TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Alhemo (concizumab-mtci)

Effective: June 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Alhemo (concizumab-mtci) is a tissue factor pathway inhibitor (TFPI) antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding in episodes in adult and pediatric patients 12 years of age and older with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors, or hemophilia B (congenital factor IX deficiency) with or without factor IX inhibitors.

COVERAGE GUIDELINES

The plan may authorize coverage of Alhemo for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of hemophilia A or B

AND

2. Documentation for use as prophylaxis to prevent or reduce the frequency of bleeding episodes

AND

3. The patient is at least 12 years of age or older

AND

4. Documentation the patient is with or without inhibitors (hemophilia A: FVIII, hemophilia B: FIX)

AND

5. Prescribed by or in consultation with a hematologist

Reauthorization Criteria

1. Documented diagnosis of hemophilia A or B

AND

2. The patient is at least 12 years of age or older

AND

3. Prescribed by or in consultation with a hematologist

AND

4. Documentation the patient is with or without inhibitors (hemophilia A: FVIII, hemophilia B: FIX)

AND

5. Documentation the Member has experienced a therapeutic response from Alhemo as defined by a reduction in the frequency of bleeds

LIMITATIONS

- Coverage of Alhemo will be authorized for 12 months
- Members new to the plan stable on Alhemo should be reviewed against Reauthorization Criteria

CODES

None

REFERENCES

1. Alhemo (concizumab-mtci) [package insert]. Plainsboro, NJ; Novo Nordisk Inc: July 2025.
2. Astermark J, et al. Efficacy and safety of concizumab prophylaxis in patients with hemophilia a or b without inhibitors: 56-week cut-off results of the Phase 3 explorer8 study. Blood. 2023;142(suppl 1):2609.
3. Chowdary P, et al. Concizumab prophylaxis in people with haemophilia A or haemophilia B without inhibitors (explorer8): a prospective, multicentre, open-label, randomised, phase 3a trial [published correction appears in Lancet Haematol. 2024;11(12):e886. doi:10.1016/S2352-3026(24)00353-3]. Lancet Haematol. 2024;11(12):e891–e904.

4. Matsushita T, et al. Phase 3 Trial of Concizumab in hemophilia with inhibitors. N Engl J Med. 2023;389(9):783–794.
5. Alok Srivastava et al on behalf of the WFH Guidelines for the Management of Hemophilia panelists and co-authors. World Federation of Hemophilia guidelines for the management of hemophilia. 3rd edition. 2020. Accessed February 2025. Available at: https://elearning.wfh.org/resource/treatment-guidelines/.

APPROVAL HISTORY

May 13, 2025: Reviewed by Pharmacy and Therapeutics Committee (P&T)
Subsequent endorsement date(s) and changes made:

- June 9, 2026: Updated overview and criteria to indicate that Alhemo can be used in patients with hemophilia A with or without factor VIII inhibitors, or hemophilia B with or without factor IX inhibitors based on expanded labeling (eff 6/1/26).

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services