



Reblozyl<sup>®</sup>

(luspatercept-aamt)

for injection 25mg • 75mg

# HOW TO ORDER AND ACCESS REBLOZYL

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Please see Important Safety Information on page 2 and full [Prescribing Information](#).

## INDICATION

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

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

## Important Safety Information

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### WARNINGS AND PRECAUTIONS

#### Thrombosis/Thromboembolism

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. 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 last dose.

### ADVERSE REACTIONS

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%).

### 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.

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# Product Information

## National Drug Codes (NDC) and Packaging Information

11-Digit NDC	Product/Strength	Package/Description
59572-0711-01	<b>REBLOZYL injection 25 mg</b>	25 mg lyophilized powder for solution for injection in a single-dose vial for reconstitution
59572-0775-01	<b>REBLOZYL injection 75 mg</b>	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.



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## 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.

<b>Authorized Distributor Network</b>
<b>Community Practices</b>
<b>Cardinal Specialty</b> Phone: 1-877-453-3972
<b>McKesson Specialty Health</b> Phone: 1-800-482-6700 • Fax: 1-800-289-9285
<b>Oncology Supply</b> Phone: 1-800-633-7555 • Fax: 1-800-248-8205
<b>Institutions/Hospital Outpatient Facilities</b>
<b>AmerisourceBergen</b> Phone: 1-844-222-2273 • Fax: 1-888-292-9774
<b>ASD Healthcare</b> Phone: 1-800-746-6273 • Fax: 1-800-547-9413
<b>Cardinal Specialty</b> Phone: 1-866-677-4844
<b>McKesson Pharma</b> Phone: 1-855-625-6285 • Fax: 1-800-599-9893
<b>Puerto Rico Hospitals and Clinics</b>
<b>Cardinal Health P.R.</b> Phone: 1-787-625-4200
<b>Cesar Castillo, Inc.</b> 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, Celgene is committed to providing product within 1 business day of your order for REBLOZYL.

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## Billing and Coding

HCPCS Codes	
J3490	Not otherwise classified drugs
J3590	Not otherwise classified biologics
J9999	Not otherwise classified anti-neoplastic drugs
C9399	Unclassified or biologicals (hospital outpatient use only)
CPT® Code	
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
ICD-10-CM Diagnosis Code	
D56.1	<ul style="list-style-type: none"><li>• Beta thalassemia major</li><li>• Cooley's anemia</li><li>• Homozygous beta thalassemia</li><li>• Severe beta thalassemia</li><li>• Thalassemia intermedia</li><li>• Thalassemia major</li></ul>
D56.5	<ul style="list-style-type: none"><li>• Hemoglobin E-beta thalassemia</li></ul>

Depending on payer preferences for billing and coding, the required miscellaneous J code for claim submission may vary. Therefore, the provider will want to confirm preference with payer prior to submitting.

Note the use of a miscellaneous C code (C9399) for when REBLOZYL is used in a hospital infusion center.

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.

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

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## Celgene Patient Support® provides

- A single Specialist assigned to help patients in each geographic area
- A Field Reimbursement Specialist in each region with information on payer policies, billing, and coding for REBLOZYL® (luspatercept-aamt)
- 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](http://www.celgenepatientsupport.com)



Email us at

[patientsupport@celgene.com](mailto: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)

\*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.



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