REBLOZYL® (luspatercept-aamt) now has a permanent J code (J0896)

Effective July 1, 2020

Important Update for REBLOZYL Coding and Pricing Information

NDCs	59572-0711-01 (REBLOZYL injection 25 mg/vial)
	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 the use of the 11-digit NDC.

HCPCS code	J0896[a] (Injection, luspatercept-aamt, 0.25 mg)
Billing units	1 unit = 0.25 mg
	25-mg vial = 100 units
	75-mg vial = 300 units
How supplied	For injection: lyophilized powder in a single-dose vial for reconstitution
Wholesale acquisition cost[b]	$3441.18 (25-mg vial)
	$10,323.53 (75-mg vial)
Generic name	Luspatercept-aamt

[a]This code for REBLOZYL may only be used for dates of service on or after July 1, 2020.
[b]As reported in AnalySource as of June 12, 2020.

Please note that the billing units for REBLOZYL have changed. With use of the permanent J code for REBLOZYL—J0896—1 billing unit is equivalent to 0.25 mg. It is recommended that each payer's specific billing preferences be confirmed when submitting a claim for REBLOZYL, as they may vary by insurer.

For more information:

- Contact your Access & Reimbursement Manager for general assistance and to schedule an office visit
- Call your Celgene Patient Support® Specialist at 1-800-931-8691, Monday–Friday, 8 am–8 pm ET (translation services available)

Click here for the HCPCS Code Application Summaries and CMS Decisions for Q1 2020

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

Abbreviations: CMS, Centers for Medicare & Medicaid Services; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code.

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

Important Safety Information

WARNINGS AND PRECAUTIONS

Thrombosis/Thromboembolism

In adult patients with beta thalassemia, thromboembolic events (TEE) were reported in 8/223 (3.6%) 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.

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.

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.

Bristol Myers Squibb™ | ACCELERON

06/20 US-RBZ-20-0236