MEDICAL MUTUAL®

Drug Policy

Policy:	**250201**	**Initial Effective Date:**
Code(s):	**HCPCS J3590**	**Annual Review Date: 07/17/2025**
SUBJECT:	**Alhemo ® (concizumab-mtci)**	**Last Revised Date: 07/17/2025**

Subject to: ☐Site of Care
☐Medication Sourcing

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 8 weeks.
- Renewal: Prior authorization validity may be renewed every 12 months thereafter.

II. Dosing Limits

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

- Load: 115 mg
- Maintenance: 30 mg 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**
- 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)*; **AND**
- Female patients of reproductive potential are not pregnant prior to initiating therapy with concizumab; **AND**

Universal Criteria

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

Hemophilia A (congenital factor VIII deficiency) with inhibitors † Φ

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Patient has inhibitors to Factor VIII with a current or historical titer of ≥ 5 Bethesda Units (BU)******; **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 VIII deficiency (factor VIII level of <1%); **OR**
  - Secondary prophylaxis in patients with at least TWO documented episodes of spontaneous bleeding into joints; **AND**
- Patient has had previous prophylaxis therapy

Hemophilia B (congenital factor IX deficiency aka Christmas Disease) with inhibitors † Φ

- Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing; **AND**
- Patient has inhibitors to Factor IX with a current or historical titer of ≥ 5 Bethesda Units (BU)******; **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 IX deficiency (factor IX level of <1%); **OR**
  - Secondary prophylaxis in patients with at least TWO documented episodes of spontaneous bleeding into joints; **AND**
- Patient has had previous prophylaxis therapy

*****Note:** Patients with inhibitor titer levels >0.6 BU to <5 BU who are not responding to or are not a candidate for standard factor replacement, will be evaluated on a case-by-case basis.*

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

IV. Renewal Criteria [1-3,8]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other 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 concizumab plasma concentrations at least 200 ng/mL*

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

V. Dosage/Administration [1]

Indication	Dose
Routine Prophylaxis in Congenital Hemophilia A or Hemophilia B with inhibitors	**Day 1:** • Loading dose of 1 mg/kg subcutaneously **Day 2:** • Once-daily dose of 0.2 mg/kg subcutaneously until individualization of maintenance dose ◊ **Maintenance**: • Once the concizumab concentration result is available, individualize the maintenance dose no later than 8 weeks after initiation of treatment, based on the following concizumab 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 *◊ 4 weeks after initiation of treatment: For dose optimization measure concizumab plasma concentration by Concizumab Enzyme-Linked Immunosorbent Assay (ELISA) prior to administration of next scheduled dose. An FDA-authorized test for the measurement of concizumab concentration in plasma is not currently available.* *Note: Additional measurements of concizumab 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 concizumab plasma concentration above 200 ng/mL is important to decrease the risk of bleeding episodes. If concizumab plasma concentration remains below 200 ng/mL at two consecutive measurements, the benefits of continued concizumab treatment should be evaluated versus the potential risk of bleeding events, and alternative therapies if available should be considered.*
• Treatment is intended for use under the guidance of a healthcare provider. Treatment should be initiated in a non-bleeding state. concizumab 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.	

Indication	Dose
• As concizumab 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)	

VI. Billing Code/Availability Information

HCPCS Code(s):

- J3590 – Unclassified biologic
- C9399 – Unclassified drugs or biologicals

NDC(s):

- 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

VII. References

1. Alhemo [package insert]. Plainsboro, NJ; Novo Nordisk, Inc. May 2025. Accessed May 2025.
2. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised October 2, 2024. National Hemophilia Foundation. MASAC Document #290. Available at: https://www.bleeding.org. Accessed May 2025.
3. Guidelines for the Management of Hemophilia. 3rd Edition. World Federation of Hemophilia 2020. Available at: https://www1.wfh.org/publications/files/pdf-1863.pdf. Accessed May 2025.
4. Annual Review of Factor Replacement Products. Oklahoma Health Care Authority Review Board. Updated Dec 2020.
5. Graham A1, Jaworski K. Pharmacokinetic analysis of anti-hemophilic factor in the obese patient. Haemophilia. 2014 Mar;20(2):226-9.
6. Croteau SE1, Neufeld EJ. Transition considerations for extended half-life factor products. Haemophilia. 2015 May;21(3):285-8.
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; Available at: https://www.bleeding.org. Accessed May 2025.
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.
10. Malec L. (2025). Hemophilia A and B: Routine management including prophylaxis. In Leung LLK, Tirnauer JS (Eds.), *UptoDate*. Last updated: April 29, 2025. Accessed May 1, 2025. Available from https://www.uptodate.com/contents/hemophilia-a-and-b-routine-management-including-prophylaxis
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: .

Appendix 1 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.

MEDICAL MUTUAL®

Drug Policy

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J3590

†When *unclassified biologics* (J3590) is determined to be Alhemo

Edits and Denials:

Prior approval: Prior approval is required for *** **(HCPCS Codes J3490 , J3590, J9999)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Codes J3490, J3590, J9999** will pend with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

HCPCS Code(s):	
J3590	Unclassified biologics