Medical Policy

Reblozyl® (luspatercept-aamt)	
MEDICAL POLICY NUMBER	Med_Clin_Ops-057
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

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PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Reblozyl® (luspatercept-aamt) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Coverage for Reblozyl will be provided for 12 months and may be renewed.

Initial Therapy

Anemia related to beta-thalassemia

1. The patient 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 hemoglobin electrophoresis or high-performance liquid chromatography (HPLC): **AND**

2. Patient is 18 years of age and older; **AND**
3. Patient has symptomatic anemia defined as a pretreatment or pretransfusion Hgb level less than or equal to 11 g/dL: **AND**
   Note: If the pre-dose Hgb is greater than or equal to 11.5 g/dL and the Hgb level is not influenced by recent transfusion, delay dosing until the Hgb is less than or equal to 11 g/dL)
4. Patient required at least 6 red blood cell (RBC) units transfused in the previous 24 weeks.

Myelodysplastic Syndromes with Ring Sideroblasts or Myelodysplastic/ Myeloproliferative Neoplasm with Ring Sideroblasts and Thrombocytosis Associated Anemia

1. Patient has symptomatic anemia defined as a pretreatment or pretransfusion Hgb level less than or equal to 11 g/dL; **AND**
2. Patient has been receiving regular RBC transfusions; **AND**
3. Patient meets **one** of the following:
   - **a.** Ring sideroblasts are greater than or equal to 15%; **OR**
   - **b.** Ring sideroblasts are greater than or equal to 5% and less than 15% and the patient has an SF3B1 mutation; **AND**
4. Patient meets **one** of the following:
   - **a.** Pretreatment serum erythropoietin levels greater than 500 mU/mL; **OR**
   - **b.** Pretreatment serum erythropoietin levels less than or equal to 500mU/mL following no response to the combination of an erythropoiesis-stimulating agent (ESA) and granulocyte-colony stimulating factor (G-CSF).

Continuation Therapy

1. The need for regular RBC transfusions has been decreased as indicated by prescriber.
2. Patient must have a pre-dose Hgb level less than or equal to 11 grams per deciliter; if the Hgb level is greater than 11 grams per deciliter, the prescriber agrees to hold the dose until the level falls to 11 grams per deciliter.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

BACKGROUND

Reblozyl (luspatercept-aamt) is an erythroid maturation agent. Luspatercept-aamt is a receptor fusion protein consisting of a modified extracellular domain of the human activin receptor type IIB linked to a human IgG1 Fc domain with a calculated molecular mass of approximately 76 kD. Luspatercept-aamt is produced in Chinese hamster ovary cells by recombinant DNA technology.

DEFINITIONS

1. REBLOZYL (luspatercept-aamt) for injection, for subcutaneous use. Initial U.S. Approval: 2019

a. REBLOZYL (luspatercept-aamt) for injection is a white to off-white lyophilized powder supplied in a single-dose vial. Each carton contains one vial.

CODING

Applicable NDC Codes	
59572-0775-01	Reblozyl (luspatercept-aamt) PDS 75MG
59572-0711-01	Reblozyl (luspatercept-aamt) PDS 25MG

Applicable Procedure Code	
J0896	Injection, luspatercept-aamt, 0.25 mg (Reblozyl)

Applicable ICD-10 Codes	
D46.1	Refractory anemia with ring sideroblasts
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.4	Refractory anemia, unspecified
D46.Z	Other myelodysplastic syndromes
D46.9	Myelodysplastic syndrome, unspecified
D56.1	Beta-thalassemia major and intermediate Cooley's anemia Homozygous beta thalassemia Severe beta thalassemia Thalassemia intermedia Thalassemia major
D56.5	Hemoglobin E-beta thalassemia

EVIDENCE BASED REFERENCES

1. Reblozyl [package insert]. Celgene Corporation Summit, NJ 07901 and Acceleron Pharma, Inc. Cambridge, MA 02139; 2019.
2. Luspatercept-aamt. IBM Micromedex® DRUGDEX®. IBM Watson Health, Greenwood Village, Colorado, USA January 2020.

POLICY HISTORY

Original Effective Date	May 24, 2021
Revised Date	November 1, 2021: Annual review – no changes made. November 8, 2022: Annual review – no changes made. March 01, 2023: Adopted by MA UMC - no changes made. January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

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Approved by Pharmacy and Therapeutics Committee on 11/8/2022