CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Reblozyl (luspatercept-aamt)
BILLING CODE	J0896 (1 unit = 0.25 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-preferred product) QUANTITY LIMIT – see Dosage Allowed
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Reblozyl (luspatercept-aamt) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

BETA THALASSEMIA

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a hematologist or oncologist; AND
3. Member has a confirmed diagnosis of beta thalassemia or Hemoglobin E/Beta-thalassemia; AND
4. Member requires regular red blood cell (RBC) transfusions, defined by **BOTH** of the following:
    a. Received a total of at least 6 units of RBC in the last 6 months ;
    b. No transfusion-free period for ≥ 35 days during the last 6 months; AND
5. Member does **NOT** have any of the following:
    a. Active Hepatitis B or C infection or positive human immunodeficiency virus (HIV);
    b. Major organ damage, including:
        i. Liver disease with ALT > 3x the upper limit of normal or evidence of cirrhosis;
        ii. Heart disease, heart failure as classified by the New York Heart Association (NYHA) classification 3 or higher, significant arrhythmia, or recent myocardial infarction within the last 6 months;
        iii. Lung disease, including significant pulmonary fibrosis or pulmonary hypertension;
        iv. Kidney disease.
6. **Dosage allowed**: 1mg/kg once every 3 weeks by subcutaneous injection. Dose can be increased to 1.25mg/kg if lack of response.

If member meets all the requirements listed above, the medication will be approved for 3 months (or up to 5 doses).

For **reauthorization**:

1. Member is in compliance with all other initial criteria; AND
2. Member has a reduction in RBC transfusion requirements of at least 2 units from baseline (prior to starting treatment); AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource

MYELODYSPLASTIC SYNDROMES WITH RING SIDEROBLASTS

Any request for myelodysplastic syndromes must be submitted through NantHealth/Eviti portal.

CareSource considers Reblozyl (luspatercept-aamt) not medically necessary for the treatment of the following disease states based on lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Acute severe anemia (in the setting that requires RBC transfusion)
- Alpha thalassemia
- Anemia not due to beta thalassemia
- Non-transfusion dependent beta thalassemia (intermediate beta thalassemia)
- Sickle beta thalassemia

DATE	ACTION/DESCRIPTION
05/04/2020	New policy for Reblozyl created.

References:

1. Reblozyl [Package Insert]. Summit, NJ: Celgene Corporation; November 2019.
2. Celgene. An Efficacy and Safety Study of Luspatercept (ACE-536) Versus Placebo in Adults Who Require Regular Red Blood Cell Transfusions Due to Beta Thalassemia (BELIEVE). NLM Identifier: NCT02604433.
3. Piga A, Perrotta S, Gamberini MR, et al. Luspatercept improves hemoglobin levels and blood transfusion requirements in a study of patients with beta thalassemia. Blood. 2019;133(12):1279-1289.
4. Muncie LH. Beta Thalassemia. *National Organization for Rare Disorders (NORD)*.

Effective date: 07/20/2020
Revised date: 05/04/2020