Neighborhood Health Plan OF RHODE ISLAND™
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Alhemo ® (concizumab-mtci)
(Subcutaneous)

Effective Date: 11/01/2025

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. Summary of Evidence

Alhemo (concizumab-mtci) is a subcutaneously administered tissue factor pathway inhibitor (TFPI) antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with hemophilia A or B with inhibitors. Its mechanism of action involves inhibition of TFPI, thereby enhancing thrombin generation and improving hemostasis. The efficacy of Alhemo was demonstrated in the Phase 3 explorer7 trial, a prospective, multicenter, open-label study enrolling 133 male patients aged ≥12 years with hemophilia A or B with inhibitors. The primary endpoint was the annualized bleeding rate (ABR) of treated spontaneous and traumatic bleeding episodes. Alhemo met its primary endpoint, demonstrating a significant 86% reduction in ABR compared to no prophylaxis. Additionally, 64% of members receiving Alhemo prophylaxis experienced zero treated bleeds during the evaluation period. The most common adverse reactions reported with Alhemo were injection site reactions and urticaria.

IV. Initial Approval Criteria [1-3,8,10-11]

Coverage is provided in the following conditions:

- Member is at least 12 years of age; **AND**
- Documentation that the member weighs more than ≥ 25kg
- 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 members being treated with Alhemo (concizumab)*; **AND**

- Female members 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; **AND***)***see chart below*.

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

- Member 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: Members 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 members with severe factor deficiency
    OR
  - Secondary prophylaxis in members with at least TWO documented episodes of spontaneous bleeding into joints; **AND**
- One of the following apply:
  - Member has Hemophilia A without inhibitors; **AND**
    - Member 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**
  - Member has Hemophilia A with inhibitors; **AND**
    - Member 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**
  - Member has Hemophilia B without inhibitors; **AND**
    - Member 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**
  - Member has Hemophilia B with inhibitors; **AND**

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

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

- Prescriptions cannot be filled without an expressed need from the member, 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 member 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

VI. Renewal Criteria [1-3,8]

Coverage can be renewed based upon the following criteria:

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

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

VII. Dosage/Administration [1]

Indication	Dose
Routine Prophylaxis in Congenital Hemophilia A or Hemophilia B	**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 Alhemo(concizumab-mtci) concentration result is available, individualize the maintenance dose of Alhemo. 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 ** 4 weeks after initiation of treatment: For dose optimization measure concizumab-mtci plasma concentration by Alhemo(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.* *Note: Additional measurements of Alhemo(concizumab-mtci) plasma concentration should be taken at routine clinical follow-ups provided the member has been on the same maintenance dose for 8 weeks of treatment to ensure steady-state plasma concentration. Maintenance of Alhemo(concizumab) plasma concentration above 200 ng/mL is important to decrease the risk of bleeding episodes. If Alhemo(concizumab- mtci) plasma concentration remains below 200 ng/mL at two consecutive measurements, the benefits of continued Alhemo 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. Alhemo 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 Alhemo is dosed by body weight (mg/kg), it is important to recalculate the dose when members 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).	

VIII. Billing Code/Availability Information

- J7173 – Injection, concizumab-mtci, 0.5 mg

NDC:

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

IX. References

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7. Mingot-Castellano, et al. Application of Pharmacokinetics Programs in Optimization of Haemostatic Treatment in Severe Hemophilia a Members: 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.
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11. Frei-Jones M, Cepo K, d'Oiron R, et al. Subcutaneous Concizumab Prophylaxis in Members 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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outmember (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 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.
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

Policy Rationale:
Alhemo was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Alhemo according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria

will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.