

Reblozyl (luspatercept-aamt) Effective 03/01/2025

Plan	 □ MassHealth UPPL ⊠ Commercial/Exchange 		 ☑ Prior Authorization □ Quantity Limit □ Step Therapy
Benefit	 Pharmacy Benefit Medical Benefit 	Program Type	
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Reblozyl (luspatercept) is an erythroid maturation agent indicated for the treatment of:

- Anemia in adults with beta thalassemia who require regular red blood cell (RBC) transfusions
- Anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions
- Anemia failing an erythropoiesis stimulating agent and requiring two or more RBC units over eight weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication and are stable, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when all of the following criteria are met:

Beta Thalassemia

- 1. Documented diagnosis (e.g., medical records, genetic testing) of transfusion-dependent beta thalassemia
- 2. Member is 18 years of age or older
- 3. Member requires at least 6 red blood cell units every 24 weeks with no transfusion-free period greater than 35 days
- 4. Requested medication is prescribed by or in consultation with a hematologist

Myelodysplastic Syndromes (MDS)

- 1. Member is 18 years of age or older
- 2. Requested medication is prescribed by or in consultation with a hematologist or oncologist
- 3. Documented diagnosis of one of the following:
 - a. Very low- to intermediate-risk myelodysplastic syndromes (MDS)
 - b. Very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS)
 - c. Very low- to intermediate-risk myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
- 4. 4. Member requires at least 2 red blood cell units over an 8 week time period
- 5. **Members with MDS-RS or MDS/MPN-RS-T:** Member has had an inadequate response, adverse reaction, or contraindication to an erythropoiesis stimulating agent

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Documentation member has had a positive response to therapy (e.g., decrease in transfusion requirements)

Limitations

- 1. Initial approvals will be granted for 6 months
- 2. Reauthorization may be granted for 12 months

References

1. Reblozyl (luspatercept) [prescribing information]. Summit, NJ: Celgene Corporation; May 2024.

Review History

03/18/2020 - Created and Reviewed P&T Mtg (effective 6/1/20)

11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes.

12/11/2024 – Reviewed at December P&T. Added criteria for myelodysplastic syndrome. Updated initial criteria for beta thalassemia to include baseline transfusion requirements. Effective 3/1/2025.