Bristol Myers Squibb™
Access Support®

Reblozyl®
(luspatercept-aamt)
for injection 25mg • 75mg

Important Billing and Coding Information for REBLOZYL® (luspatercept-aamt)

NDCs	
11-digit NDC: 59572-0711-01	REBLOZYL injection 25 mg/vial
11-digit NDC: 59572-0775-01	REBLOZYL injection 75 mg/vial

The red zero converts the 10-digit NDC to the 11-digit NDC. Payer requirements regarding the use of NDCs may vary. Electronic data exchange generally requires use of the 11-digit NDC.

HCPCS Code	
J0896	Injection, luspatercept-aamt, 0.25 mg

CPT® Codes	
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96401 (for potential use only in MDS)	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

ICD-10-CM Diagnosis Codes

Beta thalassemia		MDS	
D56.1	• Beta thalassemia major • Cooley's anemia • Homozygous beta thalassemia • Severe beta thalassemia • Thalassemia intermedia • Thalassemia major	D46.1	• Refractory anemia with ring sideroblasts
		D46.A	• Refractory cytopenia with multilineage dysplasia
		D46.B	• Refractory cytopenia with multilineage dysplasia and ring sideroblasts
		D46.4	• Refractory anemia, unspecified
		D46.Z	• Other myelodysplastic syndromes
D56.5	• Hemoglobin E-beta thalassemia	D46.9	• Myelodysplastic syndrome, unspecified

Indications

REBLOZYL is indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions.

REBLOZYL is indicated for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 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).

REBLOZYL is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

Select Important Safety Information

WARNINGS AND PRECAUTIONS

Thrombosis/Thromboembolism

In adult patients with beta thalassemia, thromboembolic events (TEE) were reported in 8/223 (3.6%) of REBLOZYL-treated patients. TEEs included deep vein thrombosis, pulmonary embolus, portal vein thrombosis, and ischemic stroke. Patients with known risk factors for thromboembolism (splenectomy or concomitant use of hormone replacement therapy) may be at further increased risk of thromboembolic conditions. Consider thromboprophylaxis in patients at increased risk of TEE. Monitor patients for signs and symptoms of thromboembolic events and institute treatment promptly.

Click here for more information around billing and coding for REBLOZYL.

The information contained herein is not intended to provide specific coding and reimbursement advice for any specific patient or situation. You should check with your coding specialist to ensure appropriate submissions.

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

Please see additional Important Safety Information on the next page and full Prescribing Information.

Abbreviations: CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, *International Classification of Diseases*, Tenth Revision, Clinical Modification; MDS, myelodysplastic syndromes; NDC, National Drug Code.

How Supplied	
25 mg vial	For injection: 25 mg lyophilized powder in a single-dose vial for reconstitution
75 mg vial	For injection: 75 mg lyophilized powder in a single-dose vial for reconstitution

Billing Units	
1 unit = 0.25 mg	25 mg vial = 100 units 75 mg vial = 300 units

Depending on payer preferences for billing and coding, the billing unit conversion for claim submission may vary. Therefore, the provider should confirm preference with the payer prior to submitting.

Select Important Safety Information

WARNINGS AND PRECAUTIONS (cont'd)

Hypertension

Hypertension was reported in 10.7% (61/571) of REBLOZYL-treated patients. Across clinical studies, the incidence of Grade 3 to 4 hypertension ranged from 1.8% to 8.6%. In patients with beta thalassemia with normal baseline blood pressure, 13 (6.2%) patients developed systolic blood pressure (SBP) ≥130 mm Hg and 33 (16.6%) patients developed diastolic blood pressure (DBP) ≥80 mm Hg. In adult patients with MDS with normal baseline blood pressure, 26 (29.9%) patients developed SBP ≥130 mm Hg and 23 (16.4%) patients developed DBP ≥80 mm Hg. Monitor blood pressure prior to each administration. Manage new or exacerbations of preexisting hypertension using anti-hypertensive agents.

Extramedullary Hematopoietic Masses

In adult patients with transfusion-dependent beta thalassemia, EMH masses were observed in 3.2% of REBLOZYL-treated patients, with spinal cord compression symptoms due to EMH masses occurring in 1.9% of patients (BELIEVE and REBLOZYL long-term follow-up study).

In a study of adult patients with non-transfusion-dependent beta thalassemia, a higher incidence of EMH masses was observed in 6.3% of REBLOZYL-treated patients vs. 2% of placebo-treated patients in the double-blind phase of the study, with spinal cord compression due to EMH masses occurring in 1 patient with a prior history of EMH. REBLOZYL is not indicated for use in patients with non-transfusion-dependent beta thalassemia.

Possible risk factors for the development of EMH masses in patients with beta thalassemia include history of EMH masses, splenectomy, splenomegaly, hepatomegaly, or low baseline hemoglobin (<8.5 g/dL). Signs and symptoms may vary depending on the anatomical location. Monitor patients with beta thalassemia at initiation and during treatment for symptoms and signs or complications resulting from the EMH masses and treat according to clinical guidelines. Discontinue treatment with REBLOZYL in case of serious complications due to EMH masses. Avoid use of REBLOZYL in patients requiring treatment to control the growth of EMH masses.

Embryo-Fetal Toxicity

REBLOZYL may cause fetal harm when administered to a pregnant woman. REBLOZYL caused increased post-implantation loss, decreased litter size, and an increased incidence of skeletal variations in pregnant rat and rabbit studies. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 3 months after the final dose.

ADVERSE REACTIONS

Beta-Thalassemia

Serious adverse reactions occurred in 3.6% of patients on REBLOZYL. Serious adverse reactions occurring in 1% of patients included cerebrovascular accident and deep vein thrombosis. A fatal adverse reaction occurred in 1 patient treated with REBLOZYL who died due to an unconfirmed case of acute myeloid leukemia (AML).

Most common adverse reactions (at least 10% for REBLOZYL and 1% more than placebo) were headache (26% vs 24%), bone pain (20% vs 8%), arthralgia (19% vs 12%), fatigue (14% vs 13%), cough (14% vs 11%), abdominal pain (14% vs 12%), diarrhea (12% vs 10%) and dizziness (11% vs 5%).

Myelodysplastic Syndromes

Grade ≥3 (≥2%) adverse reactions included fatigue, hypertension, syncope and musculoskeletal pain. A fatal adverse reaction occurred in 5 (2.1%) patients.

The most common (≥10%) adverse reactions included fatigue, musculoskeletal pain, dizziness, diarrhea, nausea, hypersensitivity reactions, hypertension, headache, upper respiratory tract infection, bronchitis, and urinary tract infection.

LACTATION

It is not known whether REBLOZYL is excreted into human milk or absorbed systemically after ingestion by a nursing infant. REBLOZYL was detected in milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Because many drugs are excreted in human milk, and because of the unknown effects of REBLOZYL in infants, a decision should be made whether to discontinue nursing or to discontinue treatment. Because of the potential for serious adverse reactions in the breastfed child, breastfeeding is not recommended during treatment and for 3 months after the last dose.

Please see full Prescribing Information for REBLOZYL.

To find out more, call your BMS Access Support® Specialist at 1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday (translation services available).