

PHARMACY POLICY STATEMENT

Marketplace

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 reduced or absent 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

Myelodysplastic Syndromes

Any request for cancer must be submitted through [NantHealth/Eviti](#) portal.

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.