Pharmacy Medical Necessity Guidelines: Reblozyl® (luspatercept-aamt)

Effective: July 20, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	PRECERT /MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

All plans except Tufts Health Public Plans
PRECERT: 617.972.9409

Tufts Health Public Plans
MM: 888.415.9055

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Reblozyl (luspatercept-aamt) is an erythroid maturation agent indicated for the treatment of

- **Beta Thalassemia**
  Anemia in adult patients with beta thalassemia who require regular blood cell transfusions
- **Myelodysplastic Syndromes with Ring Sideroblasts or Myelodysplastic/Myeloproliferative Neoplasm with Ring Sideroblasts and Thrombocytosis Associated Anemia**
  Anemia failing an erythropoiesis stimulating agent and requiring two or more red blood cell units over eight 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).

Reblozyl (luspatercept-aamt) is not indicated for use as a substitute for red blood cell transfusions in patients who require immediate correction of anemia.

Reblozyl (luspatercept-aamt) should be reconstituted and administered by a healthcare professional.

COVERAGE GUIDELINES

The plan may authorize the coverage of Reblozyl (luspatercept-aamt) for Members, when all of the following criteria are met:

Beta Thalassemia

Initial Criteria

1. Documented diagnosis of beta thalassemia

AND

2. Prescribed by or in consultation with a hematologist

AND

3. Documentation the Member requires regular red blood cell transfusions as defined by a minimum of 6 red blood cell units in a 24-week period and no transfusion-free period greater than 35 days during that period

Reauthorization Criteria

1. Documented diagnosis of beta thalassemia

AND

2. Prescribed by or in consultation with a hematologist

AND

3. Documentation of a reduction in transfusion requirements from pretreatment baseline of at least 2 units packed red blood cells

Myelodysplastic Syndromes

Initial Therapy

1. Documented diagnosis of very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis

AND

2. Documentation of anemia requiring 2 or more red blood cell units over 8 weeks

AND

3. Documentation of one of the following:
    a. Inadequate response to an erythropoiesis stimulating agent
    a. Clinical inappropriateness with an erythropoiesis stimulating agent

AND

4. Member is at least 18 years of age

AND

5. Prescribed by or in consultation with a hematologist or oncologist

Reauthorization Criteria

1. Documented diagnosis of very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis

AND

2. Members is at least 18 years of age

AND

3. Prescribed by or in consultation with a hematologist or oncologist

AND

4. Documentation the Member has experienced a therapeutic response as defined by the provider indicating a decrease in the need for red blood cell transfusions

LIMITATIONS

- For beta thalassemia, initial approval of Reblozyl (luspatercept-aamt) will be authorized for 6 months. Subsequent authorization requests may be given in 12-month intervals when Reauthorization criteria above have been met.
- For myelodysplastic syndromes, initial approval of Reblozyl (luspatercept-aamt) will be authorized for 6 months. Subsequent authorization requests may be given in 12-month intervals when Reauthorization criteria above have been met.
- Members new to the plan stable on Reblozyl (luspatercept-aamt) should be reviewed against Reauthorization Criteria.

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J0896	Injection, luspatercept-aamt, 0.25 mg

REFERENCES

1. Angelucci E. A new medical therapy for anemia in thalassemia. Blood. 2019;133(12):1267.
2. Cappellini MD, Cohen A, Porter J, et al. Guidelines for the management of transfusion dependent thalassaemia, 3rd edition. 2014 [Accessed January 2020]. Available on the Internet. URL: https://thalassaemia.org.cy/publications/tif-publications/guidelines-for-the-management-of-transfusion-dependent-thalassaemia-3rd-edition-2014/.
3. Estey EH. Prognosis of the myelodysplastic syndromes in adults. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on April 28, 2020).
4. Estey EH. Treatment of lower-risk myelodysplastic syndromes (MDS). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on July 2, 2020).
5. Fenaux P, Platzbecker U, Mufti GJ, et al. Luspatercept in patients with lower-risk myelodysplastic syndromes. N Engl J Med. 2020;382:140-51.
6. Reblozyl (luspatercept-aamt) [prescribing information]. South San Francisco, CA: Genentech, Inc.; April 2020.

APPROVAL HISTORY

February 11, 2020: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 12, 2020: Added coverage criteria for the supplemental indication of myelodysplastic syndromes. Updated duration of approval rules for beta thalassemia in the Limitations to: "For beta thalassemia, initial approval of Reblozyl (luspatercept-aamt) will be authorized for 6 months. Subsequent authorization requests may be given in 12-month intervals when Reauthorization criteria above have been met."
2. July 14, 2020: Added the HCPCS code J0896 to the Medical Necessity Guideline. Added coverage criteria for the supplemental indication of treatment of myelodysplastic syndromes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.