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: Alhemo® (concizumab-mtci) (J3590) (Medical)

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:** _____

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 Dosing:

- SUBQ: 1 mg/kg once on day 1 (loading dose) then 0.2 mg/kg once daily starting on day 2; continue for 4 to 8 weeks, then maintenance dosage is based on plasma concentrations

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- Hemophilia A & B – concizumab initial dosage adjustments based on trough plasma concentration (4 to 8 weeks after initiation)

Concizumab plasma concentration	Dosage adjustment (SUBQ)
<200 ng/mL	Increase dose to 0.25 mg/kg once daily
200 to 4,000 ng/mL	Continue 0.2 mg/kg once daily
>4,000 ng/mL	Decrease dose to 0.15 mg/kg once daily

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: 12 months

- ❑ Member is ≥ 12 years of age
- ❑ Member's weight is ≥ 25 kg
- ❑ Medication prescribed by a specialist familiar with treating patients with hemophilia (factor VIII or IX deficiency)
- ❑ Female patients of reproductive potential are **NOT** pregnant prior to initiating therapy with concizumab
- ❑ Requested medication concizumab will **NOT** be used in combination with hemophilia bypassing agent prophylaxis (i.e., factor VIIa or anti-inhibitor coagulant complex), immune tolerance induction with clotting factor products (i.e., factor VIII or factor IX concentrates) as prophylactic therapy, Hemlibra® (emicizumab-kxwh) in those with hemophilia A as prophylactic therapy, and Hympavzi® (marstacimab-hncq) or Qfitlia® (fitusiran) in those with hemophilia A or hemophilia B as prophylactic therapy
- ❑ Concizumab will **NOT** be used for the treatment of breakthrough bleeds (**NOTE**: bypassing agents may be administered on an as needed basis for the treatment of breakthrough bleeds in patients being treated with concizumab)
- ❑ Member does **NOT** have a history of, or is on current treatment for inherited or acquired coagulation disorder other than congenital hemophilia
- ❑ Member meets **ONE** of the following diagnosis conditions:
  - ❑ Member has a diagnosis of **Hemophilia A** (congenital factor VIII deficiency) and meets **ALL** the following:
    - ❑ Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing
    - ❑ Member has been tested and found presence of inhibitors to Factor VIII with a current or historical titer of ≥ 0.6 Bethesda Units (BU)
    - ❑ Member has **NOT** received prior gene therapy for hemophilia A (e.g., Roctavian® (valoctocogene roxaparvovec-rvox))

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- ❑ Member meets **ONE** of the following:
  - ❑ Member has a history of life-threatening hemorrhage requiring on-demand use of factor replacement therapy
  - ❑ Member has a history of repeated, serious spontaneous bleeding episodes requiring on-demand use of Factor VIII therapy was required for these serious spontaneous bleeding episodes
- ❑ Member has a diagnosis of **Hemophilia B** (congenital factor IX deficiency) and meets **ALL** the following:
  - ❑ Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing
  - ❑ Member has been tested and found presence of inhibitors to Factor IX with a current or historical titer of ≥ 0.6 Bethesda Units (BU)
  - ❑ Member has **NOT** received prior gene therapy for hemophilia B (e.g., Hemgenix® (etranacogene dezaparvovec-drlb), Beqvez™ (fidanacogene elaparvovec-dzkt))
  - ❑ Member meets **ONE** of the following:
    - ❑ Member has a history of life-threatening hemorrhage requiring on-demand use of replacement therapy
    - ❑ Member has a history of repeated, serious spontaneous bleeding episodes requiring on-demand use of Factor IX therapy was required for these serious spontaneous bleeding episode

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 the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, dosing recommendations, etc. identified in the initial criteria section
- ❑ Member has **NOT** experienced any unacceptable toxicity from the drug (e.g., thromboembolic events, hypersensitivity)
- ❑ Member has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline, in severity of bleeding episodes, and/or in the number of spontaneous bleeding events) [**NOTE:** providers must submit well-documented, quantitative assessment of bleeding events since initiating concizumab therapy]
- ❑ Member's concizumab plasma concentration are being monitored and laboratory documentation submitted with request will adhere to the following dose adjustments:
  - ❑ Less than 200 ng/mL: adjust to a once-daily dose of 0.25 mg/kg
  - ❑ 200 to 4,000 ng/mL: continue once-daily dose of 0.2 mg/kg
  - ❑ Greater than 4,000 ng/mL: adjust to once-daily dose of 0.15 mg/kg

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

- ❑ **Physician's office** **OR** ❑ **Specialty Pharmacy**

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.****

***Approved by Pharmacy and Therapeutics Committee: 3/27/2025**
REVISED/UPDATED/REFORMATTED: ~~4/16/2025,~~ **6/9/2025**