Bristol Myers Squibb™
Access Support®

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

HOW TO ORDER AND ACCESS

REBLOZYL® (luspatercept-aamt) for injection 25 mg/vial • 75 mg/vial

Please see Important Safety Information throughout and US 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/vial**	For injection: 25 mg lyophilized powder in a single-dose vial for reconstitution
59572-0775-01	**REBLOZYL injection 75 mg/vial**	For injection: 75 mg lyophilized powder 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.

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.

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.

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.

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
Physician Offices
Cardinal Health Specialty Pharmaceutical Distribution Phone: 1-877-453-3972, Monday–Friday, 7:00 AM–6:00 PM CT (24-hour emergency on call) https://specialtyonline.cardinalheath.com
CuraScript Specialty Distribution Phone: 1-877-599-7748, Monday–Friday, 8:00 AM–7:00 PM ET • https://www.curascriptsd.com
McKesson Specialty Health Phone: 1-800-482-6700, Monday–Friday, 7:00 AM–7:00 PM CT • https://mscs.mckesson.com
Morris & Dickson Specialty Phone: 1-800-710-6100, Monday–Friday, 8:00 AM–6:00 PM CT • Fax: 1-318-524-3096 • http://www.mdspecialtydist.com
Oncology Supply Phone: 1-800-633-7555, Monday–Friday, 8:00 AM–7:00 PM CT • https://www.oncologysupply.com
Hospitals and Infusion Centers
ASD Healthcare Phone: 1-800-746-6273, Monday–Thursday, 7:00 AM–6:30 PM CT; Friday, 7:00 AM–6:00 PM CT • Fax: 1-800-547-9413 https://www.asdhealthcare.com
Cardinal Health Specialty Pharmaceutical Distribution Phone: 1-866-677-4844, Monday–Friday, 7:00 AM–6:00 PM CT (24-hour emergency) • Fax: 1-614-553-6301 https://orderexpress.cardinalhealth.com
DMS Pharmaceutical Group, Inc. Phone: 1-877-788-1100, Monday–Friday, 8:30 AM–5:00 PM CT • Fax: 1-847-518-1105 • www.dmspharma.com
McKesson Plasma and Biologics Phone: 1-877-625-2566, Monday–Friday, 8:00 AM–6:30 PM CT • Fax: 1-888-752-7626 • https://connect.mckesson.com
Puerto Rico Hospitals and Clinics
Cardinal Puerto Rico (Borschow) Phone: 1-787-625-4200, cuserv@cardinalhealth.com • https://orderexpress.cardinalhealth.com
Cesar Castillo Inc. Phone: 1-787-641-5242 (hospitals), 1-787-641-5082 (specialty pharmacies) • Fax: 1-787-999-1614 https://www.facilfarmaciacci.com

Above information is accurate as of 02/22. The most updated distributors can also be found on https://www.bmsaccesssupport.bmscustomerconnect.com/reblozyl/billing-diagnosis-codes.

The REBLOZYL distribution program includes extended payment terms to Bristol Myers Squibb authorized REBLOZYL distributors. Healthcare providers and institutions should contact their REBLOZYL distributor to understand specific payment terms that may be available to them from their distributor.

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 (for potential use only in MDS)	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.

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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.

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 • Cooley's anemia • Homozygous beta thalassemia • Severe beta thalassemia • Thalassemia intermedia • 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.

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

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Select Important Safety Information

WARNINGS AND PRECAUTIONS (cont'd)

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.

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.

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.

Bristol Myers Squibb™

Access Support®

BMS Access Support® Can Provide Patient Access and Reimbursement Assistance

Bristol Myers Squibb is committed to helping patients gain access to their prescribed BMS medications. That's why we offer BMS Access Support. BMS Access Support provides resources to help patients understand their insurance coverage. In addition, we can share information on sources of financial support, including co-pay assistance for eligible commercially insured patients.

How BMS Access Support May Help
Find out how BMS can work with patients and their healthcare providers to help access a prescribed BMS medication.

Financial Support Options
There may be programs and services that could help with the cost of treatment. Learn about what options are available.

Additional Resources
We provide videos, tools, and other resources that may help with your access and reimbursement needs.

Have Questions About Our Program or Possible Financial Support?

If you have questions about coverage for a prescribed BMS medication, BMS Access Support may be able to help. Patients and their healthcare provider can complete an enrollment form to learn about programs that may be of assistance. Visit our website or contact BMS Access Support to learn more.

Call Bristol Myers Squibb Access Support at
1-800-861-0048, 8 AM to 8 PM ET, Monday–Friday

Visit **www.BMSAccessSupport.com**

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