CELGENE PATIENT SUPPORT®

REBLOZYL® (luspatercept-aamt) for injection 25 mg • 75 mg REIMBURSEMENT AND BILLING GUIDE

Resources to Support the Reimbursement Process

The information provided in this reimbursement guide is valid as of July 2020 and is subject to change.

Please see Important Safety Information on page 2 and full Prescribing 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

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.

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Important Information

This guide is a resource to help with reimbursement and billing for REBLOZYL. The information provided in this guide is compiled from various resources and has the potential to change. This billing guide is intended to convey general information relative to a specific point in time and is current as of July 2020.

The information included in this guide addresses general coding and billing and is not intended to imply coverage for any individual patient or treatment. It is the responsibility of the provider or physician to evaluate reimbursement requirements and apply the appropriate billing codes for a particular patient, procedure, or treatment. The information provided in this document does not guarantee coverage or reimbursement for any product or service.

Please see Important Safety Information on page 2 and full Prescribing Information.

Product Information for REBLOZYL

Dosage and Administration[1]

Recommended dosage in beta thalassemia, MDS-RS, or MDS/MPN-RS-T

The recommended starting dose of REBLOZYL is 1 mg/kg once every 3 weeks by subcutaneous injection for patients with beta thalassemia or patients with anemia of MDS-RS or MDS/MPN-RS-T. Prior to each REBLOZYL dose, review the patient's hemoglobin and transfusion record. Titrate the dose based on responses according to the respective tables below. Interrupt treatment for adverse reactions as described in the table below. Discontinue REBLOZYL if a patient does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose level or if unacceptable toxicity occurs at any time.

If a planned administration of REBLOZYL is delayed or missed, administer REBLOZYL as soon as possible and continue dosing as prescribed, with at least 3 weeks between doses.

Assess and review hemoglobin results prior to each administration of REBLOZYL. If an RBC transfusion occurred prior to dosing, use the pretransfusion hemoglobin for dose evaluation.

Dose modifications for response in beta thalassemia

Do not increase the dose beyond the maximum dose of 1.25 mg/kg. Dose level modifications for response are provided in the following table.

Beta Thalassemia—REBLOZYL Dose Titration for Response

	REBLOZYL dosing recommendation[a]
Starting dose	• 1 mg/kg every 3 weeks
Dose increases for insufficient response at initiation of treatment	
No reduction in RBC transfusion burden after at least 2 consecutive doses (6 weeks) at the 1 mg/kg starting dose	• Increase the dose to 1.25 mg/kg every 3 weeks
No reduction in RBC transfusion burden after 3 consecutive doses (9 weeks) at 1.25 mg/kg	• Discontinue treatment
Dose modications for predose Hgb levels or rapid Hgb rise	
Predose Hgb is ≥11.5 g/dL in the absence of transfusions	• Interrupt treatment • Restart when the Hgb is no more than 11 g/dL
Increase in Hgb >2 g/dL within 3 weeks in the absence of transfusions and • current dose is 1.25 mg/kg • current dose is 1 mg/kg • current dose is 0.8 mg/kg • current dose is 0.6 mg/kg	• Reduce dose to 1 mg/kg • Reduce dose to 0.8 mg/kg • Reduce dose to 0.6 mg/kg • Discontinue treatment

[a]Do not increase the dose if the patient is experiencing a Grade 3 or 4 adverse reaction.

At least 5 doses (15 weeks of treatment) unless unacceptable toxicity occurs at any time

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.

Abbreviations: Hgb, hemoglobin; MDS-RS, myelodysplastic syndromes with ring sideroblasts; MDS/MPN-RS-T, myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis; RBC, red blood cell.

Dose modifications for response in MDS-RS and MDS/MPN-RS-T

Do not increase the dose more frequently than every 6 weeks (2 doses) or beyond the maximum dose of 1.75 mg/kg.

If, upon dose reduction, the patient loses response (ie, requires a transfusion) or Hgb concentration drops by 1 g/dL or more in 3 weeks in the absence of transfusion, increase the dose by 1 dose level. Wait a minimum of 6 weeks between dose increases. Dose modifications for response are provided in the following table.

MDS-RS and MDS/MPN-RS-T—REBLOZYL Dose Titration for Reponse

	REBLOZYL dosing recommendation[a]
Starting dose	• 1 mg/kg every 3 weeks
Dose increases for insufficient response at initiation of treatment	
Not RBC transfusion-free after at least 2 consecutive doses (6 weeks) at the 1 mg/kg starting dose	• Increase the dose to 1.33 mg/kg every 3 weeks
Not RBC transfusion-free after at least 2 consecutive doses (6 weeks) at 1.33 mg/kg	• Increase the dose to 1.75 mg/kg every 3 weeks
No reduction in RBC transfusion burden after at least 3 consecutive doses (9 weeks) at 1.75 mg/kg	• Discontinue treatment
Dose modifications for predose Hgb levels or rapid Hgb rise	
Predose Hgb is ≥11.5 g/dL in the absence of transfusions	• Interrupt treatment • Restart when the Hgb is no more than 11 g/dL
Increase in Hgb >2 g/dL within 3 weeks in the absence of transfusions and • current dose is 1.75 mg/kg • current dose is 1.33 mg/kg • current dose is 1 mg/kg • current dose is 0.8 mg/kg • current dose is 0.6 mg/kg	• Reduce dose to 1.33 mg/kg • Reduce dose to 1 mg/kg • Reduce dose to 0.8 mg/kg • Reduce dose to 0.6 mg/kg • Discontinue treatment

[a]Do not increase the dose if the patient is experiencing an adverse reaction.

At least 7 doses (21 weeks of treatment) unless unacceptable toxicity occurs at any time

Dose modifications for toxicity

For patients experiencing Grade 3 or higher adverse reactions, modify treatment as described in the following table.

Beta Thalassemia and MDS-RS and MDS/MPN-RS-T—REBLOZYL Dosing Modifications for Adverse Reactions

	REBLOZYL dosing recommendation[a]
Grade 3 or 4 hypersensitivity reactions	• Discontinue treatment
Other Grade 3 or 4 adverse reactions	• Interrupt treatment • Restart when the adverse reaction resolves to no more than Grade 1 (beta thalassemia) • When the adverse reaction resolves to no more than Grade 1, restart treatment at the next lower dose level[b] (MDS-RS and MDS/MPN-RS-T) • If the dose delay is >12 consecutive weeks, discontinue treatment (MDS-RS and MDS/MPN-RS-T)

[a]Grade 1 is mild, Grade 2 is moderate, Grade 3 is severe, and Grade 4 is life-threatening.
[b]Per dose reductions in MDS-RS and MDS/MPN-RS-T dose titration for response table above.

Please see Important Safety Information on page 2 and full Prescribing Information.

Product Information for REBLOZYL (cont'd)

NDC and Packaging Information[1]

Product/strength	Package/description	National Drug Code (NDC)
REBLOZYL injection 25 mg	25 mg lyophilized powder for solution for injection in a single-dose vial for reconstitution	11-digit NDC: 59572-0711-01
REBLOZYL injection 75 mg	75 mg lyophilized powder for solution for injection in a single-dose vial for reconstitution	11-digit NDC: 59572-0775-01

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.

Billing Codes for REBLOZYL

Overview of Billing Codes

There are 4 main codes required to accurately submit a claim.[2-4] Each is discussed in more detail within this resource.

Code	Purpose
NDC	Allows payers to identify the drug administered when a miscellaneous J code is used (NDC is required for billing)
HCPCS (Healthcare Common Procedure Coding System)	States which drugs were given and/or which supplies were used during the patient visit
CPT® (Current Procedural Terminology)	Describes the medical services and procedures performed and/or the drug or medical supply administered
ICD-10-CM (*International Classification of Diseases*, Tenth Revision, Clinical Modification)	Indicates the patient's diagnosis (or the purpose of the procedure)

The codes provided in this resource are for reference. It is recommended that each payer's specific billing requirements be confirmed when submitting a claim for REBLOZYL, as they may vary by insurer.

It is important to note that costs associated with administration are separate from the cost of the product.

HCPCS Codes

HCPCS codes are used for billing drugs and services to Medicare, Medicaid, and the commercial payer.[3]

HCPCS Code[5]	Descriptor
J0896	Injection, luspatercept-aamt, 0.25 mg

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

It is important to note that for accurate reimbursement, any quantity of REBLOZYL that is discarded after treatment should be coded with a JW modifier. A JW modifier indicates unused drug or biological from a single-use vial in the event that the entire dose/quantity is not administered and the remainder is discarded.[6]

Revenue Codes (Hospital Use)

Revenue codes categorize services in the hospital by revenue center. Medicare and most Medicaid and private payer claims must include revenue codes in field 42 of form UB-04 (CMS-1450).

Revenue codes that may be used for administration of REBLOZYL	
Code	**Revenue Center**
0636	Drugs requiring detailed coding
0250	Pharmacy
0331	Chemo admin, injected

Selected 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: CMS, Centers for Medicare & Medicaid Services; MDS, myelodysplastic syndromes.

Please see Important Safety Information on page 2 and full Prescribing Information.

Billing Codes for REBLOZYL (cont'd)

CPT® Code for Administration

CPT codes are used to indicate which medical services and procedures were performed on a patient and/or how a drug or medical supply was administered.[4]

CPT code that may be used for administration of REBLOZYL[4]	
CPT Code	**Descriptor**
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

ICD-10-CM Diagnosis Codes for Beta Thalassemia[7-9]

ICD-10-CM Code[a]	Descriptor
D56.1	Beta thalassemia major and intermediate • 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[10]

ICD-10-CM Code[a]	Descriptor
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

Selected 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.

[a]The 2020 version of ICD-10-CM took effect on October 1, 2019.
Abbreviations: CPT, Current Procedural Terminology; ICD-10-CM, *International Classification of Diseases*, Tenth Revision, Clinical Modification; MDS, myelodysplastic syndromes.

Sample Claim Forms

Physician Office Sample Claim Form: CMS-1500

Coding specifics for the CMS-1500 claim form:

- For reimbursement of REBLOZYL administered in an infusion center or a physician's office, providers must submit a CMS-1500 claim form for the drug and associated services
- As of July 1, 2020, REBLOZYL has been assigned a product-specific permanent J code

A claim for REBLOZYL should include the following:[2]

- A proper HCPCS code to define the drug and billing unit
- The quantity of billing units provided to the patient
- A CPT code that indicates how the physician administered the drug

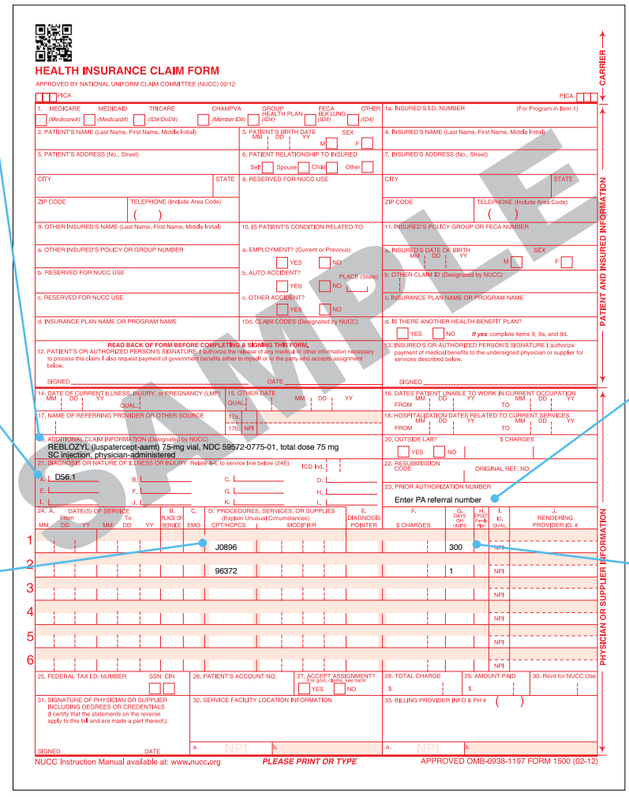
In addition to coding specifics, some payers may require additional information, such as a drug purchase invoice or documentation of medical necessity.

ICD-10-CM diagnosis codes will differ for beta thalassemia and MDS

Indicate drug name, NDC, drug strength and dosage (in total mg based on weight and strength of dose), and route of administration (usually physician administered, subcutaneous)

Enter the ICD-10-CM diagnosis code (this should be reflected in the patient's medical record)

Enter the appropriate HCPCS code*; enter the appropriate CPT code(s)* for drug administration services; include modifiers, if applicable



Document prior authorization referral number from the payer (if applicable)

Enter the number of billing units for the associated HCPCS and CPT codes

Please see Important Safety Information on page 2 and full Prescribing Information.

*Any outpatient red blood cell transfusions given to address hemoglobin levels in patients with beta thalassemia or MDS entail their own set of HCPCS and CPT codes.
Abbreviations: CMS, Centers for Medicare & Medicaid Services; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code; NOC, not otherwise classified.

Sample Claim Forms (cont'd)

Hospital Outpatient Department Sample Claim Form: UB-04 (CMS-1450)

- UB-04 is used for reimbursement of REBLOZYL administered in an institutional setting, such as a hospital, a clinic, or an ambulatory surgical center.[11] Providers must submit a UB-04 claim form documenting the drug administered and associated services
- Coding specifics for the UB-04 claim form:
  - As of July 1, 2020, REBLOZYL has been assigned a product-specific permanent J code

Medicare and most Medicaid and private payer claims must include revenue codes in field 42; a description or NDC must be indicated

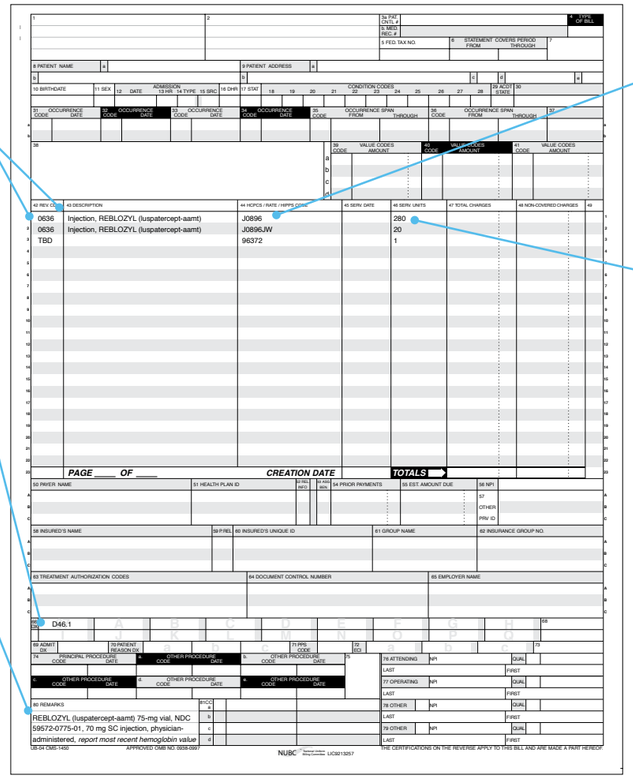
Enter the appropriate ICD-10-CM diagnosis code (this should be reflected in the patient's medical record)

Indicate the name of the drug, NDC, drug strength and dosage (in total mg based on weight and strength of dose), and route of administration (physician administered, subcutaneous)

Enter the HCPCS code for the outpatient service (and modifier[s],* if applicable)

Indicate the units of service used†

Enter the number of units discarded (if applicable) on a separate line, and include the JW modifier from field 44



Selected Important Safety Information

ADVERSE REACTIONS

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

*Any outpatient red blood cell transfusions given to address hemoglobin levels in patients with beta thalassemia or MDS entail their own set of HCPCS and CPT codes and revenue codes. Certain level II HCPCS codes and CPT codes require the use of modifiers to improve coding accuracy.

†When HCPCS codes are required, the units equal the number of times the reported procedure or service was performed.

Abbreviations: CMS, Centers for Medicare & Medicaid Services; CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; MDS, myelodysplastic syndromes; NDC, National Drug Code; NOC, not otherwise classified.

Commercial and Private Payer Coverage

Prior Authorization Checklist

Some insurers may require prior authorization. It is essential to confirm which form should be used and ensure it is filled out completely. It is also important to become familiar with the insurer's requirements.

The following checklist can help with the process:

Checklist

- ☑ **Prior authorization request form**
- ☑ **Patient information**
  (eg, name, date of birth, insurance policy numbers)
- ☑ **Diagnosis and clinical notes/patient history**
- ☑ **Physician or facility information**
- ☑ **Date of service**
- ☑ **Relevant procedure and HCPCS codes for services or products to be performed/provided**
- ☑ **Product NDC**
- ☑ **Letter of medical necessity**
- ☑ **Patient chart/notes in support of the treatment decision, including:**
  - Previous treatments
  - Patient clinical notes detailing the relevant diagnosis
  - Relevant laboratory results
  - Product prescribing information

Celgene

Please see Important Safety Information on page 2 and full Prescribing Information.

Commercial and Private Payer Coverage (cont'd)

Letter of Medical Necessity

A letter of medical necessity may be required by some insurers.

This Letter of Medical Necessity Template is made available as a convenience to you. The medical and health information disclosed through the use of this Template is subject to applicable confidentiality and security obligations under state and federal law, including the Health Insurance Portability and Accountability Act. The responsibility for meeting these requirements rests with the entities transmitting the medical and health information. In providing this Template, BMS assumes no responsibility for complying with these obligations.

<Date>

ATTENTION: <Medical Director Name>
<Insurer Name>
<Insurer Address>

REGARDING: Medical Necessity for <Product Name>
PATIENT NAME: <Patient Name>
DATE OF BIRTH: <Patient Date of Birth>
POLICY AND GROUP NUMBER: <Policy and Group Number>

Dear <Medical Director Name>,

On behalf of my patient, <Patient Name>, I am writing to request authorization for <Product Name>, which has been FDA approved for <Indication>. Please accept this letter as documentation that <Patient Name> has been diagnosed with <Diagnosis> and this treatment is medically necessary.

Summary of Patient's Diagnosis
<Insert patient's diagnosis, date of diagnosis, lab results and date, current condition>

Summary of Patient History
<Insert previous therapies/procedures, response to those interventions, description of patient's recent symptoms/condition. Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.>

In my professional opinion, <Product Name> is medically necessary and reasonable for <Patient Name>, as supported by <Patient Name>'s diagnosis, history, and the FDA approval letter and Prescribing Information for <Product Name>.

Please do not hesitate to contact me with any questions that can help to expedite this review. Thank you for your time and attention in this matter, and I look forward to your prompt response and approval of this treatment.

Sincerely,

<Physician Signature>
<Physician Name>
<Provider ID Number>

Enclosures/Attachments:
- <Product Name> FDA approval letter
- <Product Name> Prescribing Information

The letters provided are samples; use of these letters does not guarantee reimbursement.

Selected Important Safety Information

ADVERSE REACTIONS (cont'd)

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%)

Abbreviation: FDA, Food and Drug Administration.

Appeals Checklist

If a claim is denied, there may be an appeal process for requesting review of coverage. The required documentation and appeal process will vary by insurer, so it is important to review the insurer's guidelines.

The following checklist may help in the navigation of the appeal process:

It is important to check that:

- ☑ **The patient's information was correctly entered** (eg, name, date of birth, insurance information)
- ☑ **The patient's insurer covers the medication for the specific diagnosis**
- ☑ **Prior authorization was obtained** (if required by the insurer)
- ☑ **The correct product coding was used**

Some claims may be denied for submission errors. It is critical to ensure that the claim was submitted with the correct information.

Ideally, the components of the appeal process—including necessary forms and guidelines as outlined by the insurer—should be confirmed. It is also essential to note any deadlines for submission and timelines for review. Understanding the reason for the denial (often outlined in the explanation of benefits [EOB]) helps determine what documentation needs to be provided for review.

Your local Access & Reimbursement Manager can help identify what documentation would support your appeal to the insurance provider. Documents such as:

- Letter of medical necessity
- Letter of appeal
- The EOB containing the specifics of the denial
- Documentation supporting treatment decisions related to the claim:
  - Charts/notes with patient history and diagnosis
  - Prior therapies and outcomes
  - Relevant laboratory results
  - Product prescribing information

Please see Important Safety Information on page 2 and full Prescribing Information.

Commercial and Private Payer Coverage (cont'd)

Letter of Appeal

Prescribers may submit a letter of appeal as part of the appeal process when a request for PA or coverage is denied. In this way, they are able to request reconsideration of coverage by addressing the reason(s) for denial and by reiterating the documentation that supports a particular treatment for their patient.

This Letter of Medical Necessity Template is made available as a convenience to you. The medical and health information disclosed through the use of this Template is subject to applicable confidentiality and security obligations under state and federal law, including the Health Insurance Portability and Accountability Act. The responsibility for meeting these requirements rests with the entities transmitting the medical and health information. In providing this Template, BMS assumes no responsibility for complying with these obligations.

<Date>

ATTENTION: <Medical Director Name and/or Medical Review/Appeals>
<Payer/Health Plan Name>
<Payer Address>

REGARDING: Denied Claim for <Product Name>
PATIENT NAME: <Patient Name>
DATE OF BIRTH: <Patient Date of Birth>
POLICY ID NUMBER: <Policy ID Number>

Dear <Medical Director Name and/or Medical Review/Appeals>,

On behalf of my patient, <Patient Name>, I am requesting reconsideration of a denied claim for <Product Name>. The reason it was denied is <Reason for Denial>. Below is documentation that supports the use of this FDA-approved medication for <Patient Name> as well as their medical history. <If applicable: A prior authorization was previously approved and is attached for reference.>

Summary of Patient's Diagnosis
<Insert patient's diagnosis, date of diagnosis, lab results and date, current condition>

Summary of Patient History
<Insert previous therapies/procedures, response to those interventions, description of patient's recent symptoms/condition. Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.>

<Product Name> is indicated for <Indication>. In my professional opinion, <Patient Name> would benefit from use of <Product Name> for <Diagnosis>.

Thank you for your time and attention in this matter, and I look forward to your prompt response and approval of this treatment.

Sincerely,

<Physician Signature>
<Physician Name>
<Provider ID Number>

ATTACHMENTS TO CONSIDER:
- <Product Name> FDA approval letter
- <Product Name> Prescribing Information
- Patient clinical notes and any other relevant supporting documentation
- Prior authorization letter (if previously approved)
- Denial letter

The letters provided are samples; use of these letters does not guarantee reimbursement.

Selected Important Safety Information

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.

Abbreviations: FDA, Food and Drug Administration; PA, prior authorization.

Medicare Coverage

Coverage of REBLOZYL by Medicare is expected to follow guidance within chapter 15 of the *Medicare Benefit Policy Manual*, which states that "the program covers drugs that are furnished 'incident to' a physician's service provided that the drugs are not usually self-administered by the patients who take them."[12] An injectable drug or biologic is typically eligible for inclusion under the "incident to" benefit when it is FDA approved, in a form not usually self-administered, furnished by a physician, and administered by the physician or by auxiliary personnel employed by the physician and under the physician's personal supervision.[12] It also can be furnished by other healthcare professionals. In addition, the drug must also be reasonable and necessary for an individual patient, as well as safe and effective.

Medicaid Coverage[13,14]

Medicaid is a joint federal-state program that pays for medical assistance for individuals and families with low incomes and relatively few assets. Medicaid programs are established and administered by each individual state. Although pharmacy coverage is an optional benefit under federal Medicaid law, all states currently provide coverage for outpatient prescription drugs to all categorically eligible individuals and most other enrollees within their state Medicaid programs. Benefits for Medicaid patients should be verified to identify additional needs, such as prior authorizations.

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

Please see Important Safety Information on page 2 and full Prescribing Information.

CELGENE PATIENT SUPPORT®

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*)

*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.

References

1. REBLOZYL (luspatercept-aamt) [package insert]. Summit, NJ: Celgene Corp; 2020. **2.** Centers for Medicare & Medicaid Services. Completing and processing form CMS-1500 data set. In: *Medicare Claims Processing Manual*. Revision 4472. Baltimore, MD: Centers for Medicare & Medicaid Services; Updated December 5, 2019. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c26.pdf. Accessed June 11, 2020. **3.** Centers for Medicare & Medicaid Services. HCPCS release & code sets. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/index.html. Updated November 4, 2019. Accessed June 11, 2020. **4.** Synovec MS, Brin KP, Jagmin CL, et al; American Medical Association. *CPT® 2020 Professional Edition*. Chicago, IL: American Medical Association; 2019. **5.** Centers for Medicare & Medicaid Services. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions: First Quarter, 2020 Coding Cycle for Drug and Biological Products. https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-1-2020-drugs-and-biologicals-updated-04142020.pdf. Accessed June 5, 2020. **6.** Centers for Medicare & Medicaid Services. Drugs and biologicals. In: *Medicare Claims Processing Manual*. Revision 4384. Baltimore, MD: Centers for Medicare & Medicaid Services; August 30, 2019. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf. Accessed June 11, 2020. **7.** Centers for Medicare & Medicaid Services. 2020 ICD-10 CM. https://www.cms.gov/Medicare/Coding/ICD10/2020-ICD-10-CM. Updated March 30, 2020. Accessed June 11, 2020. **8.** ICD10Data.com. 2020 ICD-10-CM diagnosis code D56.1: beta thalassemia. https://www.icd10data.com/ICD10CM/Codes/D50-D89/D55-D59/D56-/D56.1. Accessed June 11, 2020. **9.** ICD10Data.com. 2020 ICD-10-CM diagnosis code D56.5 Hemoglobin E-beta thalassemia. https://www.icd10data.com/ICD10CM/Codes/D50-D89/D55-D59/D56-/D56.5. Accessed June 11, 2020. **10.** ICD10Data.com. 2020 ICD-10-CM diagnosis code D46. https://www.icd10data.com/search?s=D46. Accessed June 11, 2020. **11.** Centers for Medicare & Medicaid Services. Completing and processing the form CMS-1450 data set. In: *Medicare Claims Processing Manual*. Revision 4194. Baltimore, MD: Centers for Medicare & Medicaid Services; January 11, 2019. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c25.pdf. Accessed June 11, 2020. **12.** Centers for Medicare & Medicaid Services. Covered medical and other health services. In: *Medicare Benefit Policy Manual.* Revision 259. Baltimore, MD: Centers for Medicare & Medicaid Services; July 12, 2019. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Accessed June 11, 2020. **13.** Centers for Medicare & Medicaid Services. Benefits. Medicaid.gov website. https://www.medicaid.gov/medicaid/benefits/index.html. Accessed June 11, 2020. **14.** Centers for Medicare & Medicaid Services. Prescription drugs. Medicaid.gov website. https://www.medicaid.gov/medicaid/prescription-drugs/index.html. Accessed June 11, 2020.

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07/20 US-RBZ-20-0235