

Reblozyl® (luspatercept-aamt)

When requesting Reblozyl® (luspatercept-aamt) for non-oncology indications, the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Non-oncology Indication

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

Coverage Guidelines

Transfusion Dependent Beta Thalassemia

The individual must meet all of the following criteria for initial authorization:

- Is 18 years of age or older;
- Requires regular RBC transfusions as defined by the following:
 - o Has received at least 6 units of packed RBCs within the preceding 24 weeks; AND
 - o Has not had any transfusion-free period > 35 days within the preceding 24 weeks;
- Has not received a gene therapy for transfusion dependent beta-thalassemia in the past (e.g., Zynteglo [betibeglogene autotemcel], Casgevy [exagamglogene autotemcel]);
- Reblozyl is prescribed by or in consultation with a hematologist.

The individual must meet the following criteria for reauthorization:

- Has experienced a clinically meaningful decrease in transfusion burden as defined by a decrease in at least 2 units in RBC transfusion burden over the past 6 months compared to the pretreatment baseline;
- Has not received a gene therapy for transfusion dependent beta-thalassemia in the past (e.g., Zynteglo [betibeglogene autotemcel], Casgevy [exagamglogene autotemcel]).

Approval duration (Initial): 4 months

Approval duration (Renewal): 12 months

Dosing Recommendation

The recommended starting dose is 1 mg/kg once every 3 weeks by subcutaneous injection. The dose may be increased to 1.25 mg/kg once every 3 weeks.

References

1. Reblozyl® subcutaneous injection [prescribing information]. Summit; NJ and Cambridge, MA: Celgene/Acceleron; May 2024.
2. Cappellini MD, Viprakasit V, Taher AT, et al; BELIEVE Investigators. A Phase 3 Trial of Luspatercept in Patients with Transfusion-Dependent β -Thalassemia. *N Engl J Med*. 2020 Mar 26;382(13):1219-1231.
3. Farmakis D, Porter J, Taher A, et al, for the 2021 TIF Guidelines Taskforce. 2021 Thalassaemia International Federation guidelines for the management of transfusion-dependent thalassemia. *Hemasphere*. 2022;6:8(e732).