

# SENTARA HEALTH PLANS

## MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST\*

**Directions:** The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed.**

**For Medicare Members:** Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>. Additional indications may be covered at the discretion of the health plan.

**Drug Requested:** **Reblozyl<sup>®</sup>** (luspatercept-aamt) **(J0896) (Medical)**  
(NDC: 59572-0711-01 and 59572-0775-01)  
Applicable ICD-10 diagnosis Codes: D56.1, D56.5

**MEMBER & PRESCRIBER INFORMATION:** Authorization may be delayed if incomplete.

Member Name: \_\_\_\_\_

Member Sentara #: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

Prescriber Name: \_\_\_\_\_

Prescriber Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Office Contact Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

DEA OR NPI #: \_\_\_\_\_

**DRUG INFORMATION:** Authorization may be delayed if incomplete.

Drug Name/Form/Strength: \_\_\_\_\_

Dosing Schedule: \_\_\_\_\_ Length of Therapy: \_\_\_\_\_

Diagnosis: \_\_\_\_\_ ICD Code, if applicable: \_\_\_\_\_

Weight (if applicable): \_\_\_\_\_ Date weight obtained: \_\_\_\_\_

Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

### **Recommended Dosage:**

#### **Luspatercept-aamt Recommended Dosing Titration for Response**

<b>Starting Dose</b>	• 1 mg/kg every 3 weeks
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**Recommended Dosage:**

<b>Dose Increases for Insufficient Response at Initiation of Treatment</b>	
No reduction in RBC transfusion burden after at least 2 consecutive doses (6 weeks) at the 1 mg/kg starting dose	<ul style="list-style-type: none"> <li>• Increase the dose to 1.25 mg/kg every 3 weeks</li> </ul>
No reduction in RBC transfusion burden after 3 consecutive doses (9 weeks) at 1.25 mg/kg	<ul style="list-style-type: none"> <li>• Discontinue treatment</li> </ul>
<b>Dose Modifications for Predose Hemoglobin Levels or Rapid Hemoglobin Rise</b>	
Predose hemoglobin is greater than or equal to 11.5 g/dL in the absence of transfusions	<ul style="list-style-type: none"> <li>• Interrupt treatment</li> <li>• Restart when the hemoglobin is no more than 11 g/dL</li> </ul>
Increase in hemoglobin greater than 2 g/dL within 3 weeks in the absence of transfusions and <ul style="list-style-type: none"> <li>• Current dose is 1.25 mg/kg</li> <li>• Current dose is 1 mg/kg</li> <li>• Current dose is 0.8 mg/kg</li> <li>• Current dose is 0.6 mg/kg</li> </ul>	<ul style="list-style-type: none"> <li>• Reduce dose to 1 mg/kg</li> <li>• Reduce dose to 0.8 mg/kg</li> <li>• Reduce dose to 0.6 mg/kg</li> <li>• Discontinue treatment</li> </ul>

**CLINICAL CRITERIA:** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

**Initial Authorization: 4 months**

- Provider is a hematologist, has been in consultation with one, or a specialist in treating patients with beta-thalassemia ( $\beta$ -thalassemia)
- Member is 18 years of age or older
- For female patients, a negative pregnancy test has been confirmed prior to start of therapy and an effective method of contraception will continue during treatment and for  $\geq 3$  months after the last luspatercept dose
- Member has a documented diagnosis of  $\beta$ -thalassemia including  $\beta^+$ ,  $\beta^0$ , hemoglobin E/  $\beta$ -thalassemia, or non-deletional Hb H (**please submit medical history and chart notes containing hematological findings, electrophoresis analysis, and/or molecular analysis where available**) **NOTE: This criteria excludes other types of alpha thalassemia and hemoglobin S/ $\beta$ -thalassemia variants**
- Member is dependent on red blood cell transfusions with **BOTH** of the following met:
  - For the past 6 months, member has regularly received transfusions of 6 to 20 units of packed red cells (**send most recent chart notes/procedural notes/therapy orders detailing current and past transfusion requirements**)

**Please Provide Pretreatment Transfusion Requirements: \_\_\_\_\_ units**

- Member has never been transfusion-free for any period greater than 35 days, in the past 6 months

