Clinical Criteria

Subject: Reblozyl (luspatercept)

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Overview

This document addresses the use of Reblozyl (luspatercept). Reblozyl is an erythroid maturation agent used to treat anemia in adults with beta thalassemia who require regular red blood cell transfusions.

Beta thalassemia is an inherited blood disorder caused by mutations in the beta-globin (*HBB*) gene. These mutations result in defective red blood cells (RBC) that have little or no hemoglobin, the iron-containing protein that is responsible for oxygen transport. People who inherit just one *HBB* gene mutation (thalassemia minor or thalassemia trait) are usually asymptomatic. People who inherit two defective genes develop beta thalassemia with moderate anemia that can be managed with intermittent RBC transfusions (beta thalassemia intermedia) or severe anemia that is transfusion-dependent (beta thalassemia major, also called Cooley's anemia). Hemoglobin E beta thalassemia (E/β-thalassemia) and hemoglobin S beta thalassemia (S/β-thalassemia, also known as sickle beta thalassemia) are related disorders that occur when beta thalassemia is combined with another gene mutation or abnormality.

One of the risks that occurs with multiple blood transfusion is iron overload. Therefore, many of these patients also require life-long iron chelation therapy to manage this complication.

Reblozyl is the first drug to receive FDA approval to treat anemia in adults with transfusion-dependent beta thalassemia. It is also the first erythroid maturation agent to receive FDA approval. While Reblozyl may reduce the transfusion burden and, therefore, lower the need for iron chelation therapy, it does not completely eliminate the need for RBC transfusions. Per labeling, Reblozyl is to be administered by a healthcare professional as a subcutaneous injection. At this time, Reblozyl is not recommended for pediatric use due to findings from toxicity studies in juvenile animals.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Reblozyl (luspatercept)

Requests for Reblozyl (luspatercept) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; AND
II. Individual has a diagnosis of beta thalassemia or hemoglobin E beta (E/β)-thalassemia; AND
III. Individual required regular red blood cell transfusions at initiation, defined as *both* of the following (NCT02604433):
   A. Individual received six to twenty (6-20) RBC units in the last 24 weeks; AND
   B. Individual had no transfusion-free period greater than 35 days in the last 24 weeks; AND
IV. Individual has a baseline hemoglobin (Hgb) level less than or equal to 11 g/dL.

Reblozyl (luspatercept) may not be approved for the following:

I. Individual has a diagnosis of sickle beta thalassemia (S/β-thalassemia); OR
II. Individual has a diagnosis of alpha (α)-thalassemia; OR
III. Individual has a platelet count greater than 1000 x 10^9/L; OR
IV. History of deep vein thrombosis (DVT) or stroke within the last 24 weeks; OR
V. Use beyond 9 weeks of treatment (i.e., administration of 3 doses) in the absence of response (response defined as decrease in transfusion burden from baseline) at maximum dose level (i.e., 1.25 mg/kg every 3 weeks); OR
VI. When the above criteria are not met and for all other indications.

Quantity Limits

Reblozyl (luspatercept) Quantity Limits

Drug	Limit
Reblozyl 25 mg, 75 mg vial	1.25 mg/kg per 3 weeks

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT

96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

HCPCS

C9399	Unclassified drugs or biologicals (when specified as luspatercept-aamt [REBLOZYL]) (Hosptial outpatient use only)
J3490	Unclassified drugs (when specified as luspatercept-aamt [REBLOZYL])
J3590	Unclassified Biologics (when specified as luspatercept-aamt [REBLOZYL])

ICD-10 Diagnosis

D56.1	Beta Thalassemia
D56.5	Hemoglobin E-Beta thalassemia

Document History

New: 02/21/2020
Document History:

- 02/21/2020 – Annual Review: Add new clinical criteria document for Reblozyl (luspatercept). Coding Reviewed: Added: 96372 CPT, C9399, J3490, J3590, HCPCS, AND D56.1, D56.5 ICD-10-CM

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