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® (luspatercept-aamt) **(Medical) (J0896)**
(NDC: 59572-0711-01 and 59572-0775-01)
Applicable ICD-10 diagnosis Codes: D56.1, D56.5

For oncology-related diagnoses, the most efficient way to submit a prior authorization request is through the Carelon Provider Portal at www.providerportal.com

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: _____ **Date:** _____

❑ 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	
Starting Dose	• 1 mg/kg every 3 weeks

(Continued on next page)

Recommended Dosage:

Dose Increases for Insufficient Response at Initiation of Treatment	
No reduction in RBC transfusion burden after at least 2 consecutive doses (6 weeks) at the 1 mg/kg starting dose	• Increase the dose to 1.25 mg/kg every 3 weeks
No reduction in RBC transfusion burden after 3 consecutive doses (9 weeks) at 1.25 mg/kg	• Discontinue treatment
Dose Modifications for Predose Hemoglobin Levels or Rapid Hemoglobin Rise	
Predose hemoglobin is greater than or equal to 11.5 g/dL in the absence of transfusions	• Interrupt treatment • Restart when the hemoglobin is no more than 11 g/dL
Increase in hemoglobin greater than 2 g/dL within 3 weeks in the absence of transfusions and • Current dose is 1.25 mg/kg • Current dose is 1 mg/kg • Current dose is 0.8 mg/kg • Current dose is 0.6 mg/kg	• Reduce dose to 1 mg/kg • Reduce dose to 0.8 mg/kg • Reduce dose to 0.6 mg/kg • Discontinue treatment

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 (β-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 ≥3 months after the last luspatercept dose
- ❑ Member has a documented diagnosis of β-thalassemia including β+, β0, hemoglobin E/ β-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/β-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

(Continued on next page)

- ❑ Member has a baseline hemoglobin (Hb) < 11.5 g/dL **(please provide medical laboratory documentation of hemoglobin level prior to starting therapy) NOTE: If Hb is 11.5 g/dL or higher, the dose must be delayed until the Hb is 11 g/dL or less**

Reauthorization: 12 months. 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.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has experienced an absence of any unacceptable toxicity from drug therapy such as severe/uncontrolled hypertension or thromboembolic events
- ❑ There has been a reduction in member's transfusion requirements from pretreatment baseline of at least 2 units while on the maximum titrated dose **(send most recent chart notes/procedural notes/therapy orders detailing current and past transfusion requirements)**:

  Please Provide Current Transfusion Requirements: _____ units

  NOTE: If there is no reduction in RBC transfusion burden after 3 consecutive doses (9 weeks) at 1.25 mg/kg, therapy is to be discontinued and this request will be denied
- ❑ Please provide current hemoglobin level: _____

  NOTE: If there is an increase in hemoglobin greater than 2 g/dL within 3 weeks in the absence of transfusions, follow dosing chart above. If Hb is 11.5 g/dL or higher, the dose must be delayed until the Hb is 11 g/dL or less

Medication being provided by (check applicable box(es) below):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****