

POLICY NUMBER UM_Onc_1392	SUBJECT Reblozyl™ (luspatercept-aamt)	DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 04/08/20	APPROVAL DATE April 8, 2020	EFFECTIVE DATE April 24, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 04/08/20
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 All

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 is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- 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**
- 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**
- 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: **Error! Hyperlink reference not valid. AND**
- Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- When available, generic alternatives are preferred over brand-name drugs.

2. Myelodysplastic Syndromes

- Reblozyl (luspatercept-aamt) is being used for **ALL** of the following conditions:
 - 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
 - Serum erythropoietin level > 500 mU/ml
 - Serum erythropoietin level < 500 mU/ml **AND** failure of a trial of therapy (generally 3-6 months) with an ESA- Erythropoiesis Stimulating Agent.

3. Beta Thalassemia Anemia



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- a. Reblozyl (luspatercept-aamt) is being used for **ALL** of the following conditions:
 - i. 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
 - ii. Initiate if hemoglobin (Hgb) is ≤ 11 gm/dL
 - iii. Continue if Hgb is ≤ 11 gm/dL **OR** transfusion burden is not reduced after at least 2 consecutive doses
 - iv. 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

- 1. Reblozyl (luspatercept-aamt) is not being used as a substitute for RBC transfusions in members who require immediate correction of anemia.
- 2. Concurrent use with an erythropoiesis-stimulating agent, cytotoxic agents, or immunosuppressants.
- 3. Dosing exceeds single dose limit of Reblozyl (luspatercept-aamt) 1.25 mg/kg.
- 4. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

- 1. Review – Utilization Management Department
- 2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

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