PHARMACY POLICY STATEMENT
Michigan Medicaid

DRUG NAME	Reblozyl (luspatercept-aamt)
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's pre-dose hemoglobin is no more than 11 g/dL; AND
6. Member does NOT have any of the following:
   a) Deep vein thrombosis (DVT) or stroke in the past 6 months
   b) Major organ damage
   c) Sickle beta thalassemia or alpha thalassemia.
7. **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). Titration based on response per prescribing information.

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 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.

HAP 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).
01/19/2024	Updated references. Added that the predose hemoglobin is no more than 11 (prescribing info).
01/30/2026	Updated references. Added "titration based on response per prescribing information" to dosing section. Removed hepatitis/HIV exclusion (was from clinical trial). Removed specific number of RBC unit reduction from renewal.

References:

1. Reblozyl [prescribing information]. Celgene Corporation, a Bristol-Myers Squibb Company; 2024.
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. 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
4. Cappellini MD, Taher AT. The use of luspatercept for thalassemia in adults. *Blood Adv*. 2021;5(1):326-333. doi:10.1182/bloodadvances.2020002725
5. Langer AL. Beta-Thalassemia. 2000 Sep 28 [Updated 2024 Feb 8]. In: Adam MP, Bick S, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2026. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1426/
6. Longo F, Motta I, Pinto V, et al. Treating Thalassemia Patients with Luspatercept: An Expert Opinion Based on Current Evidence. *J Clin Med*. 2023;12(7):2584. Published 2023 Mar 29. doi:10.3390/jcm12072584
7. Thalassaemia International Federation (TIF). Guidelines for the Management of Transfusion-Dependent β-Thalassaemia (5th edition – 2025). https://thalassaemia.org.cy/publications/tif-publications/

Effective date: 07/01/2026
Revised date: 01/30/2026