

Alhemo ® (concizumab-mtci) (Subcutaneous)

Effective Date: 10/01/2025

Review Date: 09/17/2025

Pharmacy Scope: Medicaid

Medical Scope: Medicaid, Commercial, Medicare

I. Length of Authorization

Coverage will be provided for 8 weeks initially and may be renewed every 12 months thereafter.

II. Dosing Limits

A. Max Units (per dose and over time) [HCPCS Unit]:

- Load: 230 billable units
- Maintenance: 60 billable units daily

III. Initial Approval Criteria ^{1-3,8,10-11}

Coverage is provided in the following conditions:

- Patient is at least 12 years of age; **AND**
- Documentation that the patient weighs more than $\geq 25\text{kg}$; **AND**
- 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 Alhemo (concizumab)*); **AND**
- Female patients of reproductive potential are not pregnant prior to initiating therapy with Alhemo (concizumab); **AND**
- Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

Universal Criteria

- Will NOT be used in combination with another agent used as prophylactic therapy for Hemophilia A or B (****see chart below*); **AND**

Hemophilia A or B (with or without factor VIII or IX inhibitors) †Φ

- Patient has a diagnosis of Hemophilia A (congenital factor VIII deficiency) or Hemophilia B (congenital factor IX deficiency aka Christmas Disease) as confirmed by blood coagulation testing (*Note: Patients WITHOUT inhibitors must have a FVIII level < 1% or FIX level ≤ 2%*); **AND**
- Must be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- Used as treatment in one of the following:
 - Primary prophylaxis in patients with severe factor deficiency; **OR**
 - Secondary prophylaxis in patients with at least TWO documented episodes of spontaneous bleeding into joints; **AND**

One of the following apply:

- Patient has Hemophilia A without inhibitors; **AND**
 - Patient has tried and had an inadequate response to Hemlibra (emicizumab) **AND** an antihemophilic Factor VIII agent product (e.g., Advate, Koate/Koate DVI, Hemofil, etc.) , that are used for prophylaxis, unless contraindicated or not tolerated; **OR**
 - Patient has Hemophilia A with inhibitors; **AND**
 - Patient has tried and had an inadequate response to Hemlibra (emicizumab) and had previous prophylaxis therapy with an antihemophilic Factor VIII agent product (e.g., Advate, Koate/Koate DVI, Hemofil, etc. with bypassing agent [i.e., Novoseven, FEIBA, etc.]); **OR**
 - Patient has Hemophilia B without inhibitors; **AND**
 - Patient has tried and had an inadequate response to an antihemophilic Factor IX agent (e.g., Benefit, Alprolix, Idelvion, Rebinyn, etc.) prophylaxis, unless contraindicated or not tolerated; **OR**
 - Patient has Hemophilia B with inhibitors; **AND**
 - Patient has had previous prophylaxis therapy with an antihemophilic Factor IX agent (e.g., Benefit, Alprolix, Idelvion, Rebinyn, etc. with bypassing agents, [i.e., Novoseven, FEIBA, etc.])
- ***see chart below for Hemophilia products

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

*****Drugs to treat Hemophilia A or B**

Hemophilia A & B Drug Chart	
Factor VIIa (Hemophilia A or B)	
Novoseven RT	J7189
Sevenfact	J7212
Anti-Inhibitor Coagulant Complex (Hemophilia A or B)	
Feiba	J7198
Factor VIII (Hemophilia A)	
Advate	J7192
Kogenate FS	J7192
Helixate FS	J7192
Recombinate	J7192
Kovaltry	J7211
Eloctate	J7205
Koate / Koate-DVI	J7190
Hemofil M	J7190
Novoeight	J7182
Nuwiq	J7209
Obizur	J7188
Xyntha / Xyntha Solofuse	J7185
Afstyla	J7210
Adynovate	J7207
Jivi	J7208
Esperoct	J7204

Altuviiiio	J7214
Factor IX (Hemophilia B)	
AlphaNine SD	J7193
Mononine	J7193
Alprolix	J7201
Profilnine	J7194
BeneFIX	J7194
Ixinity	J7213
Rixubis	J7200
Idelvion	J7202
Rebinyn	J7203

IV. Dispensing Requirements for Rendering Providers (Hemophilia Management Program)

- Prescriptions cannot be filled without an expressed need from the patient, caregiver or prescribing practitioner. Auto-filling is not allowed.
- Monthly, rendering provider must submit for authorization of dispensing quantity before delivering factor product.
- The cumulative amount of medication(s) the patient has on-hand should be taken into account when dispensing factor product.
- Dispensing requirements for renderings providers are a part of the hemophilia management program. This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide

V. Renewal Criteria^{1-3,8}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: thromboembolic events, hypersensitivity, etc.; **AND**
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline); **AND**
- Patient measurement of Alhemo (concizumab) plasma concentrations is at least 200 ng/mL*

**Note: Requests for patients with measurements of Albemio (concizumab) plasma concentrations that remain below 200 ng/mL at two consecutive measurements, will be reviewed on a case-by-case basis.*

VI. Dosage/Administration ¹

Indication	Dose
Routine Prophylaxis in Congenital Hemophilia A or Hemophilia B	<u>Day 1:</u> - Loading dose of 1 mg/kg subcutaneously <u>Day 2:</u> - Once-daily dose of 0.2 mg/kg subcutaneously until individualization of maintenance dose*. <u>Maintenance:</u> - Once the Albemo(concizumab-mtci) concentration result is available, individualize the maintenance dose of Albemo. No later than 8 weeks after initiation of treatment, based on the following concizumab-mtci- plasma concentrations: ☐ 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 a once-daily dose of 0.15 mg/kg <i>* 4 weeks after initiation of treatment: For dose optimization measure concizumab-mtci plasma concentration by Albemo(concizumab) Enzyme-Linked Immunosorbent Assay (ELISA) prior to administration of next scheduled dose. An FDA-authorized test for the measurement of concizumab-mtci concentration in plasma is not currently available.</i> <i><u>Note:</u> Additional measurements of Albemo(concizumab-mtci) plasma concentration should be taken at routine clinical follow-ups provided the patient has been on the same maintenance dose for 8 weeks of treatment to ensure steady-state plasma concentration. Maintenance of Albemo(concizumab) plasma concentration above 200 ng/mL is important to decrease the risk of bleeding episodes. If Albemo(concizumab- mtci) plasma concentration remains below 200 ng/mL at two consecutive measurements, the benefits of continued Albemo treatment should be evaluated versus the potential risk of bleeding events, and alternative therapies if available should be considered.</i>
- Treatment is intended for use under the guidance of a healthcare provider. Treatment should be initiated in a non-bleeding state. Albemo may be self-administered or administered by a caregiver after appropriate training and reading the Instructions for Use, if a healthcare provider determines that is appropriate. - As Albemo is dosed by body weight (mg/kg), it is important to recalculate the dose when patients experience body weight changes. - The calculated dose is rounded off to the nearest injectable dose as follows: 60 mg/1.5 mL (40 mg/mL) in increments of 0.4 mg (brown label) 150 mg/1.5 mL (100 mg/mL) in increments of 1 mg (gold label) 300 mg/3 mL (100 mg/mL) in increments of 1 mg (white label).	

VII. Billing Code/Availability Information

- J7173 – Injection, concizumab-mtci, 0.5 mg

NDC:

- Alhemo 60 mg single-patient use multi-dose prefilled pen (brown): 00169-2084-xx
- Alhemo 150 mg single-patient use multi-dose prefilled pen (gold): 00169-2080-xx
- Alhemo 300 mg single-patient use multi-dose prefilled pen (white): 00169-2081-xx

VIII. References

1. Alhemo [package insert]. Plainsboro, NJ; Novo Nordisk, Inc. May 2025. Accessed July 2025.
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4. Annual Review of Factor Replacement Products. Oklahoma Health Care Authority Review Board. Updated Dec 2020. Accessed May 2024.
5. Graham A1, Jaworski K. Pharmacokinetic analysis of anti-hemophilic factor in the obese patient. *Haemophilia*. 2014 Mar;20(2):226-9.
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7. Mingot-Castellano, et al. Application of Pharmacokinetics Programs in Optimization of Haemostatic Treatment in Severe Hemophilia a Patients: Changes in Consumption, Clinical Outcomes and Quality of Life. *Blood*. 2014 December; 124 (21).
8. MASAC Recommendation Concerning Prophylaxis for Hemophilia A and B with and without Inhibitors. Revised April 27, 2022. National Hemophilia Foundation. MASAC Document #267; April 2022. Available at: <https://www.bleeding.org>. Accessed May 2024.
9. UKHCDO protocol for first line immune tolerance induction for children with severe haemophilia A: A protocol from the UKHCDO Inhibitor and Paediatric Working Parties. 2017. Available at: <http://www.ukhcdo.org/guidelines>. Accessed May 2024.
10. Hoots, WK. (2024). Hemophilia A and B: Routine management including prophylaxis. In Leung LLK, Tirnauer JS (Eds.), *UptoDate*. Last updated: April 16, 2024. Accessed May 13, 2024. Available from https://www.uptodate.com/contents/hemophilia-a-and-b-routine-management-including-prophylaxis?search=hemophilia%20a&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2#H978189 854.
11. Frei-Jones M, Cepo K, d'Oiron R, et al. Subcutaneous Concizumab Prophylaxis in Patients with Hemophilia A or B with Inhibitors: Efficacy and Safety Results By Hemophilia Subtype from the Phase 3 Explorer7 Trial. *Blood* 2022; 140 (Supplement 1): 466–468.
doi: <https://doi.org/10.1182/blood-2022-166522>.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D66	Hereditary factor VIII deficiency
D67	Hereditary factor IX deficiency