UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2369-3
Program	Prior Authorization/Medical Necessity
Medication	Alhemo® (concizumab-mtci)
P&T Approval Date	3/2025, 8/2025, 11/2025
Effective Date	1/1/2026

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[a]:

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)

-AND-

(4) **One** of the following:

(a) Based on clinical patient assessment, the provider has determined that the patient is not an appropriate candidate for Hympavzi (document reason)

-OR-

(b) Both of the following:

i. Patient is currently on Alhemo therapy

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from NovoCare® (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of **Alhemo***

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from NovoCare® **shall be required** to meet initial authorization criteria as if patient were new to therapy.

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)

      -AND-

      (4) **One** of the following:

         (a) Based on clinical patient assessment, the provider has determined that the patient is not an appropriate candidate for Hympavzi (document reason)

         -OR-

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

            i. Patient is currently on Alhemo therapy

            -AND-

            ii. Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from NovoCare® (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of **Alhemo***

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from NovoCare® **shall be required** to meet initial authorization criteria as if patient were new to therapy.

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.

[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., 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)
Change Control	
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.
11/2025	Added preferred therapy criteria for hemophilia A or B without inhibitors.