SENTARA HEALTH PLANS

PHARMACY 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 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Alhemo® (concizumab-mtci)

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:** _____

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
- 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

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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))
    - ❑ 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

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- ❑ 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

Medication being provided by Specialty Pharmacy – Proprium Rx

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.*