blue california
Promise Health Plan

luspatercept-aamt (Reblozyl)

Medical Benefit Drug Policy

Place of Service
Hospital Administration
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

For oncology-related indications, coverage will be made based on medical necessity. Medical necessity determinations are made based on U.S. Food and Drug Administration (FDA) labeling, peer-reviewed medical literature, Medi-Cal coverage guidelines, and Centers for Medicare & Medicaid Services (CMS) approved compendia support (i.e., Clinical Pharmacology, National Comprehensive Cancer Network® (NCCN), American Hospital Formulary Service Drug Information, Thomson Micromedex DrugDex,® and Lexicomp®).

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Erythroid maturation agent
HCPCS:
J0896:Injection, luspatercept-aamt, 0.25 mg
How Supplied:
25 mg or 75 mg lyophilized powder in a single-dose vial for reconstitution

Condition(s) listed in policy *(see coverage criteria for details)*

- Transfusion-Dependent Beta Thalassemia

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Transfusion-Dependent Beta Thalassemia

Meets medical necessity if all the following are met:

1. Age 18 years or older
2. Patient is transfusion-dependent
3. Either of the following:
   a. Patient has not received prior therapy with Zynteglo
   b. Patient had inadequate response with Zynteglo

Covered Doses:

Up to 1.25 mg/kg given subcutaneously every 3 weeks

Coverage Period:

Initial: 6 months

Reauthorization: 6 months if meets below criteria

1. Physician attestation that patient has experienced a reduction in transfusion burden [at least 2 red blood cell (RBC) units in the past 24 weeks]
2. Either of the following:
   a. Patient has not received prior therapy with Zynteglo
   b. Patient had inadequate response with Zynteglo

ICD-10:

D56.1, D56.5

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Reblozyl (luspatercept-aamt) Prescribing Information. Celgene Corporation, Summit, NJ: 5/2024.

Review History

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- For oncology-related indications, coverage will be made based on medical necessity

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee