JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP120
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	Subject **Reblozyl**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Reblozyl

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I. POLICY

A. Reblozyl (luspatercept-aamt) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Reblozyl may be approved for patients who meet the following:
   1. Anemia with Beta Thalassemia
      a. Patient is 18 years of age or older
      b. Documentation has been submitted showing the following
         I. Diagnosis of beta thalassemia (#-thalassemia) or hemoglobin E/#-thalassemia (#-thalassemia with mutation and/or multiplication of alpha globin is allowed) confirmed by one of the following:
            i. Hemoglobin electrophoresis or high-performance liquid chromatography (HPLC)
            ii. Molecular genetic testing
         II. Patient has symptomatic anemia evidenced by a pretreatment or pretransfusion Hgb level less than or equal to 11 grams per deciliter
         III. Patient required at least 6 red blood cell (RBC) units to be transfused in the previous 24 weeks
            i. *Note: If a red blood cell (RBC) transfusion occurred prior to dosing, the pretransfusion hemoglobin (Hgb) level must be considered for dosing purposes.
   2. Anemia of Myelodysplastic Syndrome or Myelodysplastic/Myeloproliferative Neoplasm
      a. Patient is 18 years of age or older
      b. Documentation has been submitted showing the following:
         I. Diagnosis of very low- to intermediate-risk myelodysplastic syndrome or myelodysplastic/ myeloproliferative neoplasm
         II. Patient has symptomatic anemia evidenced by a pretreatment or pretransfusion Hgb level less than or equal to 11 grams per deciliter
         III. Patient has been receiving regular red blood cell (RBC) transfusions as defined by greater than or equal to 2 units per 8 weeks
         IV. Patient meets either of the following:

i. Ring sideroblasts are greater than or equal to 15%
ii. Ring sideroblasts are greater than or equal to 5% and less than 15% and the patient has an SF3B1 mutation

V. Patient meets either of the following:
i. Pretreatment serum erythropoietin levels greater than 500 mU/mL
ii. Pretreatment serum erythropoietin levels less than or equal to 500mU/mL following no response to the combination of an erythropoiesis-stimulating agent (ESA) and granulocyte-colony stimulating factor (G-CSF)

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to the following:
1. Four months for treatment of anemia with beta thalassemia
2. Six months for the treatment of very low- to intermediate-risk myelodysplastic syndrome or myelodysplastic/ myeloproliferative neoplasm

B. Continuation of therapy may be approved in 6-month intervals with documentation showing the following:
1. Patient has achieved or maintained red blood cell transfusion burden reduction
2. Patient has not experienced an unacceptable toxicity from Reblozyl

IV. EXCLUSIONS

A. Reblozyl will not be covered for the following:
1. Patients with hemoglobin S/beta-thalassemia or alpha-thalassemia
2. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, luspatercept-aamt, 0.25 mg	J0896

VII. REFERENCES

1. Reblozyl [prescribing information]. Summit, NJ: Celgene Corporation, a Bristol-Myers Squibb Company; July 2022.
2. Capellini MD, Viprakasit V, Taher AT, et al. A Phase 3 Trial of Luspatercept in Patients with Transfusion-Dependent Beta-Thalassemia. N Engl J Med 2020;382:1219-31.Benz EJ.
3. Fenaux P., Platzbecker U, Mufti GJ, et.al. Luspatercept in Patients with Lower-Risk Myelodysplastic Syndromes. N Engl J Med 2020;382:140-51.

4. The NCCN Drugs & Biologics Compendium 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 9, 2024.

VIII. APPROVALS

Signature on file at JHHP

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