

Prior Authorization Group Description	Reblozyl (luspatercept-aamt)
Drugs	Reblozyl (luspatercept-aamt) vial for subcutaneous injection
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Members are excluded if they have hemoglobin S/beta-thalassemia, isolated alpha-thalassemia, or myelodysplastic syndrome without ring sideroblasts.
Required Medical Information	See “other criteria”
Age Restrictions	Member must be 18 years of age or older
Prescriber Restrictions	Prescriber must be a hematologist or oncologist
Coverage Duration	Initial requests will be approved for 3 months. Reauthorization requests will be approved for 6 months.
Other Criteria	<p>Criteria for initial approval:</p> <ul style="list-style-type: none"> • Requested dose is appropriate per labeling • The member’s weight has been provided with the request • The member’s most recent hemoglobin level (within the last month) has been provided with the request • Diagnosis appropriate per Covered Uses • For requests for anemia due to beta thalassemia, documentation of all of the following is required: <ul style="list-style-type: none"> ○ Member requires regular RBC transfusions (defined as no transfusion-free period of more than 35 days over the last 6 months) • For requests for anemia due to myelodysplastic syndrome, documentation of all of the following is required: <ul style="list-style-type: none"> ○ Documentation of 5% or greater ring sideroblasts present in bone marrow ○ Myelodysplastic Syndrome Revised International Prognostic Scoring System (IPSS-R) categorization as very low, low, or intermediate risk of progression. ○ Member has tried and failed (or medical justification provided for not using) at least one erythropoiesis stimulating agent (ESA) at a dose equivalent to one of the following regimens: <ul style="list-style-type: none"> ▪ Recombinant human erythropoietin \geq 40,000 IU/week of for at least 8 doses ▪ Darbepoetin \geq 500 ug every 3 weeks for at least 4 doses OR ▪ If erythropoietin > 500 mU/mL, trial of ESA is not

<p>Revision/Review Date: 1/2023</p>	<p>required</p> <ul style="list-style-type: none"> ○ Member has required transfusion of 2 or more red blood cell (RBC) units within an 8 week period in the last 4 months ○ Hemoglobin less than 10 g/dl <p>Reauthorization:</p> <ul style="list-style-type: none"> • For diagnosis of anemia due to beta thalassemia, documentation of the following: <ul style="list-style-type: none"> ○ Fewer transfusions compared with baseline AND ○ A reduction in transfusion requirement of at least 2 red-cell units compared with baseline • Diagnosis of anemia due to myelodysplastic syndrome: documentation of ONE of the following: <ul style="list-style-type: none"> ○ Hemoglobin increase of at least 1.5 g/dl from baseline over a period of 3-6 months OR ○ Reduction in red blood cell transfusion by at least 4 units over a period of 3-6 months compared with baseline transfusion requirement • Prescriber states that the member did not experience a Grade 3 or 4 hypersensitivity reaction. <p>If the above conditions are not met, the request will be referred to a Medical Director for medical necessity review.</p>
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