CELGENE PATIENT SUPPORT®

# HOW TO ORDER AND ACCESS REBLOZYL® (luspatercept-aamt) for injection 25 mg • 75 mg

**Please see Important Safety Information on page 7 and full Prescribing Information.**

# Product Information

## 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

## National Drug Codes (NDC) and Packaging Information

| 11-Digit NDC | Product/strength | Package/description |
|---|---|---|
| 59572-0711-01 | **REBLOZYL injection 25 mg** | 25 mg lyophilized powder for solution for injection in a single-dose vial for reconstitution |
| 59572-0775-01 | **REBLOZYL injection 75 mg** | 75 mg lyophilized powder for solution for injection in a single-dose vial for reconstitution |

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.

## Storage

Store vials refrigerated at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not freeze.


# SELECTED 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.



# Authorized Distributors

REBLOZYL can only be purchased through authorized distributors for administration in physician offices, hospital outpatient facilities, institutions, Veterans Affairs, and the Department of Defense. The following distributors are authorized to sell REBLOZYL and are able to service qualified accounts.

| Authorized Distributor Network |
|---|
| **Community Practices** |
| **Cardinal Specialty**<br>Phone: 1-877-453-3972 |
| **McKesson Specialty Health**<br>Phone: 1-800-482-6700 \| Fax: 1-800-289-9285 |
| **Oncology Supply**<br>Phone: 1-800-633-7555 \| Fax: 1-800-248-8205 |
| **Institutions/Hospital Outpatient Facilities** |
| **AmerisourceBergen**<br>Phone: 1-844-222-2273 \| Fax: 1-888-292-9774 |
| **ASD Healthcare**<br>Phone: 1-800-746-6273 \| Fax: 1-800-547-9413 |
| **Cardinal Specialty**<br>Phone: 1-866-677-4844 |
| **McKesson Pharma**<br>Phone: 1-855-625-6285 \| Fax: 1-800-599-9893 |
| **Puerto Rico Hospitals and Clinics** |
| **Cardinal Health P.R.**<br>Phone: 1-787-625-4200 |
| **Cesar Castillo, Inc.**<br>Phone: 1-787-641-5242 (Hospitals) \| 1-787-641-5082 (Specialty Pharmacy) \| Fax: 1-787-999-1614 |

Extended dating terms may be available for REBLOZYL. Please contact your authorized distributor for more information.

Pursuant to the agreement with your authorized distributor, Bristol Myers Squibb (BMS) is committed to providing product within 1 business day of your order for REBLOZYL.

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## Billing and Coding

| 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 | Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic |

| Billing Unit Conversion | | | |
|---|---|---|---|
| 0.25 mg | 1 unit | 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.

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.

## SELECTED IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

#### 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.

Abbreviations: CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System.





## Billing and Coding (cont'd)

| ICD-10-CM Diagnosis Codes for Beta Thalassemia | |
|---|---|
| D56.1 | • Beta thalassemia major<br>• Cooley's anemia<br>• Homozygous beta thalassemia<br>• Severe beta thalassemia<br>• Thalassemia intermedia<br>• Thalassemia major |
| D56.5 | • Hemoglobin E-beta thalassemia |

| ICD-10-CM Diagnosis Codes for MDS | |
|---|---|
| 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 |
| D46.9 | Myelodysplastic syndrome, unspecified |

The 2020 version of ICD-10-CM took effect on October 1, 2019.

**Please see Important Safety Information on page 7 and full Prescribing Information.**

Abbreviation: ICD-10-CM, *International Classification of Diseases*, Tenth Revision, Clinical Modification; MDS, myelodysplastic syndromes.

## Celgene Patient Support® Program

### Celgene Patient Support® provides

- A single Specialist assigned to help patients in each geographic area
- A dedicated Access & Reimbursement Manager with information on payer policies, billing, and coding for REBLOZYL
- Assistance with understanding patient insurance coverage for REBLOZYL
- Information about financial assistance for REBLOZYL

### Financial assistance

There are programs and organizations that may help pay for REBLOZYL, depending on a patient's insurance situation:

***Celgene Commercial Co-pay Program***

Co-pay responsibility for REBLOZYL is reduced to $0 (subject to annual benefit limit) for eligible patients with commercial or private insurance (including healthcare exchanges).*

***Celgene Patient Assistance Program (PAP)***

REBLOZYL may be available at no cost for qualified patients who are uninsured or underinsured.†

***Independent third-party organizations***

Patients who are unable to afford their medication (including patients with Medicare, Medicaid, or other government-sponsored insurance) may be able to receive help from independent third-party organizations.‡

### Insurance-related assistance

Our Specialists are available to assist with each of the following steps in the insurance approval process for REBLOZYL:§

- Benefits investigation
- Prior authorization/precertification assistance¶
- Appeals assistance¶
- Educating patients about insurance coverage or other programs for which they may qualify

**Enrolling in Celgene Patient Support®**

**Visit us at** www.celgenepatientsupport.com

**E-mail us at** patientsupport@celgene.com **or fax to** 1-800-822-2496

**For more information on Celgene Patient Support®**

**Call us at** 1-800-931-8691, Monday–Friday, 8 AM–8 PM ET
(*translation services available*)

**Please see Important Safety Information on page 7 and full Prescribing Information.**

*Other eligibility requirements and restrictions apply. Please see full Terms and Conditions on the Celgene Patient Support® website.

†Patients must meet specified financial and insurance eligibility requirements to qualify for assistance. Please see Eligibility Requirements on the Celgene Patient Support® website.

‡Financial and medical eligibility requirements vary by organization.

§Celgene cannot provide insurance advice or make insurance decisions.

¶Celgene provides a facilitation service and will not provide any medical input into a prior authorization or an appeal.



## Important Safety Information

### WARNINGS AND PRECAUTIONS

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**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


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