# Important Billing and Coding Information for REBLOZYL

| 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 <sup>®</sup> Codes |   |  |
|------------------------|---|--|
| 96372                  | Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular |  |
| 96401                  | Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic                      |  |

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

| Billing Units    |  |
|------------------|--|
| 1 unit = 0.25 mg | 25-mg vial = 100 units<br>75-mg vial = 300 units |

| ICD-10-CM Diagnosis Codes |   |  |  |  |  |
|---------------------------|---|--|--|--|--|
| Beta thalassemia          |   | MDS  |  |  |  |
| D56.1                     | D56.1 • Beta thalassemia major  | D46.1  | Refractory anemia with ring sideroblasts                               |  |  |
| Cooley's anemia           | D46.A   | Refractory cytopenia with multilineage dysplasia |  |  |  |
|                           | <ul> <li>Homozygous<br/>beta thalassemia</li> <li>Severe beta thalassemia</li> <li>Thalassemia intermedia</li> <li>Thalassemia major</li> </ul> | 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                                  |  |  |

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.

## 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.

#### Please see 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.

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# REBLOZYL® (luspatercept-aamt)

#### 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 Hq. 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 postimplantation 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 Celgene Patient Support® Specialist at 1-800-931-8691, Monday-Friday, 8 AM-8 PM ET (translation services available).



