Alhemo® (concizumab-mtci)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits 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 or without factor VIII inhibitors, or
- Hemophilia B (congenital factor IX deficiency) with or without factor IX inhibitors

POLICY

Required Documentation

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

1. For initial requests:
    a. Chart notes
    b. Lab tests documenting all of the following (where applicable):
        i. Absence or confirmation of factor VIII or factor IX inhibitors (lab test results required)
        ii. Baseline hematologic, hepatic, and renal assessments
2. For continuation requests:
    a. Chart notes documenting benefit from therapy (e.g., reduced frequency or severity of bleeds).

Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following:

1. Hematologist

Criteria for Initial Approval

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:

1. Member is 12 years of age or older
2. Member is > 25 kg
3. Member has documented history of or no detectable factor VIII or factor IX inhibitors (≥0.6 Bethesda units [BU])
4. Member must be using the requested medication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
5. Member has been prescribed, or in need of, treatment with a bypassing agent within the past 6 months (e.g., FEIBA, NovoSeven)
6. Member does not have a history, current signs or symptoms, or is at high risk of thromboembolic events
7. Member is not currently undergoing or is planning to undergo immune tolerance treatment
8. Member does not have the following laboratory assessments at baseline:
    A. Platelets less than 100,000 cells/microL
    B. Alanine transaminase (ALT) and/or aspartate aminotransferase (AST) greater than 3 times the upper limit of normal (ULN)
    C. Total bilirubin greater than 1.5 times ULN (unless there is a diagnosis of Gilbert's Syndrome and member is otherwise stable)
    D. Fibrinogen below the laboratory lower limit of normal
    E. Estimated glomerular filtration rate (eGFR) ≤30 mL/min/1.73 m^2
9. Member will not use the requested medication in combination with Hemlibra, Hympavzi, or Qfitlia
10. Member has not previously received treatment with a gene therapy product (e.g., Beqvez, Hemgenix, Roctavian) for the treatment of hemophilia A or B
11. 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.
12. Provider attests that concizumab-mtci plasma concentrations will be monitored per the protocol outlined in the prescribing information

Continuation of Therapy

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

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:

1. Member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds)
2. 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

Other

Alhemo (concizumab-mtci) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Alhemo (concizumab-mtci) 60 mg/1.5 mL prefilled pen injection 150 mg/1.5 mL prefilled pen injection 300 mg/3 mL prefilled pen injection	4 pens per 28 days	Day 1: Loading dose of 1 mg/kg Day 2: Once-daily dose of 0.2 mg/kg until individualization of maintenance dose (see below) Plasma concentration of Alhemo (concizumab-mtci)*: < 200 ng/mL: adjust to a once-daily dose of 0.25 mg/kg 200 to 4000 ng/mL: continue once-daily dose of 0.2 mg/kg > 4000 ng/mL: adjust to a once-daily dose of 0.15 mg/kg

*Plasma concentration of Alhemo (concizumab-mtci) is measured at 4 weeks after treatment initiation and prior to the next scheduled dose. Maintenance dose should be calculated no later than 8 weeks after treatment initiation.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J7173 - Injection, concizumab-mtci, 0.5 mg (effective 10/1/25)

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

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.05.85

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