UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2369-1
Program	Prior Authorization/Medical Necessity
Medication	Alhemo® (concizumab-mtci)
P&T Approval Date	3/2025
Effective Date	6/1/2025

1. Background:

Alhemo (concizumab-mtci) is a tissue factor pathway inhibitor (TFPI) antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with:
• hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors
• hemophilia B (congenital factor IX deficiency) with FIX inhibitors

2. Coverage Criteria[a]:

A. Hemophilia A With Inhibitors

1. **Initial Authorization**

a. **Alhemo** will be approved based on **all** of the following criteria:

(1) Diagnosis of hemophilia A

-AND-

(2) Patient is 12 years of age or older

-AND-

(3) Patient has developed high-titer factor VIII inhibitors (≥ 5 Bethesda units [BU])

-AND-

(4) Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

Authorization of therapy will be issued for 12 months.

2. **Reauthorization**

a. **Alhemo** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Alhemo therapy

Authorization will be issued for 12 months.

B. Hemophilia B With Inhibitors

1. **Initial Authorization**

   a. **Alhemo** will be approved based on **all** of the following criteria:

      (1) Diagnosis of hemophilia B

      -AND-

      (1) Patient is 12 years of age or older

      -AND-

      (2) Patient has developed high-titer factor IX inhibitors (≥ 5 Bethesda units [BU])

      -AND-

      (3) Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

   Authorization of therapy will be issued for 12 months.

2. **Reauthorization**

   a. **Alhemo** will be approved based on the following criterion:

      (1) Documentation of positive clinical response to Alhemo therapy

   Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Alhemo® [package insert]. Plainsboro, NJ: Novo Nordisk Inc., December 2024.
2. Matsushita T, Shapiro A, Abraham A, et al. Phase 3 Trial of Concizumab in Hemophilia with Inhibitors. N Engl J Med. 2023;389(9):783-794. doi:10.1056/NEJMoa2216455

Program	Prior Authorization/Medical Necessity - Alhemo (concizumab-mtci)
Change Control	
3/2025	New program.