Medical Policy:

Reblozyl (luspatercept-aamt) subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.205	February 24, 2025	February 7th, 2020

Definitions

Reblozyl is an erythroid maturation agent. Luspatercept-aamt is a receptor fusion protein consisting of a modified extracellular domain of the human activin receptor type IIB linked to a human IgG1 Fc domain with a calculated molecular mass of approximately 76 kD. Luspatercept is produced in Chinese hamster ovary cells by recombinant DNA technology.

Length of Authorization

Beta Thalassemia: Coverage will be provided initially for 15 weeks (5 initial doses) and may be renewed annually thereafter.

Anemia due to Myelodysplastic Syndrome: Coverage will be provided initially for 21 weeks (7 initial doses) and may be renewed every 6 months thereafter.

Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis: Coverage will be provided initially for 24 weeks (8 initial doses) and may be renewed every 6 months thereafter.

Dosing Limits [Medical Benefit]

1.25mg/kg every 3 weeks (Anemia related to beta-thalassemia)- 600 billable units every 21 days

1.75mg/kg every 3 weeks (Myelodysplastic syndromes associated anemia and Myeloproliferative Neoplasms) - 800 billable units every 21 days

Guideline

I. Initial Approval Criteria

Reblozyl *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

Coverage is provided in the following conditions:
• Patient is at least 18 years of age, unless otherwise specified**; **AND**

Universal Criteria

• Females of reproductive potential have a negative pregnancy test prior to start of therapy and will use an effective method of contraception during treatment and for at least 3 months after treatment; **AND**
• Patient has not had a deep vein thrombosis or a thrombotic stroke which required medical intervention within 6 months prior to therapy; **AND**
• Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency, etc.) have been ruled out; **AND**
• Reblozyl is not being used as a substitute for RBC transfusions in patients requiring immediate correction of anemia; **AND**
• Patient has a pre-dose Hemoglobin (Hb) < 11.5 g/dL* obtained within 7 days of the date of administration (unless otherwise specified); **AND**
**Note: If Hb is > 11.5 g/dL, the dose must be delayed until the Hb is < 11 g/dL. If an RBC transfusion occurred prior to dosing, the pretransfusion Hb must be considered for dosing purposes*

1. **Anemia related to beta-thalassemia**
   A. Patient has a documented diagnosis of beta thalassemia (excludes isolated alpha-thalassemia and hemoglobin S/ß-thalassemia variants) as outlined by the following:
      i. Patient diagnosis is confirmed by HBB sequence gene analysis showing biallelic pathogenic variants; **OR**
      ii. Patient has severe microcytic hypochromic anemia, absence of iron deficiency, anisopoikilocytosis with nucleated red blood cells on peripheral blood smear, and hemoglobin analysis that reveals decreased amounts or complete absence of hemoglobin A (HbA) and increased HbA2 with or without increased amounts of hemoglobin F (HbF); **AND**
   B. Patient is red blood cell (RBC) transfusion dependent as defined by requiring 6-20 RBC units per 24 weeks; **AND**
   C. Patient does not have major end organ damage§, defined as any of the following:
      i. Liver disease with an ALT > 3x the ULN or history of evidence of cirrhosis; **OR**
      ii. Heart disease, heart failure NYHA classification 3 or higher, or significant arrhythmia requiring treatment, or recent myocardial infarction within 6 months of treatment; **OR**
      iii. Lung disease, including pulmonary fibrosis or pulmonary hypertension which are clinically significant i.e., ≥ Grade 3; **OR**
      iv. Creatinine clearance < 60 mL/min

§Requests for patients deemed to have any major end organ damage will be reviewed on a case-by-case basis.
***Requests for patients <18 years will be considered on a case-by-case basis for those with high transfusion burden and symptomatic iron overload, history of alloimmunization, or history of transfusion*

reactions

2. **Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis ‡**
   A. Patient has anemia with symptomatic splenomegaly and/or constitutional symptoms; **AND**
      i. Used in combination with ruxolitinib; **OR**
   B. Patient has anemia with no symptomatic splenomegaly and/or constitutional symptoms; **AND**
      i. Used as a single agent

3. **Anemia Due to Myelodysplastic Syndromes (MDS) † ‡**
   A. Used as a single agent; **AND**
      i. Used for the treatment of symptomatic anemia with Myelodysplastic Syndromes (MDS); **AND**
         a. Patient has lower risk disease (IPSS-R very low, low, or intermediate-risk); **AND**
            1.) Patient has ring sideroblasts <15% (or ring sideroblasts <5% with an SF3B1 mutation); **AND**
               - Patient has serum erythropoietin < 500 mU/mL; AND
                 - Used as first-line treatment (i.e. erythropoiesis stimulating agent-naïve); **OR**
                 - Used following no response* to first-line treatment with a single agent erythropoiesis stimulating agent (ESA) (despite adequate iron stores); **OR**
            2.) Patient has ring sideroblasts ≥15% (or ring sideroblasts ≥5% with an SF3B1 mutation); **OR**

      ii. Used for the treatment of anemia with Myelodysplastic Syndromes/Myeloproliferative Neoplasm Overlap (MDS/MPN) and thrombocytosis with an SF3B1 mutation; **OR**

      iii. Used for the treatment of anemia with MDS/MPN with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T); **AND**
         a. Patient has ring sideroblasts >15% and a wild-type SF3B1 mutation; **OR**
         b. Patient has ring sideroblasts ≥ 5% (but < 15%) with a SF3B1 mutation; **AND**
            1.) Patient has required 2 or more red blood cell units over an 8-week timeframe
               - Patient is erythropoiesis stimulating agent (ESA) ineligible (i.e. serum erythropoietin > 200 mU/mL and not previously treated with ESA); **OR**
               - Patient has had an inadequate response to prior treatment with an ESA (i.e. epoetin alpha ≥ 40,000 units/week for at least 8 doses or darbepoetin alpha ≥ 500 mcg every 3 weeks for at least 4 doses or equivalent); **OR**
               - Patient has a documented contraindication or intolerance to the use of an ESA

** Note: No response defined as a lack of ≥1.5 gm/dL rise in hemoglobin OR lack of a decrease in RBC transfusion requirement within 6-8 weeks when treated with ESAs.*

† FDA Approved Indications; ‡ Compendia Recommended Indication(s); Φ Orphan Drug

Limitations/Exclusions

Reblozyl is not considered medically necessary when any of the following selection criteria is met:

1. When it is being used as a substitute for RBC transfusions in patients who require immediate correction of anemia.

II. Renewal Criteria

1. Patient continues to meet initial approval criteria; **AND**
2. Patient will not receive doses < 21 days apart; **AND**
3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: thromboembolic events, severe hypertension, extramedullary hematopoietic masses in patients with beta thalassemia, etc.

4. **Beta Thalassemia**
   • Patient is experiencing disease response as evidenced by a decrease in the number of RBC transfusions from baseline; **OR**
   • For new starts: Patient has not achieved a reduction in RBC transfusion burden after at least 2 consecutive, initial (1 mg/kg) doses (6 weeks) and requires a dose increase to 1.25 mg/kg; **OR**
   • Patient experienced a response followed by a lack/loss of response and requires a dose increase to 1.25 mg/kg (from 1 mg/kg)
5. **Anemia Due to Myelodysplastic Syndromes (MDS)**
   • Patient is experiencing disease response as evidenced by a decrease in the number of RBC transfusions from baseline; **OR**
   • For new starts: Patient has not achieved a reduction in RBC transfusion burden after at least 2 consecutive, initial (1 mg/kg) doses (6 weeks) and requires a dose increase to 1.33mg/kg; **OR**
   • Patient has not achieved a reduction in RBC transfusion burden after at least 2 consecutive, 1.33 mg/kg doses (6 weeks) and requires a dose increase to 1.75 mg/kg; **OR**
   • Patient experienced a response followed by a lack/loss of response and requires a dose increase by one dose level from the level in which response was lost (not to exceed a dose of 1.75 mg/kg)
6. **Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis**
   • Patient is experiencing disease response from baseline (e.g. decrease in the number of RBC transfusions from baseline, ≥ 1.5 g/dL hemoglobin increase without RBC transfusions from baseline, reduction in anemia-related fatigue symptoms, etc.); **OR**
   • For new starts: Patient has not achieved disease response after at least 2 consecutive, initial (1 mg/kg or 1.33 mg/kg) doses (6 weeks) and requires a dose increase by one dose level from the initial level (1.33 mg/kg or 1.75mg/kg); **OR**
   • Patient experienced a response followed by a lack/loss of response and requires a dose increase by one dose level from the level in which response was lost (not to exceed a dose of 1.75 mg/kg)

Dosage/Administration

	Dose
Beta Thalassemia	The recommended starting dose of Reblozyl is 1 mg/kg once every 3 weeks by subcutaneous injection. If a patient does not achieve a reduction in RBC transfusion burden after at least 2 consecutive doses (6 weeks) at the 1 mg/kg starting dose, increase the Revlozyl dose to 1.25 mg/kg. Do not increase the dose beyond the maximum dose of 1.25 mg/kg.
Anemia Due to Myelodysplastic Syndromes (MDS)	The recommended starting dose of Reblozyl is 1 mg/kg once every 3 weeks by subcutaneous injection. **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**

Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis	The recommended starting dose is 1 mg/kg to 1.33 mg/kg once every 3 weeks by subcutaneous injection. − Dose increases for insufficient response: If a patient is not having beneficial response after at least 2 consecutive doses (6 weeks) at the current dose level, increase the Reblozyl dose to 1.33 mg/kg (in those on 1 mg/kg) or 1.75mg/kg (in those on 1.33 mg/kg). Do not increase the dose more frequently than every 6 weeks (2 doses) or beyond the maximum dose of 1.75 mg/kg.
The recommended starting dose is 1 mg/kg to 1.33 mg/kg once every 3 weeks by subcutaneous injection. − Dose increases for insufficient response: If a patient is not having beneficial response after at least 2 consecutive doses (6 weeks) at the current dose level, increase the Reblozyl dose to 1.33 mg/kg (in those on 1 mg/kg) or 1.75mg/kg (in those on 1.33 mg/kg). Do not increase the dose more frequently than every 6 weeks (2 doses) or beyond the maximum dose of 1.75 mg/kg.	

Applicable Procedure Codes

Code	Description
J0896	Injection, luspatercept-aamt, 0.25 mg (Reblozyl). J-Code effective date: 07/01/2020

Applicable NDCs

Code	Description
59572-0775-01	Reblozyl (luspatercept-aamt) PDS 75mg
59572-0711-01	Reblozyl (luspatercept-aamt PDS 25mg

ICD-10 Diagnoses

Code	Description
D46.1	Refractory anemia with ring sideroblasts
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasiaand ring sideroblasts
D46.4	Refractory anemia, unspecified
D46.Z	Other myelodysplastic syndromes
D46.9	Myelodysplastic syndrome, unspecified
D56.1	Beta-thalassemia
D56.5	Hemoglobin E-beta thalassemia

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/24/2025	Annual Review: Length of authorization: added: Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis: Coverage will be provided initially for 24 weeks (8 initial doses) and may be renewed every 6 months thereafter. Also added MPN to dosing limits. Initial Criteria: added: "Patient is at least 18 years of age, unless otherwise specified**; AND Universal Criteria Females of reproductive potential have a negative pregnancy test prior to start of therapy and will use an effective method of contraception during treatment and for at least 3 months after treatment; AND Patient has not had a deep vein thrombosis or a thrombotic

		stroke which required medical intervention within 6 months prior to therapy; AND Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency, etc.) have been ruled out; AND Reblozyl is not being used as a substitute for RBC transfusions in patients requiring immediate correction of anemia; AND Patient has a pre-dose Hemoglobin (Hb) < 11.5 g/dL* obtained within 7 days of the date of administration (unless otherwise specified); AND*Note: If Hb is > 11.5 g/dL, the dose must be delayed until the Hb is < 11 g/dL. If an RBC transfusion occurred prior to dosing, the pretransfusion Hb must be considered for dosing purposes." Anemia related to beta-thalassemia: Removed the following and reworded: "Patient is 18 years of age and older; AND According to the prescriber, the patient requires regular red blood cell transfusions as defined by meeting both of the following (i and ii): Patient has received at least 6 units of packed red blood cells within the preceding 24 weeks; AND Patient has not had any transfusion-free period > 35 days within the preceding 24 weeks; AND The patient has Hgb less than or equal to 11 g/dL (If the pre-dose Hgb is greater than or equal to 11.5 g/dL and the Hgb level is not influenced by recent transfusion, delay dosing until the Hgb is less than or equal to 11 g/dL); AND" Removed the following: "Patient has not received Zynteglo (betibeglogene autotemcel intravenous infusion) in the past; AND The medication is being prescribed by or in consultation with a hematologist." Added: " Patient has a documented diagnosis of beta thalassemia (excludes isolated alphathalassemia and hemoglobin S/ß-thalassemia variants) as outlined by the following: Patient diagnosis is confirmed by HBB sequence gene analysis showing biallelic pathogenic variants; OR Patient has severe microcytic hypochromic anemia, absence of iron deficiency, anisopoikilocytosis with nucleated red blood cells on peripheral blood smear, and hemoglobin analysis that reveals decreased amounts or complete absence of hemoglobin A (HbA) and increased HbA2 with or without increased amounts of hemoglobin F (HbF); AND Patient is red blood cell (RBC) transfusion dependent as defined by requiring 6-20 RBC units per 24 weeks; AND Patient does not have major end organ damage§, defined as any of the following: Liver disease with an ALT > 3x the ULN or history of evidence of cirrhosis; OR Heart disease, heart failure NYHA classification 3 or higher, or significant arrhythmia requiring treatment, or recent myocardial infarction within 6 months of treatment; OR Lung disease, including pulmonary fibrosis or pulmonary hypertension which are clinically significant i.e., ≥ Grade 3; OR Creatinine clearance < 60 mL/min *§Requests for patients deemed to have any major end organ damage will be reviewed on a case-by-case basis.**Requests for patients <18 years will be considered on a case-by-case basis for those with high transfusion burden and symptomatic iron overload, history of alloimmunization, or history of transfusion reactions"* Changed heading from "Myelodysplastic/Myeloproliferative Neoplasm" to " Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis ‡" removed the following (some was reworded): "Patient is ≥ 18 years of age; AND According to the prescriber, the patient has myelodysplastic/myeloproliferative neoplasm and meets both of the following (i and ii): Ring sideroblast positivity; AND *Note: This is defined as ring sideroblasts ≥ 15% or ring sideroblasts ≥ 5% with an SF3B1 mutation.* Thrombocytosis defined as platelet count ≥ 450 x 10^9/L; AND Patient has very low- to intermediate-risk disease, as determined by the prescriber; AND *Note: This is determined using the International Prognostic Scoring System (IPSS).* Patient does not have a confirmed mutation with deletion 5q [del(5q)]; AND Patient currently requires blood transfusions, defined as at least two red blood cell units over the previous 8 weeks; AND Pretreatment hemoglobin level is < 10.0 g/dL; AND Reblozyl will not be used in combination with an erythropoiesis stimulating agent; AND The medication is being prescribed by or in consultation with an oncologist or hematologist."Added: " Patient has anemia with symptomatic splenomegaly and/or constitutional symptoms; AND Used in combination with ruxolitinib; OR Patient has anemia with no symptomatic splenomegaly and/or constitutional symptoms; AND Used as a single agent"

		Changed Heading from: "Myelodysplastic Syndromes Associated Anemia" to "Anemia Due to Myelodysplastic Syndromes (MDS) † ‡" Removed the following (some was reworded): "Patient is 18 years of age or older; AND According to the prescriber, the patient has myelodysplastic syndromes and meets one of the following (i or ii): Ring sideroblast positivity; OR *Note: This is defined as ring sideroblasts ≥ 15% or ring sideroblasts ≥ 5% with an SF3B1 mutation.* Serum erythropoietin level is ≤ 500 mU/mL; AND Patient has very low- to intermediate-risk myelodysplastic syndromes, as determined by the prescriber; AND *Note: This is determined using the International Prognostic Scoring System (IPSS).* Patient does not have a confirmed mutation with deletion 5q [del(5q)]; AND Patient currently requires blood transfusions, defined as at least two red blood cell units over the previous 8 weeks; AND Pretreatment hemoglobin level is < 10.0 g/dL; AND will not be used in combination with an erythropoiesis stimulating agent; AND The medication is being prescribed by or in consultation with an oncologist or hematologist" Added: " Used as a single agent; AND Used for the treatment of symptomatic anemia with Myelodysplastic Syndromes (MDS); AND Patient has lower risk disease (IPSS-R very low, low, or intermediate-risk); AND Patient has ring sideroblasts <15% (or ring sideroblasts <5% with an SF3B1 mutation); AND Patient has serum erythropoietin < 500 mU/mL; AND Used as first-line treatment (i.e. erythropoiesis stimulating agent-naïve); OR Used following no response* to first-line treatment with a single agent erythropoiesis stimulating agent (ESA) (despite adequate iron stores); OR Patient has ring sideroblasts ≥15% (or ring sideroblasts ≥5% with an SF3B1 mutation); OR Used for the treatment of anemia with Myelodysplastic Syndromes/Myeloproliferative Neoplasm Overlap (MDS/MPN) and thrombocytosis with an SF3B1 mutation; OR Used for the treatment of anemia with MDS/MPN with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T); AND Patient has ring sideroblasts >15% and a wild-type SF3B1 mutation; OR Patient has ring sideroblasts ≥ 5% (but < 15%) with a SF3B1 mutation; AND Patient has required 2 or more red blood cell units over an 8-week timeframe Patient is erythropoiesis stimulating agent (ESA) ineligible (i.e. serum erythropoietin > 200 mU/mL and not previously treated with ESA); OR Patient has had an inadequate response to prior treatment with an ESA (i.e. epoetin alpha ≥ 40,000 units/week for at least 8 doses or darbepoetin alpha ≥ 500 mcg every 3 weeks for at least 4 doses or equivalent); OR Patient has a documented contraindication or intolerance to the use of an ESA** Note: No response defined as a lack of ≥1.5 gm/dL rise in hemoglobin OR lack of a decrease in RBC transfusion requirement within 6-8 weeks when treated with ESAs."* Renewal Criteria: Removed and reworded: "The need for regular RBC transfusions has been decreased as indicated by prescriber" Added: "Beta Thalassemia Patient is experiencing disease response as evidenced by a decrease in the number of RBC transfusions from baseline; OR For new starts: Patient has not achieved a reduction in RBC transfusion burden after at least 2 consecutive, initial (1 mg/kg) doses (6 weeks) and requires a dose increase to 1.25 mg/kg; OR Patient experienced a response followed by a lack/loss of response and requires a dose increase to 1.25 mg/kg (from 1 mg/kg) Anemia Due to Myelodysplastic Syndromes (MDS) Patient is experiencing disease response as evidenced by a decrease in the number of RBC transfusions from baseline; OR For new starts: Patient has not achieved a reduction in RBC transfusion burden after at least 2 consecutive, initial (1 mg/kg) doses (6 weeks) and requires a dose increase to 1.33mg/kg; OR Patient has not achieved a reduction in RBC transfusion burden after at least 2 consecutive, 1.33 mg/kg doses (6 weeks) and requires a dose increase to 1.75 mg/kg; OR Patient experienced a response followed by a lack/loss of response and requires a dose increase by one dose level from the level in which response was lost (not to exceed a dose of 1.75 mg/kg) Anemia Due to Myeloproliferative Neoplasms (MPN) – Myelofibrosis Patient is experiencing disease response from baseline (e.g. decrease in the number of RBC transfusions from baseline, ≥ 1.5 g/dL hemoglobin increase without RBC transfusions from baseline, reduction in

		anemia-related fatigue symptoms, etc.); OR <u>For new starts</u>: Patient has not achieved disease response after at least 2 consecutive, initial (1 mg/kg or 1.33 mg/kg) doses (6 weeks) and requires a dose increase by one dose level from the initial level (1.33 mg/kg or 1.75mg/kg); OR Patient experienced a response followed by a lack/loss of response and requires a dose increase by one dose level from the level in which response was lost (not to exceed a dose of 1.75 mg/kg). Updated dosing chart. Removed: C93.10, D46, D46.2, added: D56.5
EmblemHealth & ConnectiCare	1/11/2024	Annual Review: Initial Criteria: Anemia related to beta-thalassemia Further defined "Requires regular blood transfusions" as According to the prescriber, the patient requires regular red blood cell transfusions as defined by meeting both of the following (i and ii): Patient has received at least 6 units of packed red blood cells within the preceding 24 weeks; AND Patient has not had any transfusion-free period > 35 days within the preceding 24 weeks; AND Patient has not received Zynteglo (betibeglogene autotemcel intravenous infusion) in the past; AND The medication is being prescribed by or in consultation with a hematologist." Renamed "Anemia failing an erythropoiesis stimulating agent" indication to: "Myelodysplastic/Myeloproliferative Neoplasm. " and updated all criteria as follows: A. Patient is ≥ 18 years of age; AND B. According to the prescriber, the patient has myelodysplastic/myeloproliferative neoplasm and meets both of the following (i and ii): i. Ring sideroblast positivity; AND ii. Thrombocytosis defined as platelet count ≥ 450 x 10^9/L; AND C. Patient has very low- to intermediate-risk disease, as determined by the prescriber; AND D. Patient does not have a confirmed mutation with deletion 5q [del(5q)]; AND E. Patient currently requires blood transfusions, defined as at least two red blood cell units over the previous 8 weeks; AND F. Pretreatment hemoglobin level is < 10.0 g/dL; AND G. Reblozyl will not be used in combination with an erythropoiesis stimulating agent; AND H. The medication is being prescribed by or in consultation with an oncologist or hematologist. Myelodysplastic Syndromes Associated Anemia: Reworded and separated the following "Patient has anemia without previous erythropoiesis stimulating agent use (ESA-naïve) with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions." To: "According to the prescriber, the patient has myelodysplastic syndromes and meets one of the following (i or ii): Ring sideroblast positivity; OR Serum erythropoietin level is ≤ 500 mU/mL; AND Patient has very low- to intermediate-risk myelodysplastic syndromes, as determined by the prescriber; AND Patient does not have a confirmed mutation with deletion 5q [del(5q)]; AND Patient currently requires blood transfusions, defined as at least two red blood cell units over the previous 8 weeks; AND Pretreatment hemoglobin level is < 10.0 g/dL; AND Reblozyl will not be used in combination with an erythropoiesis stimulating agent; AND The medication is being prescribed by or in consultation with an oncologist or hematologist" Renewal Criteria: added: "Patient will not receive doses < 21 days apart; AND Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: thromboembolic events, severe hypertension, extramedullary hematopoietic masses in patients with beta thalassemia, etc."
EmblemHealth & ConnectiCare	9/20/2023	Updated length of authorization: from: "Coverage will be provided for 12 months and may be renewed." To "Beta Thalassemia: Coverage will be provided initially for 15 weeks (5 initial doses) and may be renewed annually thereafter. Myelodysplastic

		Syndrome: Coverage will be provided initially for 21 weeks (7 initial doses) and may be renewed every 6 months thereafter." Add indication and criteria: Myelodysplastic Syndromes Associated Anemia; Updating dosing chart name from "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)." to "Myelodysplastic Syndromes Associated Anemia"
EmblemHealth & ConnectiCare	1/11/2023	Transfer to New Template; Added codes C93.10, D46.0, D46.20, removed code D56.5
EmblemHealth & ConnectiCare	6/10/2020	Added J-Code (J0896): Injection, luspatercept-aamt, 0.25 mg (Reblozyl). J-Code effective date: 07/01/2020
EmblemHealth & ConnectiCare	04/13/2020	Added Max Billable Units: 1.75mg/kg every 3 weeks (Anemia failing an erythropoiesis stimulating agent) Updated dosing for Anemia failing an erythropoiesis stimulating agent) per FDA Label: Dose Increases for Insufficient Response at Initiation of Treatment & Dose Modifications for Predose Hemoglobin Levels or Rapid Hemoglobin Rise
EmblemHealth & ConnectiCare	04/10/2020	Updated indications per FDA Label to include: Added: Anemia failing an erythropoiesis stimulating agent Added the following Applicable Diagnosis Codes: 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
EmblemHealth & ConnectiCare	02/07/2020	New Medical Policy

References

1. Reblozyl [package insert]. Celgene Corporation Summit, NJ 07901 and Acceleron Pharma, Inc. Cambridge, MA 02139; 2019.
2. Luspatercept-aamt. IBM Micromedex® DRUGDEX®. IBM Watson Health, Greenwood Village, Colorado, USA January 2020.