WELL SENSE HEALTH PLAN

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Pharmacy Policy

Reblozyl

Policy Number: 9.613
Revision Number: R0
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☒ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☐ MassHealth - MCO ☐ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Reblozyl (luspatercept-aamt)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Required Medical Information	Documentation of all the following: 1. Diagnosis of beta thalassemia; ***AND*** a. The member requires regular blood cell transfusions defined as a minimum of 6 red blood cell units in the most recent 24 weeks; ***AND*** *b.* The member has not had a transfusion-free period for ≥ 35 days during the

	most recent 24 weeks; ***OR*** 2. Diagnosis of anemia with Myelodysplastic Syndromes with Ring Sideroblasts or Myelodysplastic/Myeloproliferative Neoplasm with Ring Sideroblasts and thrombocytosis; ***AND*** a. Member has tried and failed or had an inadequate response or contraindication to an erythropoiesis stimulating agent (ESA); ***AND*** b. The member requires 2 or more RBC units over an 8 week period
Age Restriction	18 years of age and older
Prescriber Restriction	Prescribed by or in consultation with a hematologist.
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Other criteria	Reauthorization: 1. Documentation of a positive clinical response to therapy demonstrated by a reduction in transfusion requirements from pretreatment baseline of at least 2 units packed red blood cells while receiving Reblozyl.

Applicable Coding:

Code	Medication
J0896	**luspatercept-aamt (Reblozyl)**

Clinical Background Information and References

1. Cappellini MD, Cohen A, Porter J, et al. Guidelines for the management of transfusion dependent thalassaemia, 3rd edition. 2014 [Accessed January 2020].
2. Reblozyl (luspatercept-aamt) [prescribing information]. South San Francisco, CA: Genentech, Inc.; June 2019.
3. Uptodate.com/contents/management-and-prognosis-of-the-thalassemias

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.201 Reblozyl Policy retired, new policy created.	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.