Commercial PA Criteria

Effective: March 24, 2025

Prior Authorization: Alhemo (concizumab-mtci)

Products Affected: Alhemo (concizumab-mtci) subcutaneous injection

Medication Description: Alhemo, a tissue factor pathway inhibitor (TFPI) antagonist, is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatric patients ≥ 12 years of age with: hemophilia A (congenital Factor VIII deficiency) with Factor VIII inhibitors, **or** 2) hemophilia B (congenital Factor IX deficiency) with Factor IX inhibitors.

Covered Uses:

1. Hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors
2. Hemophilia B (congenital factor IX deficiency) without Factor IX inhibitors

Exclusion Criteria:

1. Concurrent Use with Hemlibra (emicizumab-kxwh subcutaneous injection)
2. Concurrent Use with Hympavzi (marstacimab-hncq subcutaneous injection)
3. Concurrent Use of Bypassing Agents for Routine Prophylaxis.
4. Patient Receiving Immune Tolerance Induction Therapy.

Required Medical Information:

1. Diagnosis
2. Medical History
3. Past therapies tried and failed

Prescriber Restriction: The medication is prescribed by or in consultation with a hemophilia specialist.

Age Restriction: The patient is > 12 years of age.

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. **Hemophilia A with Factor VIII Inhibitors.** Approve for 1 year if the patient meets ONE of the following (A **or** B):
   - A. Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, **AND** iv):
     - i. Patient is ≥ 12 years of age; **AND**
     - ii. Patient is using Alhemo for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
     - iii. Patient meets BOTH of the following (a **AND** b):
       - a. Factor VIII inhibitor titer testing has been performed within the past 30 days; **AND**
       - b. Patient has a positive test for Factor VIII inhibitors of ≥ 0.6 Bethesda units/mL; **AND**
     - iv. The medication is prescribed by or in consultation with a hemophilia specialist; **OR**

B. Patient is Currently Receiving Alhemo. Approve if the patient meets ALL of the following (i, ii, **AND** iii):
   i. Patient is using Alhemo for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
   ii. The medication is prescribed by or in consultation with a hemophilia specialist; **AND**
   iii. According to the prescriber, patient experienced a beneficial response to therapy.
   Note: Examples of a beneficial response to therapy include a reduction in bleeding events, in the severity of bleeding episodes, in the number of bleeding events that required treatment, and/or in the number of spontaneous bleeds.

2. **Hemophilia B with Factor IX Inhibitors.** Approve for 1 year if the patient meets ONE of the following (A **OR** B):
   A. Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, **and** iv):
      i. Patient is ≥ 12 years of age; **AND**
      ii. Patient is using Alhemo for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
      iii. Patient meets BOTH of the following (a **and** b):
         a. Factor IX inhibitor titer testing has been performed within the past 30 days; **AND**
         b. Patient has a positive test for Factor IX inhibitors of ≥ 0.6 Bethesda units/mL; **AND**
      iv. The medication is prescribed by or in consultation with a hemophilia specialist; **OR**
   B. Patient is Currently Receiving Alhemo. Approve if the patient meets ALL of the following (i, ii, **and** iii):
      i. Patient is using Alhemo for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
      ii. The medication is prescribed by or in consultation with a hemophilia specialist; **AND**
      iii. According to the prescriber, patient experienced a beneficial response to therapy.
      Note: Examples of a beneficial response to therapy include a reduction in bleeding events, in the severity of bleeding episodes, in the number of bleeding events that required treatment, and/or in the number of spontaneous bleeds.

References:

1. Alhemo® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; December 2024.
2. Mancuso ME, Mahlangu JN, Pipe SW. The changing treatment landscape in haemophilia: from standard half-life clotting factor concentrates to gene editing. *Lancet*. 2021;397:630-640.
3. Franchini M, Mannucci PM. The more recent history of hemophilia treatment. *Semin Thromb Hemost*. 2022;48(8):904-910.
4. Croteau SE. Hemophilia A/B. *Hematol Oncol Clin North Am*. 2022;36(4):797-812.
5. Centers for Disease Control and Prevention. Data and statistics on hemophilia. Available at: https://www.cdc.gov/hemophilia/data-research/. Accessed on January 2, 2025.
6. National Bleeding Disorders Foundation. Hemophilia A: An overview of symptoms, genetics, and treatments to help you understand hemophilia A. Available at: https://www.bleeding.org/bleeding-disorders-a-z/types/hemophilia-a. Accessed on January 2, 2025.
7. National Hemophilia Foundation. Hemophilia B. An overview of symptoms, genetics, and treatments to help you understand hemophilia B. Available at: https://www.hemophilia.org/bleeding-disorders-a-z/types/hemophilia-b. Accessed on January 2, 2025.
8. Hemlibra® subcutaneous injection [prescribing information]. South San Francisco, CA and Tokyo, Japan: Genentech/Roche and Chugai; January 2024.
9. Hympavzi™ subcutaneous injection [prescribing information]. New York, NY: Pfizer; October 2024

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	03/24/2025