# SmartPA Criteria Proposal

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|---|---|
| **Drug/Drug Class:** | Reblozyl® (luspatercept-aamt) Clinical Edit |
| **First Implementation Date:** | TBD |
| **Proposed Date:** | March 19, 2020 |
| **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) 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. Reblozyl 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.

**Program-Specific Information:**

| Date Range FFS 1-1-2019 to 12-31-2019 | | | |
|---|---|---|---|
| **Drug** | **Claims** | **Cost per vial** | **Cost per treatment/year (based on a 75kg participant)** |
| Reblozyl 25mg vial | 0 | $3,406.76 MAC | $10,220.29 per treatment |
| Reblozyl 75mg vial | 0 | $10,220.29 MAC | $177,151.69 per year |

**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

- Participant aged ≥ 18 years or older **AND**

- Documented diagnosis of Beta Thalassemia or Hemoglobin E-beta thalassemia in the past 2 years **AND**
- Prescribed by or in consultation with an appropriate specialist for the disease state **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) **AND**
- Participant is not currently pregnant
- Renewal Criteria:
  - 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 no approval criteria are met
- 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

## 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

6 months

## References


- Reblozyl [package insert]. Summit, NJ: Celgene Corporation; 2019.
- Reblozyl [Prescribing Information]. Summit, NJ: Celgene Corporation; 2019.
- IPD Analytics. Reblozyl New Drug Review. Accessed November 26, 2019.