Reblozyl® (Luspatercept-Aamt)

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➲ Instructions for Use

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Community Plan Policy

- Reblozyl® (Luspatercept-Aamt)

Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

➲ See Benefit Considerations

Reblozyl is proven and medically necessary for the treatment of anemia in adult patients with beta thalassemia who meet all of the following criteria:

- **Initial Therapy**
  - Diagnosis of anemia due to beta thalassemia including beta^{+} thalassemia, beta^{0} thalassemia, and hemoglobin E/beta thalassemia; **and**
  - Patient is 18 years of age or older; **and**
  - Patient is transfusion dependent as evidenced by **both** of the following in the previous 24 weeks:
    - Has required regular transfusion of at least six units of packed red blood cells (PRBC); **and**
    - No transfusion free period greater than 35 days

    and
  - Prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of beta thalassemia; **and**
  - Dosing is in accordance with the U.S. Food and Drug Administration (FDA)–approved labeling; **and**
  - Initial authorization will be for no more than 12 months
- **Continuation of Therapy**
  - Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline); **and**
  - Prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of beta thalassemia; **and**
  - Dosing is in accordance with the FDA-approved labeling; **and**
  - Reauthorization will be for no more than 12 months

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Reblozyl is proven and medically necessary for the treatment of symptomatic anemia in patients with myelodysplastic syndromes who meet all of the following criteria:

- **Initial Therapy**
  - Diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS); **and**
  - Patient has lower risk disease as defined as International Prognostic Scoring System (IPSS-R): Very Low, Low, Intermediate; **and**
  - Patient does not have a confirmed mutation with deletion 5q [del(5q)]; **and**
  - **One** of the following:
    - **Both** of the following:
      - Ring sideroblasts < 15% (or ring sideroblasts < 5% with an SF3B1 mutation); **and**
      - Serum erythropoietin ≤ 500 mU/mL

      or
    - Ring sideroblasts ≥ 15% (or ring sideroblasts ≥ 5% with an SF3B1 mutation)

    and
  - Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelodysplastic syndromes; **and**
  - Dosing is in accordance with the FDA-approved labeling; **and**
  - Initial authorization will be for no more than 12 months
- **Continuation of Therapy**
  - Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline); **and**
  - Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelodysplastic syndromes; **and**
  - Dosing is in accordance with the FDA-approved labeling; **and**
  - Reauthorization will be for no more than 12 months

Reblozyl is proven and medically necessary for the treatment of anemia in patients with myelodysplastic syndrome/myeloproliferative overlap neoplasm (MDS/MPN) who meet all of the following criteria:

- **Initial Therapy**
  - Diagnosis of anemia due to myelodysplastic syndrome/myeloproliferative overlap neoplasm (MDS/MPN); **and**
  - Presence of a SF3B1 mutation; **and**
  - Thrombocytosis defined as platelet count ≥ 450 x 10^9/L; **and**
  - Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of MDS/MPN; **and**
  - Dosing is in accordance with the FDA-approved labeling; **and**
  - Initial authorization will be for no more than 12 months
- **Continuation of Therapy**
  - Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline); **and**
  - Reblozyl is prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of MDS/MPN; **and**
  - Dosing is in accordance with the FDA-approved labeling; **and**
  - Reauthorization will be for no more than 12 months

Reblozyl is proven and medically necessary for the treatment of myelofibrosis-associated anemia who meet all of the following criteria:

- **Initial Therapy**
  - Diagnosis of myelofibrosis-associated anemia; **and**
  - **One** of the following:
    - **Both** of the following:
      - Symptomatic splenomegaly and/or constitutional symptoms; **and**
      - Used in combination with a JAK inhibitor [e.g., Inrebic (fedratinib), Jakafi (ruxolitinib), Ojjaara (momelotinib),Vonjo (pacritinib)]

      or
    - No splenomegaly or constitutional symptoms

    and
  - Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelofibrosis; **and**
  - Dosing is in accordance with the FDA-approved labeling; **and**
  - Initial authorization will be for no more than 12 months

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- **Continuation of Therapy**
  - Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline); **and**
  - Reblozyl is prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelofibrosis; **and**
  - Dosing is in accordance with the FDA-approved labeling; **and**
  - Reauthorization will be for no more than 12 months

Reblozyl is not proven or medically necessary for the treatment of:
- Alpha thalassemia
- Beta thalassemia in pediatric patients
- Non-transfusion dependent beta thalassemia
- Sickle beta thalassemia [hemoglobin S (HbS)/beta thalassemia]

UnitedHealthcare recognizes indications and uses of injectable oncology medications, including therapeutic radiopharmaceuticals, listed in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and medically necessary, and Categories of Evidence and Consensus of 3 as unproven and not medically necessary.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

HCPCS Code	Description
J0896	Injection, luspatercept-aamt, 0.25 mg

Diagnosis Code	Description
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.22	Refractory anemia with excess of blasts 2
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D56.1	Beta thalassemia
D56.5	Hemoglobin E-beta thalassemia

Background

Beta-thalassemias are a group of hereditary blood disorders characterized by anomalies in the synthesis of the beta chains of hemoglobin resulting in variable phenotypes ranging from severe anemia to clinically asymptomatic individuals. Three main forms have been described: thalassemia major, thalassemia intermedia and thalassemia minor. Individuals with thalassemia major usually present within the first two years of life with severe anemia, requiring regular red blood cell (RBC) transfusions. Findings in untreated or poorly transfused individuals with thalassemia major, as seen in some developing countries, are growth retardation, pallor, jaundice, poor musculature, hepatosplenomegaly, leg ulcers, development of masses from extramedullary hematopoiesis, and skeletal changes that result from expansion of the bone marrow. Regular transfusion therapy leads to iron overload related complications including endocrine complication (growth retardation, failure of sexual maturation, diabetes mellitus, and insufficiency of the parathyroid, thyroid, pituitary, and less commonly, adrenal glands), (dilated myocardiopathy, liver fibrosis and cirrhosis). Patients with thalassemia intermedia present later in life with moderate anemia and do not require regular transfusions. Main clinical features in these patients are hypertrophy of erythroid marrow with medullary and extramedullary hematopoiesis and its complications (osteoporosis, masses of erythropoietic tissue that primarily affect the spleen, liver, lymph nodes, chest and spine, and bone deformities and typical facial changes), gallstones, painful leg ulcers and increased predisposition to thrombosis. Thalassemia minor is clinically asymptomatic, but some subjects may have moderate anemia. Beta-

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thalassemias are caused by point mutations or, more rarely, deletions in the beta globin gene on chromosome 11, leading to reduced (beta^{+}) or absent (beta^{0}) synthesis of the beta chains of hemoglobin. Transmission is autosomal recessive; however, dominant mutations have also been reported. Diagnosis of thalassemia is based on hematologic and molecular genetic testing. Treatment of thalassemia major includes regular RBC transfusions, iron chelation and management of secondary complications of iron overload. In some circumstances, spleen removal may be required. Bone marrow transplantation remains the only definitive cure currently available. Individuals with thalassemia intermedia may require splenectomy, folic acid supplementation, treatment of extramedullary erythropoietic masses and leg ulcers, prevention, and therapy of thromboembolic events. Prognosis for individuals with beta-thalassemia has improved substantially following recent medical advances in transfusion, iron chelation and bone marrow transplantation therapy. However, cardiac disease remains the main cause of death in patients with iron overload.

Myelodysplastic syndromes (MDS) are a heterogeneous group of malignant hematopoietic stem cell disorders characterized by dysplastic and ineffective blood cell production and a risk of transformation to acute leukemia. Patients with MDS have impaired blood cell production and function that often leads to anemia, bleeding, and increased risk of infection. MDS occurs most commonly in male patients 65 years of age and older. Anemia is the most common cytopenia and can manifest as fatigue, weakness, exercise intolerance, angina, etc. Other symptoms include infection, easy bruising, or bleeding. MDS can be classified by one of three prognostic systems, based upon a combination of morphology, immunophenotype, genetics, and clinical features. These scoring systems are the Revised International Prognostic Scoring System (IPSS-R), International Prognostic Scoring System (IPSS) and the WHO-Based Prognostic Scoring System (WPSS). The IPSS should be used for initial prognostic and planning purposes. WPSS permits dynamic estimation of prognosis at multiple time points during the course of MDS.

Luspatercept is a recombinant fusion protein that binds to select transforming growth factor β (TGF-β) superfamily ligands and enhances late-stage erythropoiesis.

Benefit Considerations

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy.

Clinical Evidence

Beta Thalassemia

The efficacy of Reblozyl was evaluated in adult patients with beta thalassemia in the BELIEVE trial (NCT02604433). BELIEVE is a multicenter, randomized, double-blind, placebo-controlled trial in which (n = 336) patients with beta thalassemia (including beta^{+} thalassemia, beta^{0} thalassemia, and hemoglobin E/beta thalassemia; beta thalassemia with mutation and/or multiplication of alpha globin was also allowed) requiring regular red blood cell transfusions (6-20 RBC units per 24 weeks) with no transfusion-free period greater than 35 days during that period were randomized 2:1 to Reblozyl (n = 224) or placebo (n = 112). In BELIEVE, Reblozyl was administered subcutaneously once every 3 weeks as long as a reduction in transfusion requirement was observed or until unacceptable toxicity. All patients were eligible to receive best supportive care, which included RBC transfusions; iron-chelating agents; use of antibiotic, antiviral, and antifungal therapy; and/or nutritional support, as needed. The BELIEVE trial excluded patients with hemoglobin S/beta-thalassemia or alpha-thalassemia or who had major organ damage (liver disease, heart disease, lung disease, renal insufficiency). Patients with recent deep vein thrombosis or stroke or recent use of ESA, immunosuppressant, or hydroxyurea therapy were also excluded. The median age was 30 years (range: 18-66). The primary efficacy outcome measure was the proportion of patients achieving RBC transfusion burden reduction from baseline of at least 33%, with a reduction of at least 2 units from week 13 to week 24. Of the patients who received Reblozyl, 21.4% (n = 48) achieved the primary endpoint compared with 4.5% (n = 5) of those who received placebo (risk difference 17.0; 95% CI 10.4, 23.6; $p < 0.0001$). Secondary outcome measures included the proportion of patients achieving RBC transfusion burden reduction from baseline of at least 33%, with a reduction of at least 2 units from week 37 to 48 and the proportion of patients achieving RBC transfusion burden reduction from baseline of at least 50%, with a reduction of at least 2 units for 12 consecutive weeks from week 13 to week 24 and from week 37 to 48. Of the patients who received Reblozyl, 19.6% (n = 44) achieved a 33% reduction and 2-unit reduction in transfusion burden from week 37 to 48 compared to 3.6% (n = 4) with placebo (risk difference 16.1; 95% CI 9.8, 22.4; $p < 0.0001$). 7.6% (n = 17) and 10.3% (n = 23) of patients receiving Reblozyl experienced a 50% reduction in transfusion burden with a 2 unit reduction for 12 consecutive weeks compared

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to 1.8% (n = 2) and 0.9% (n = 1) from week 13 to 24 and from week 37 to week 48 respectively (p < 0.05 for both comparisons).

Myelodysplastic Syndromes

The efficacy and safety of Reblozyl for the treatment of patients with symptomatic anemia and lower-risk myelodysplastic syndromes was evaluated in a double-blind, placebo-controlled, phase 3 trial (MEDALIST). Patients with symptomatic anemia and very-low, low, or intermediate-risk myelodysplastic syndromes where erythropoiesis-stimulating agent therapy was not effective, were randomized (n = 229) to receive either luspatercept (n = 153, at a dose of 1.0mg up to 1.75mg per kilogram body weight) or placebo (n = 76), administered subcutaneously every 3 weeks. The primary end point was transfusion independence for 8 weeks or longer during weeks 1 through 24, and the key secondary end point was transfusion independence for 12 weeks or longer, assessed during weeks 1 through 24 and 1 through 48. Transfusion independence for 8 weeks or longer was observed in 38% of the patients in the luspatercept group, as compared with 13% of those in the placebo group (p < 0.001). A higher percentage of patients in the luspatercept group than in the placebo group met the key secondary end point (28% vs. 8% for weeks 1 through 24, and 33% vs. 12% for weeks 1 through 48; p < 0.001 for both comparisons). The most common luspatercept associated adverse events (of any grade) included fatigue, diarrhea, asthenia, nausea, and dizziness. The authors concluded that luspatercept reduced the severity of anemia in patients with lower-risk myelodysplastic syndromes with ring sideroblasts who had been receiving regular red-cell transfusions and who had disease that was refractory to or unlikely to respond to erythropoiesis stimulating agents or who had discontinued such agents owing to an adverse event.

The efficacy Reblozyl for the treatment of MDS with associated anemia in erythropoietin-naïve patients was evaluated in the COMMANDS trial, a phase 3, open-label, randomized controlled trial. Eligible patients were aged 18 years or older, had a diagnosis of myelodysplastic syndromes of very low risk, low risk, or intermediate risk (per the Revised International Prognostic Scoring System), were ESA-naive, and required red blood cell transfusions (2-6 packed red blood cell units per 8 weeks for ≥ 8 weeks immediately before randomisation). Integrated response technology was used to randomly assign patients (1:1, block size 4) to luspatercept or epoetin alfa, stratified by baseline red blood cell transfusion burden (< 4 units per 8 weeks vs ≥ 4 units per 8 weeks), endogenous serum erythropoietin concentration (≤ 200 U/L vs > 200 to < 500 U/L), and ring sideroblast status (positive vs negative). Luspatercept was administered subcutaneously once every 3 weeks starting at 1·0 mg/kg body weight with possible titration up to 1·75 mg/kg. Epoetin alfa was administered subcutaneously once a week starting at 450 IU/kg body weight with possible titration up to 1050 IU/kg (maximum permitted total dose of 80 000 IU). The primary endpoint was red blood cell transfusion independence for at least 12 weeks with a concurrent mean haemoglobin increase of at least 1·5 g/dL (weeks 1-24), assessed in the intention-to-treat population. Safety was assessed in patients who received at least one dose of study treatment. A total of 356 patients were randomly assigned to receive luspatercept (178 patients) or epoetin alfa (178 patients), comprising 198 (56%) men and 158 (44%) women [median age 74 years (IQR 69-80)]. The interim efficacy analysis was done for 301 patients (147 in the luspatercept group and 154 in the epoetin alfa group) who completed 24 weeks of treatment or discontinued earlier. 86 (59%) of 147 patients in the luspatercept group and 48 (31%) of 154 patients in the epoetin alfa group reached the primary endpoint (common risk difference on response rate 26·6; 95% CI 15·8-37·4; p < 0·0001).

The most frequently reported grade 3 or 4 treatment-emergent adverse events with luspatercept (≥ 3% patients) were hypertension, anaemia, dyspnoea, neutropenia, thrombocytopenia, pneumonia, COVID-19, myelodysplastic syndromes, and syncope; and with epoetin alfa were anaemia, pneumonia, neutropenia, hypertension, iron overload, COVID-19 pneumonia, and myelodysplastic syndromes. The most common suspected treatment-related adverse events in the luspatercept group (≥ 3% patients, with the most common event occurring in 5% patients) were fatigue, asthenia, nausea, dyspnoea, hypertension, and headache; and none (≥ 3% patients) in the epoetin alfa group. One death after diagnosis of acute myeloid leukemia was considered to be related to luspatercept treatment (44 days on treatment).

Professional Societies

The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium recommends the Reblozyl for the following:

- Treatment of lower risk* myelodysplastic syndromes associated with symptomatic anemia with no del(5q), with or without other cytogenetic abnormalities with ring sideroblasts ≥ 15% (or ring sideroblasts ≥ 5% with an SF3B1 mutation). (1)
- Treatment of lower risk* myelodysplastic syndromes associated with symptomatic anemia with no del(5q), with or without other cytogenetic abnormalities with ring sideroblasts < 15% (or ring sideroblasts < 5% with an SF3B1 mutation) and with serum erythropoietin ≤ 500 mU/mL. (2A)
- Management of myelofibrosis-associated anemia and for the treatment of myelodysplastic syndromes/myelodysplatic neoplasms associated with SF3B1 mutation and thrombocytosis. (2A)

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- Management of myelofibrosis-associated anemia with ongoing symptomatic splenomegaly and/or constitutional symptoms, to be given in combination with ruxolitinib, with no splenomegaly or constitutional symptoms, or with splenomegaly and constitutional symptoms well controlled on current JAK inhibitor, to be given in combination with a JAK inhibitor. (2A)

*Lower risk defined as IPSS-R (Very Low, Low, Intermediate).

NCCN defines a lack of response to luspatercept as a lack of 1.5 g/dL rise in hemoglobin or lack of a decrease in RBC transfusion requirement by 6 to 8 weeks of treatment.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Reblozyl (luspatercept-aamt) is an erythroid maturation agent indicated for the treatment of:

- Anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions
- Anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions
- Anemia failing an erythropoiesis stimulating agent and requiring 2 or more RBC 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)

Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

References

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Policy History/Revision Information

Date	Summary of Changes

08/01/2026	**Template Update**
	• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
	• Added *Application* section to indicate this policy applies to:
	  ○ UnitedHealthcare Commercial benefit plans
	  ○ Individual Exchange benefit plans
	Supporting Information
	• Updated *Background*, *Clinical Evidence*, and *References* sections to reflect the most current information
	• Archived previous policy versions 2025D0084K and IEXD0084.09

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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