AETNA BETTER HEALTH®
Coverage Policy/Guideline

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Effective Date:	3/21/2025	Last Review Date:	2/2025

Applies to:	☒Illinois	☐Florida	☒Florida Kids
	☐New Jersey	☒Maryland	☐Michigan
	☒Pennsylvania Kids	☐Virginia	☒Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Alhemo under the patient's prescription drug benefit.

Description:

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Alhemo is 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.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Alhemo

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

For initial requests: Chart notes, lab tests documenting all of the following (where applicable):

- Confirmation of factor VIII or factor IX inhibitors (lab test results required).
- Baseline hematologic, hepatic, and renal assessments.

For continuation requests: Chart notes documenting benefit from therapy (e.g., reduced frequency or severity of bleeds).

Prescriber Specialties

The medication must be prescribed by or in consultation with a hematologist.

Coverage Criteria

Hemophilia A (congenital factor VIII deficiency) and Hemophilia B (congenital factor IX deficiency)

Authorization of 12 months may be granted for hemophilia A (congenital factor VIII deficiency) and hemophilia B (congenital factor IX deficiency) when all of the following criteria are met:

- Member is 12 years of age or older.
- Member is > 25 kg.
- Member has documented history of factor VIII or factor IX inhibitors (≥ 0.6 Bethesda units [BU]).
- Member must be using the requested medication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
- Member has been prescribed, or in need of, treatment with a bypassing agent within the past 6 months (e.g., FEIBA, NovoSeven).
- Member does not have a history, current signs or symptoms, or is at high risk of thromboembolic events.
- Member is not currently undergoing or is planning to undergo immune tolerance treatment.
- Member does not have the following laboratory assessments at baseline:
    - Platelets less than 100,000 cells/microL.
    - Alanine transaminase (ALT) and/or aspartate aminotransferase (AST) greater than 3 times the upper limit of normal (ULN).
    - Total bilirubin greater than 1.5 times ULN (unless there is a diagnosis of Gilbert's Syndrome and member is otherwise stable).
    - Fibrinogen below the laboratory lower limit of normal.
    - Estimated glomerular filtration rate (eGFR) ≤ 30 mL/min/1.73 m^2.
- Member will not use the requested medication in combination with Hemlibra.
- Member has not previously received treatment with a gene therapy product (e.g., Beqvez, Hemgenix, Roctavian) for the treatment of hemophilia A or B.
- Prophylactic use of bypassing agents, factor VIII products (e.g., Advate, Adynovate, Eloctate), and factor IX products (e.g., Alprolix, Ixinity, Rebinyn) will be discontinued prior to starting therapy with the requested medication.
- Provider attests that concizumab-mtci plasma concentrations will be monitored per the protocol outlined in the prescribing information.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in coverage criteria section when all of the following are met:

- Member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).
- Member is not using the requested medication in combination with bypassing agents, factor VIII products (e.g., Advate, Adynovate, Eloctate) or factor IX products (e.g., Alprolix, Ixinity, Rebinyn) for prophylactic use.

Approval Duration and Quantity Restrictions:

Approval: 12 months

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 Aug 31;389(9):783-794.