

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2025 P 2369-2
Program	Prior Authorization/Medical Necessity
Medication	Alhemo® (concizumab-mtci)
P&T Approval Date	3/2025, 8/2025
Effective Date	10/1/2025

**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 or without FVIII inhibitors
- hemophilia B (congenital factor IX deficiency) with or without FIX inhibitors

**2. Coverage Criteria<sup>a</sup>:****A. Hemophilia A With Inhibitors****1. Initial Authorization**

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

- (1) **Both** of the following:

- (a) Diagnosis of hemophilia A

**-AND-**

- (b) Patient has developed high-titer factor VIII inhibitors (i.e., patient has developed factor VIII inhibitors greater than or equal to 5 Bethesda units [BU])

**-AND-**

- (2) Patient is 12 years of age or older

**-AND-**

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

**Authorization 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 A Without Inhibitors**

**1. Initial Authorization**

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

(1) **Both** of the following:

(a) Diagnosis of hemophilia A

**-AND-**

(b) Patient has not developed high-titer factor VIII inhibitors (i.e., patient has NOT developed factor VIII inhibitors greater than or equal to 5 Bethesda units [BU])

**-AND-**

(2) Patient is 12 years of age or older

**-AND-**

(3) **Alhemo** is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

**Authorization 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.**

**C. Hemophilia B With Inhibitors**

**1. Initial Authorization**

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

(1) Both of the following:

(a) Diagnosis of hemophilia B

**-AND-**

- (b) Patient has developed high-titer factor IX inhibitors (i.e., patient has developed factor IX inhibitors greater than or equal to 5 Bethesda units [BU])

-AND-

- (2) Patient is 12 years of age or older

-AND-

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

**Authorization 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.**

**D. Hemophilia B Without Inhibitors**

1. **Initial Authorization**

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

- (1) **Both** of the following:

- (a) Diagnosis of hemophilia B

-AND-

- (b) Patient has not developed high-titer factor IX inhibitors (i.e., patient has NOT developed factor IX inhibitors greater than or equal to 5 Bethesda units [BU])

-AND-

- (2) Patient is 12 years of age or older

-AND-

- (3) Alhemo is prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

**Authorization 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.**

<sup>a</sup> 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., July 2025.
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)
<b>Change Control</b>	
3/2025	New program.
8/2025	Added coverage criteria for hemophilia A or B without inhibitors per updated FDA label. Clarified high titer inhibitor criteria. Updated references.