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Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Hematological Agents	**Original Policy Date:**	April 7, 2025
Subject:	Alhemo	**Page:**	1 of 4

Last Review Date: March 6, 2026

Alhemo

Description

Alhemo (concizumab-mtci)

Background
Alhemo (concizumab-mtci) is a monoclonal antibody antagonist of endogenous tissue factor pathway inhibitor (TFPI). Through the inhibition of TFPI, Alhemo acts to enhance factor Xa production during the initiation phase of coagulation which leads to improved thrombin generation and clot formation with the goal of achieving hemostasis in patients with Hemophilia A or B regardless of their inhibitor status (1).

Regulatory Status
FDA-approved indications: Alhemo 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: (1)

- hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors
- hemophilia B (congenital factor IX deficiency) with or without factor IX inhibitors.

Alhemo has been associated with thromboembolic events, hypersensitivity reactions, and increased laboratory values of fibrin D dimer and prothrombin fragment 1+2. Alhemo treatment may increase the risk of venous and arterial thromboembolic events. Treatment should be discontinued if suspicion of thromboembolism occurs, and further investigations and management strategies should be initiated. Alhemo may cause hypersensitivity reactions

(including, but not limited to erythema, rash, pruritus, and abdominal pain). If a severe hypersensitivity reaction occurs, discontinue Alhemo and initiate medical management. Alhemo may increase levels of fibrin D-dimer and prothrombin fragment 1+2. These coagulation biomarkers may not be reliable for clinical decision-making with suspicion of thrombosis such as deep vein thrombosis (DVT) and pulmonary embolism (PE). (1).

The safety and efficacy of concomitant use of Alhemo in patients receiving ongoing Immune Tolerance Induction (ITI), a desensitization strategy for the eradication of inhibitors, have not been established, and no data are available (1).

Women of childbearing potential should use a highly effective form of contraception during treatment with Alhemo and for 7 weeks after ending treatment. The benefits and thromboembolic risks of the type of contraceptives should be evaluated by the treating physician (1).

The safety and effectiveness of Alhemo in pediatric patients less than 12 years of age have not been established (1).

Related policies
Hympavzi

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Alhemo may be considered **medically necessary** if the conditions indicated below are met.

Alhemo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Hemophilia A (congenital factor VIII deficiency)
2. Hemophilia B (congenital factor IX deficiency)

AND ALL of the following for **ALL** indications:

1. Used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
2. Patient is not currently undergoing or planning to undergo immune tolerance treatment
3. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Alhemo and for 7 weeks after the last dose

Prior – Approval *Renewal* Requirements

Age 12 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Hemophilia A (congenital factor VIII deficiency)
2. Hemophilia B (congenital factor IX deficiency)

AND ALL of the following for **ALL** indications:

1. Patient has had a clinical benefit from Alhemo therapy (e.g., reduced bleeding episodes)
2. Used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
3. Patient is not currently undergoing or planning to undergo immune tolerance treatment
4. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Alhemo and for 7 weeks after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Alhemo is a TFPI antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients 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. Alhemo has been associated with thromboembolic events, hypersensitivity reactions, and increased laboratory values of fibrin D dimer and prothrombin fragment 1+2. The safety and effectiveness of Alhemo in pediatric patients less than 12 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Alhemo while maintaining optimal therapeutic outcomes.

References

1. Alhemo [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; July 2025.

Policy History

Date	Reason
April 2025	Addition to PA
June 2025	Annual review
September 2025	Annual review. Per PI update, expanded indication to include patients without FVIII and FIX inhibitors
March 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.