# SmartPA Criteria Proposal

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|---|---|
| **Drug/Drug Class:** | Reblozyl Clinical Edit |
| **First Implementation Date:** | November 19, 2020 |
| **Proposed Date:** | July 18, 2023 |
| **Prepared for:** | MO HealthNet |
| **Prepared by:** | MO HealthNet/Conduent |
| **Criteria Status:** | ☒Existing Criteria<br>☐Revision of Existing Criteria<br>☐New Criteria |

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of Reblozyl® (luspatercept-aamt)

**Why Issue Selected:** Reblozyl® (luspatercept-aamt) is the first and only FDA-approved erythroid maturation agent, representing a new class of therapy which works by regulating late-stage red blood cell maturation to help patients reduce their RBC transfusion burden. Reblozyl was FDA approved in November 2019, for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions. Beta thalassemia is a rare, inherited blood disorder caused by a genetic defect in hemoglobin with an estimated incidence of symptomatic disease of 1 in 100,000 people. Beta thalassemia is associated with ineffective erythropoiesis, which results in the production of fewer and less healthy RBCs, often leading to severe anemia as well as other serious health issues. On April 3, 2020, Reblozyl received FDA approval for the treatment of anemia failing an erythropoiesis stimulating agent (ESA) and requiring 2 or more RBC units over 8 weeks in adults with very low to intermediate risk myelodysplastic syndrome with ring sideroblasts (MDS-RS) or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T). Myelodysplastic syndromes (MDS) are a rare group of blood disorders in which dysfunctional blood cells fail to develop normally within the bone marrow and are released into the bloodstream. The most common symptom in MDS is anemia due to low levels of circulating red blood cells. The prevalence of MDS is unknown but is estimated at 10,000 to 20,000 people diagnosed each year in the United States. In MDS-RS at least 15% of the early red blood cells must be ring sideroblasts (or at least 5% if the cells also have a pathogenic variant in the *SF3B1* gene). MDS/MPN-RS-T is characterized by anemia, bone marrow dysplasia with ring sideroblasts and persistent thrombocytosis; it is a rare disorder, accounting for < 1% of all cases of MDS. Due to the possible adverse events and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Reblozyl.

**Program-Specific Information:**

| Date Range FFS 4-1-2022 to 3-31-2023 | | | |
|---|---|---|---|
| **Drug** | **Claims** | **Spend** | **Avg Spend per Claim** |
| REBLOZYL 25MG VIAL | 0 | - | - |
| REBLOZYL 75MG VIAL | 19 | $157,928.36 | $8,312.02 |

**Type of Criteria:**

☒ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

**Data Sources:** ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

## Setting & Population

- Drug class for review: Reblozyl® (luspatercept-aamt)
- Age range: All appropriate MO HealthNet participants aged 18 years or older

## Approval Criteria

Initial Therapy:

- Participant aged ≥ 18 years or older **AND**
- Prescribed by or in consultation with an appropriate specialist for the disease state **AND**
- Participant is not currently pregnant **AND**
- Participant (of appropriate age) is utilizing concurrent birth control methods **AND**
- For Beta Thalassemia:
  - Documented diagnosis of Beta Thalassemia or Hemoglobin E-beta thalassemia **AND**
  - Documentation of regular RBC transfusions (defined as 6-20 RBC units per 24 weeks with no transfusion-free period greater than 35 days during that period)
- For MDS-RS or MDS/MPN-RS-T:
  - Documented diagnosis of MDS-RS or MDS/MPN-RS-T **AND**
  - For MDS-RS: Documented very low to intermediate risk Revised International Prognostic Scoring System (IPSS-R) score (≤ 4.5) **AND**
  - Documented ESA therapy for at least 6 to 8 weeks in the past year with an inadequate response or contraindication/ADE/ADR to ESA therapy **AND**
  - Documentation of at least 2 or more RBC transfusions in the past 8 weeks

Continuation of Therapy:

- Initial approval of prior authorization is 3 months
- Renewal of prior authorization may be up to 12 months following documentation of decrease in RBC transfusion burden

## Denial Criteria

- Therapy will be denied if all approval criteria are not met.
- For Beta Thalassemia:
  - Documented diagnosis of deep vein thrombosis in the past 6 months
  - Documented diagnosis of a stroke in the past 6 months
  - Claim for an erythropoietin stimulating agent (ESA) in the past 6 months
- For MDS-RS or MDS/MPN-RS-T: none

## Required Documentation

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| Laboratory Results: | X | Progress Notes: | X |
| MedWatch Form: | | Other: | X |

## Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

## Default Approval Period

3 months

## References


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- IPD Analytics. New Drug Review: Reblozyl (luspatercept-aamt). November 2020.
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- American Cancer Society. About Myelodyspastic Syndromes. https://www.cancer.org/content/dam/CRC/PDF/Public/8743.00.pdf. Accessed May 16, 2022.
- National Organization of Rare Disorders. Myelodysplastic Syndromes. https://rarediseases.org/rare-diseases/myelodysplastic-syndromes/. Accessed May 16, 2022.
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- National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines). Myelodysplastic Syndromes. Version 3.2022 – January 13, 2022. https://www.nccn.org/