

Reblozyl® (luspatercept-aamt)

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

FDA-approved 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

Beta Thalassemia

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

- Is 18 years of age or older;
- Requires regular red blood cell transfusions (includes transfusion-dependent individuals); AND
- 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.

Approval duration (Initial): 4 months

Approval duration (Renewal): 12 months

Dosing Recommendation

Approve up to 1.25 mg/kg by subcutaneous injection, not more frequently than once every 3 weeks.

References

1. Reblozyl® for subcutaneous injection [prescribing information]. Summit; NJ and Cambridge, MA: Celgene and Acceleron; April 2020.
2. National Organization for Rare Disorders (NORD). Beta thalassemia. Available at: <https://rarediseases.org/rare-diseases/thalassemia-major//>. Accessed on November 8, 2019.
3. Standards of Care Guidelines for Thalassemia – 2012. Children's Hospital and Research Center Oakland. Available at: <https://thalassemia.com/documents/SOCGuidelines2012.pdf>. Accessed October 25, 2019.
4. Cappellini MD, Cohen A, Porter J, et al. Guidelines for the Management of Transfusion Dependent Thalassemia (TDT) [Internet]. 3rd edition. Nicosia (CY): Thalassemia International Federation; 2014. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK269382/>. Accessed on October 28, 2019.