Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	July 10, 2020

REBLOZYL® (luspatercept-aamt)

LENGTH OF AUTHORIZATION: SIX MONTHS

CLINICAL NOTES: Reblozyl is a erythroid maturation agent indicated for the treatment of: Anemia in adult patients with beta thalassemia who 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).

REVIEW CRITERIA:

Beta Thalassemia

- Patient must be 18 years of age or older.
- Patient must have a diagnosis of anemia with beta thalassemia.
- Patient is RBC transfusion dependent defined as requiring RBC transfusions (6-20 RBC units per 24 weeks) with no transfusion-free period greater than 35 days.
- Assess and review hemoglobin and transfusion record prior to each administration of Reblozyl®.

MDS-RS or MDS/MPN-RS-T

- Patient must be 18 years of age or older
- Patient has a diagnosis of anemia with MDS-RS **OR** MDS/MPN-RS-T.
- Patient has documented lower risk disease as defined by one of the following
    - Revised International Prognostic Scoring System (IPSS-R): very low, low, intermediate (score 0 to ≤ 4.5)
    - IPPS; low to intermediate-1 (score 0-1)
    - WHO-Based Prognostic Scoring System (WPSS); very low, low, intermediate (score 0-2)
- Patient has tried and failed a erythropoiesis stimulating agent (e.g. Aranesp, Epogen), intolerant or have a serum erythropoietin of > 200U/L.
- Hemoglobin <10g/dL
- Patient requires at least 2 units of RBC over 8 weeks.

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CONTINUATION OF THERAPY:

- Patient met initial review requirements
- Patient has a reduction of at least 2 units from weeks 13-24 for beta thalassemia patients.
- Absence of any RBC transfusion during any consecutive 8 week period occurring within weeks 1-24 for MDS-RS or MDS/MPN-RS-T.
- Reduction in transfusion burden form baseline.
- Dosage and administration does not exceed FDA approved maximum for the patient's indication.

DOSING AND ADMINISTRATION:

Beta Thalasssemia

- 1mg/kg subcutaneously every 3 weeks. The dose is titrated based on the patient's response. If a patient does not experience a decrease in transfusion burden after nine weeks of treatment (3 doses) at the maximum dose level or experience unacceptable toxicity discontinue therapy.

MDS-RS or MDS/MPN-RS-T

- 1mg/kg subcutaneously every 3 weeks. The dose is titrated based on the patient's response. If a patient does not experience a decrease in transfusion burden after 9 weeks of treatment (3 doses) at the maximum dose level of if unacceptable toxicity occurs at any time discontinue therapy.