luspatercept-aamt (Reblozyl)

Commercial 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, medical necessity criteria can be found here: Blue Shield Oncology-Related Medication Policies.

For PPO, Direct Contract HMO, and when applicable, ASO, and Shared Advantage: Please access Evolent's CarePro Provider Portal to submit your request.

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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

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:

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