Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 210.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Reblozyl (luspatercept-aamt)

I. Policy:
Reblozyl (luspatercept-aamt)

II. Purpose/Objective:
To provide a policy of coverage regarding Reblozyl (luspatercept-aamt)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same ag

DESCRIPTION:
Reblozyl (luspatercept-aamt) is a recombinant fusion protein that contains a modified form of the extracellular domain of human activin receptor type IIb and links to the human IgG1 Fc domain. It binds several endogenous transforming growth factor-beta (TGF-β) superfamily ligands, which results in reduced Smad2/3 signaling. Inhibition of TGF-β superfamily results in increased differentiation and proliferation of erythroid precursors and improves hematology parameters associated with ineffective erythropoiesis

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Reblozyl (luspatercept-aamt) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

1. Anemia due to Beta thalassemia
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of beta thalassemia **AND**
- Medical record documentation that patient requires regular* red blood cell (RBC) transfusions **AND**
- Medical record documentation of baseline number of transfusions and red blood cell (RBC) units required for the previous six (6) months **AND**
- Medical record recommendation that Reblozyl is being dosed consistent with FDA-approved labeling**.

2. Anemia due to myelodysplastic syndromes or myelodysplastic/myeloproliferative neoplasm
For erythropoiesis stimulating agent (ESA)-refractory disease:
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) with one of the following:
    - Documentation of greater than or equal to 15% ring sideroblasts **OR**
    - Documentation of greater than or equal to 5% ring sideroblasts AND an SF3B1 mutation

  AND
- Medical record documentation of very low to intermediate risk disease per the Revised International Prognostic Scoring System (IPSS-R) **AND**
- Medical record documentation that patient requires 2 or more red blood cell units over 8 weeks **AND**
- Medical record documentation of baseline number of transfusions and red blood cell (RBC) units required for the previous six (6) months **AND**
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to an erythropoiesis stimulating agent **AND**
- Medical record recommendation that Reblozyl is being dosed consistent with FDA-approved labeling**.

For erythropoiesis stimulating agent (ESA)-naïve disease:
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of myelodysplastic syndromes with or without ring sideroblasts **AND**
- Medical record documentation of very low to intermediate risk disease per the Revised International Prognostic Scoring System (IPSS-R) **AND**
- Medical record documentation that patient requires an average of at least 2 red blood cell units per 8 weeks **AND**
- Medical record documentation of baseline number of transfusions and red blood cell (RBC) units required for the previous six (6) months **AND**
- Medical record recommendation that Reblozyl is being dosed consistent with FDA-approved labeling**.

AUTHORIZATION DURATION: Approval will be given for an **initial duration of six (6) months** or less if the reviewing provider feels it is medically appropriate. After the initial six (6) month approval, subsequent approvals will be for a **duration of six (6) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:
- a decrease in red blood cell (RBC) transfusion burden from baseline **AND**
- Reblozyl being dosed consistent with the FDA-approved labeling**

Ongoing subsequent approvals will be for a **duration of six (6) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:
- a sustained reduction of red blood cell (RBC) transfusion burden from baseline **AND**

- Reblozyl being dosed consistent with the FDA-approved labeling**

LIMITATIONS: Reblozyl will no longer be covered if the patient does not experience a decrease in transfusion burden after nine (9) weeks of treatment (administration of three (3) doses) at the maximum dose level or if unacceptable toxicity occurs at any time.

NOTES:
*In clinical trials For Beta Thalassemia, “regular red blood cell transfusions” was considered to be 6 to 20 red blood cell units per 24 weeks with no transfusion-free period greater than 35 days.

**Per current labeling: For Beta Thalassemia: 1mg/kg every 3 weeks increasing to a maximum of 1.25mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen. Dose should not exceed 1.25mg/kg every 3 weeks
For MDS-associated anemia: 1mg/kg every 3 weeks increasing to a dose of 1.33 mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen, then increasing up to a maximum of 1.75mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen. Dose should not exceed 1.75mg/kg every 3 weeks

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 4/15/20

Revised: 9/15/20 (MDS), 9/15/22 (Medicaid PARP statement), 9/14/23 (LOB carve out, Medicaid business segment)

Reviewed: 9/15/21