Clinical Policy: Luspatercept-aamt (Reblozyl)

Reference Number: CP.PHAR.450
Effective Date: 03.01.20
Last Review Date: 02.20
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Luspatercept-aamt (Reblozyl) is an erythroid maturation agent

FDA Approved Indication(s)

Reblozyl is indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions.

Limitation(s) of use: Not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Reblozyl is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Transfusion Dependent Beta Thalassemia (must meet all)**:**

1. Diagnosis of transfusion dependent thalassemia (TDT) with one of the following genotypes (a or b):
   a. Beta thalassemia;
   b. Hemoglobin E/beta thalassemia;
2. Prescribed by or in consultation with a hematologist;
3. Age ≥ 18 years;
4. Total volume of transfusions exceeds 6 RBC units (*see Appendix D*) within the last 6 months;
5. No transfusion-free period ≥ 35 days within the last 6 months;
6. Documentation of baseline transfusion burden within the last 6 months;
7. Dose does not exceed 1 mg/kg every 3 weeks.

Approval duration: 2 months (2 doses)

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid

II. Continued Therapy

A. Transfusion Dependent Beta Thalassemia (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member meets one of the following (a or b):
   a) Member is responding positively to therapy as evidenced by at least a 33% reduction in transfusion burden from baseline;
   b) Request is for a dose increase;
3. If request is for a dose increase, new dose does not exceed (a or b):
   a) 1 mg/kg every 3 weeks;
   b) 1.25 mg/kg every 3 weeks, and documentation supports inadequate response to 1 mg/kg dosing.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
Hb: hemoglobin
TDT: transfusion dependent thalassemia

Appendix B: Therapeutic Alternatives
None available.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): None reported
- Boxed warning(s): None reported

Appendix D: General Information

- Conversion of RBC units from mL: 1 RBC unit in this criteria refers to a quantity of packed RBCs approximately 200-350 mL.

- Sites who use transfusion bags within this range, or ≥ 350 mL, the conversion in units should be done by dividing the volume transfused to the patient by 350 mL,
- Sites who use transfusion bags < 200 mL, the conversion in units should be done by dividing the volume transfused to the patient by 200 mL.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Transfusion-dependent beta thalassemia	1 mg/kg SC once every 3 weeks Evaluation hemoglobin (Hgb) prior to next planned administration. If pre-dose Hgb ≥ 11.5 g/dL and Hgb level is not influenced by recent transfusion, delay dosing until the Hgb is ≤ 11 g/dL. If a patient does not achieve a reduction in RBC transfusion burden after at least 2 consecutive doses (6 weeks) at the 1 mg/kg starting dose, increase to max dose of 1.25 mg/kg.	1.25 mg/kg

VI. Product Availability

Single dose vial for injection: 25 mg, 75 mg

VII. References

1. Reblozyl Prescribing Information. Cambridge, MA: Acceleron Pharma, Inc. November 2019. Available at: www.reblozyl.com. Accessed December 6, 2019.
2. Cappellini MD, Vipralasit V, Taher A, et al. The BELIEVE Trial: Results of a phase 3, randomized, double-blind, placebo-controlled study of luspatercept in adult beta-thalassemia patients who require regular red blood cell (RBC) transfusions [Oral]. Oral presented at: 60th American Society of Hematology Annual Meeting and Exposition (ASH); December 1-4, 2018; San Diego, CA.
3. Cappellini MD, Cohen A, Porter J, et al. Guidelines for the management of transfusion dependent thalassemia (TDT) 3rd Edition. Thalassemia International Federation (2014):20.

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

The following is a list of diagnosis codes that support coverage for the applicable covered procedure code(s).

ICD-10-CM Code	Description
D56.1*	Beta thalassemia

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	12.05.19	02.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.