AvMed

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 1-877-535-1391**. 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: Hemlibra® (emicizumab-kxwh) **(J7170) MEDICAL**

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

Member Name: _____

Member AvMed #: _____ **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.

Quantity Limits:

A. Dosing Limit (max daily or weekly dose)
- Loading Dose Phase: 3mg/kg weekly for 4 doses
- Maintenance Dose Phase: 6mg/kg cumulative, maximum dose in a 4-week period

B. Max Units (per dose and over time) [HCPCS Unit]:
- Loading Dose: 480 billable units every 7 days x 4 doses
- Maintenance Dose: 960 billable units every 28 days

NOTE: Patient must be dosed at a frequency that will produce the least wastage per dose based on available vial sizes of 12 mg/0.4 mL, 30 mg/1 mL, 60 mg/0.4 mL, 105 mg/0.7 mL, 150 mg/1 mL, and 300 mg/2 mL

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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 has a diagnosis of hemophilia A (congenital factor VIII deficiency) which has been confirmed by blood coagulation testing **(laboratory documentation required)**
- ❑ Requesting prescriber is a hematologist, in consultation with one, or a specialist familiar in treating patients with hemophilia A (congenital factor VIII deficiency)
- ❑ Member will **NOT** use Hemlibra in combination with another agent used as prophylactic therapy for Hemophilia A [i.e., factor VIIa or anti-inhibitor coagulant complex, Immune Tolerance Induction (ITI) with clotting factor products (i.e., factor VIII or factor IX concentrates), Hympavzi® (marstacimab-hncq), Alhemo® (concizumab-mtci), or Qfitlia® (fitusiran)] **NOTE: the prophylactic use of factor VIII (FVIII) products may be continued during the first week of emicizumab prophylaxis**
- ❑ Member has **NOT** received prior gene therapy for hemophilia A (e.g., Roctavian® (valoctocogene roxaparvovec-rvox))
- ❑ Member must meet **ONE** of the following:
  - ❑ Member has a diagnosis Hemophilia A (congenital factor VIII deficiency) **WITH inhibitors** meeting **ALL** the following:
    - ❑ Documentation of inhibitors to factor VIII with a current (within the past 30 days) or historical titer of ≥ 5 Bethesda Units (BU) **[laboratory measurements required]**
    - ❑ Must be used as routine prophylaxis to prevent or reduce the frequency of bleeding episodes
    - ❑ **ONE** of the following:
      - ❑ Severe factor VIII deficiency (factor VIII level of <1%)
      - ❑ History of a life-threatening hemorrhage
      - ❑ History of at least **TWO** documented episodes of spontaneous bleeding into joints requiring on-demand use of factor replacement therapy
      - ❑ Member has documented trial and failure of, or is currently on, routine prophylaxis with a bypassing agent (i.e., NovoSeven, Feiba) **[REQUIRES PRIOR AUTHORIZATION]**

    OR
  - ❑ Member has a diagnosis of Hemophilia A (congenital factor VIII deficiency) **WITHOUT inhibitors** meeting **ALL** the following:
    - ❑ Must be used as routine prophylaxis to prevent or reduce the frequency of bleeding episodes
    - ❑ **ONE** of the following:
      - ❑ Severe factor VIII deficiency (factor VIII level of <1%)
      - ❑ History of a life-threatening hemorrhage
      - ❑ History of at least **TWO** documented episodes of spontaneous bleeding into joints requiring on-demand use of factor replacement therapy

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- ❑ Member is **NOT** a suitable candidate for treatment with shorter half-life Factor VIII (recombinant) products at a total weekly dose of 100 IU/kg or less (as attested by the prescribing physician with appropriate clinical rationale) **[REQUIRES PRIOR AUTHORIZATION]**

- ❑ Provider will initiate therapy at 3 mg/kg by subcutaneous injection once weekly for the first 4 weeks, followed by a maintenance dose of:
  - ❑ 1.5 mg/kg once every week
  - ❑ 3 mg/kg once every two weeks
  - ❑ 6 mg/kg once every four weeks

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 diagnosis and therapy preclusions listed above
- ❑ Member has **NOT** experienced unacceptable toxicity from the drug (e.g., thrombotic microangiopathy, thromboembolic events (thromboembolism, pulmonary embolism), development of neutralizing antibodies (inhibitors))
- ❑ Member has demonstrated a beneficial response to therapy (i.e., a stabilization or improvement in the frequency of bleeding episodes compared to pre-treatment baseline)
- ❑ Provider is continuing **ONE** of the following maintenance dosing regimens:
  - ❑ 1.5 mg/kg once every week
  - ❑ 3 mg/kg once every two weeks
  - ❑ 6 mg/kg once every four weeks

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

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

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed'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: 5/28/2026**
REVISED/UPDATED/REFORMATTED: 6/15/2026