

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

Initial Authorization:

- An individual is 18 years of age or older
- An individual requires regular red blood cell transfusions (includes transfusion-dependent individuals)
- Reblozyl is prescribed by or in consultation with a hematologist

Re-authorization:

- The individual has experienced a clinically meaningful decrease in transfusion burden

Approval duration (Initial): 4 months

Approval duration (Renewal): 12 months

Dosing Recommendation

The recommended starting dose of Reblozyl is 1 mg/kg once every 3 weeks by subcutaneous injection.

References

1. Reblozyl® for subcutaneous injection [prescribing information]. Summit; NJ and Cambridge, MA: Celgene and Acceleron; November 2019.
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): Thalassaemia International Federation; 2014. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK269382/>. Accessed on October 28, 2019.