

Drug Policy:

Reblozyl™ (luspatercept-aamt)

POLICY NUMBER UM ONC_1392	SUBJECT Reblozyl™ (luspatercept-aamt)	DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 04/08/20, 08/12/20	APPROVAL DATE August 12, 2020	EFFECTIVE DATE August 28, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 04/08/20, 08/12/20
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee	
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Reblozyl (luspatercept-aamt) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)
2. When health plan Exchange coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When available, generic alternatives are preferred over brand-name drugs.

B. Myelodysplastic Syndromes (MDS)

1. Reblozyl (luspatercept-aamt) is being used for ALL of the following conditions:
 - a. Member has Lower Risk MDS with symptomatic anemia, specifically either MDS with ring sideroblasts $\geq 15\%$ OR MDS with ring sideroblasts $\geq 5\%$ + SF3B1 mutation
 - b. Serum erythropoietin level > 500 mU/ml OR
 - c. Serum erythropoietin level < 500 mU/ml AND failure of a trial of therapy (generally 3-6 months) with an ESA- Erythropoiesis Stimulating Agent AND the member required 2 or more RBC units over 8 weeks.

C. Beta Thalassemia Anemia

1. Reblozyl (luspatercept-aamt) is being used for ALL of the following conditions:
 - a. The member has beta thalassemia anemia who require regular red blood cell (RBC) transfusions defined as 6-20 RBC units within the last 6 months, including the last 30 days
 - b. Initiate if hemoglobin (Hgb) is ≤ 11 gm/dL
 - c. Continue if Hgb is ≤ 11 gm/dL OR transfusion burden is not reduced after at least 2 consecutive doses
 - d. Discontinue if there is an increase in RBC transfusion burden after 3 doses (9 weeks) at the maximum dose (1.25 mg/kg) or if unacceptable toxicity occurs.

III. EXCLUSION CRITERIA

- A. Concurrent use with an erythropoiesis-stimulating agent, cytotoxic agents, or immunosuppressants.
- B. Dosing exceeds single dose limit of Reblozyl (luspatercept-aamt) 1.25 mg/kg.
- C. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

- A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

- A. Reblozyl PI prescribing information. Celgene Summit, NJ 2019.
- B. Clinical Pharmacology Elsevier Gold Standard. 2020.
- C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
- D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
- E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.