduction from baseline of at least 33%. The endpoint was met by 21.4% of patients treated with Reblozyl.

Reblozyl (luspatercept-aamt) will be considered for coverage when the following criteria are met:

Beta Thalassemia

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a hematologist; AND
3. Member has a confirmed diagnosis of beta thalassemia; AND
4. Member requires regular red blood cell (RBC) transfusions, defined by BOTH of the following:
   a) Received a total of at least 6 units of RBC in the last 6 months
   b) No transfusion-free period ≥ 35 days during the last 6 months; AND
5. Member does NOT have any of the following:
   a) Active hepatitis B or C infection or positive human immunodeficiency virus (HIV)
   b) Deep vein thrombosis (DVT) or stroke in the past 6 months
   c) Major organ damage
   d) Sickle beta thalassemia or alpha thalassemia.
6. **Dosage allowed/Quantity limit:** Start 1 mg/kg once every 3 weeks by subcutaneous injection. If no response after 2 doses, increase to 1.25 mg/kg every 3 weeks; discontinue if no response after 9 weeks (3 doses).

If all the above requirements are met, the medication will be approved for 4 months (up to 5 doses).

For **reauthorization**:
1. Member has a reduction in RBC transfusion requirements of at least 2 units from baseline (prior to starting treatment).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Myelodysplastic Syndromes

Any request for cancer must be submitted through NantHealth/Eviti portal.

CareSource considers Reblozyl (luspatercept-aamt) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/04/2020	New policy for Reblozyl created.
09/21/2022	Transferred to new template. Updated and added references. Removed oncology from prescriber type. Removed hemoglobin E. Added recent DVT or stroke as exclusion. Clarified dosing. Extended initial approval duration to 4 months (from 3 months). Removed signs/symptoms from renewal criteria (not studied in trial).

References:

1. Reblozyl [prescribing information]. Celgene Corporation; 2022.
2. Cappellini 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):1219-1231. doi:10.1056/NEJMoa1910182
3. Piga A, Perrotta S, Gamberini MR, et al. Luspatercept improves hemoglobin levels and blood transfusion requirements in a study of patients with β-thalassemia. *Blood*. 2019;133(12):1279-1289. doi:10.1182/blood-2018-10-879247
4. Farmakis D, Porter J, Taher A, Domenica Cappellini M, Angastiniotis M, Eleftheriou A. 2021 Thalassaemia International Federation Guidelines for the Management of Transfusion-dependent Thalassemia. *Hemasphere*. 2022;6(8):e732. Published 2022 Jul 29. doi:10.1097/HS9.0000000000000732
5. Cappellini MD, Taher AT. The use of luspatercept for thalassemia in adults. *Blood Adv*. 2021;5(1):326-333. doi:10.1182/bloodadvances.2020002725
6. Langer AL, Esrick EB. β-Thalassemia: evolving treatment options beyond transfusion and iron chelation. *Hematology Am Soc Hematol Educ Program*. 2021;2021(1):600-606. doi:10.1182/hematology.2021000313

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