Reference number(s)
6802-A

Standard Medicare Part B Management Alhemo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Alhemo	concizumab-mtci

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[1]

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 or without FVIII inhibitors.
- Hemophilia B (congenital factor IX deficiency) with or without FIX inhibitors.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

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

Coverage Criteria

Hemophilia A (congenital factor VIII deficiency) and Hemophilia B (congenital factor IX deficiency)[1,2]

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 must be using the requested medication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
- Member will not use the requested medication in combination with Hemlibra, Hympavzi, or Qfitlia.
- 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.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication in the coverage criteria section.
- 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.

Summary of Evidence

The contents of this policy were created after examining the following resources:

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- The prescribing information for Alhemo.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Alhemo are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Currently there are no treatment guidelines or literature supporting the concomitant use of Alhemo with Hemlibra, Hympavzi, and Qfitlia or use after having received prior gene therapy for hemophilia A or B.

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

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