Generic Name: concizumab, emicizumab, marstacimab, fitusiran

Therapeutic Class or Brand Name: Alhemo, Hemlibra, Hympavzi, Qfitlia

Applicable Drugs: Alhemo (concizumab), Hemlibra (emicizumab), Hympavzi (marstacimab), Qfitlia (fitusiran)

Preferred: Hemlibra, Hympavzi

Non-preferred: N/A

VSI Excluded Drugs: Alhemo, Qfitlia

Date of Origin: 6/2/2025

Date Last Reviewed / Revised: 6/2/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of one of the following conditions A through D AND must meet ALL criteria listed under applicable diagnosis.

A. Hemophilia A without factor VIII inhibitors (HA) and meets ONE of the following:

i. Diagnosis of severe HA with documented baseline FVIII levels below 1% of normal FVIII (<1 IU/dL)

ii. Diagnosis of moderate HA (baseline FVIII levels of 1% to 5%) AND meets the following criteria:

1. Documented treatment failure (such as continued spontaneous bleeds or inability to achieve appropriate FVIII trough level despite adherence to therapy) of trial of routine prophylaxis with FVIII replacement products.

B. Hemophilia A with factor VIII inhibitors (HAwI)

i. Documentation of high-titer FVIII inhibitors (≥5 Bethesda units [BU])

C. Hemophilia B without factor IX inhibitors (HB)

i. Diagnosis of severe HB with documented baseline FIX levels below 1% of normal FVIII (<1 IU/dL)

ii. Diagnosis of moderate HB (baseline FIX levels of 1% to 5%) AND meets the following criteria:

1. Documented treatment failure (such as continued spontaneous bleeds or inability to achieve appropriate FIX trough level despite adherence to therapy) of trial of routine prophylaxis with FIX replacement products.

D. Hemophilia B with factor IX inhibitors (HBwI)

i. Documentation of high-titer FIX inhibitors (≥5 Bethesda units [BU])

II. Treatment is prescribed by or in consultation with a hematologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines. Refer to Table 1 for medication-specific indications.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- These products are indicated for use in routine prophylaxis. The use of any of these agents solely for the treatment of breakthrough bleeding is excluded.
- Concomitant use of more than one product in this policy.
- Use of any product in this policy in combination with prophylactic factor VIII/IX concentrates or bypassing agents [note: use of factor replacement products or bypassing agents for the treatment of breakthrough bleeds is permitted].
- Qfitlia only: Baseline antithrombin (AT) activity <60%, clinically significant liver disease, or active hepatitis C infection.

OTHER CRITERIA

- Table 1: Covered Indications by Medication

	Age	HA	HAwI	HB	HBwI
Alhemo (concizumab)	≥12 years		X		X
Hemlibra (emicizumab)	Any	X	X		
Hympavzi (marstacimab)	≥12 years	X		X	
Qfitlia (fitusiran)	≥12 years	X	X	X	X

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Alhemo: Loading dose of 1 mg/kg, then maintenance dose not to exceed 0.25 mg/kg/day.
- Hemlibra: Loading dose of 3mg/kg, then maintenance dose not to exceed 1.5 mg/kg once weekly, 3mg/kg every two weeks, or 6mg/kg every four weeks.
- Hympavzi: Loading dose of 300 mg, then maintenance dose of 150 mg once weekly.
- Qfitlia: Not to exceed 50 mg per month.

APPROVAL LENGTH

- **Authorization:** 12 months
- **Re-Authorization:** 12 months, with an updated letter of medical necessity or progress notes showing adherence to therapy and improvement or maintenance with the medication.

APPENDIX

N/A

REFERENCES

1. Alhemo. Prescribing Information. Novo Nordisk; December 2024, Accessed April 14, 2025. https://www.novo-pi.com/alhemo.pdf
2. Hemlibra. Prescribing Information. Genentech; January 2024, Accessed April 15, 2025. https://www.gene.com/download/pdf/hemlibra_prescribing.pdf
3. Hympavzi. Prescribing Information. Pfizer; October 2024, Accessed April 14, 2025. https://labeling.pfizer.com/ShowLabeling.aspx?id=20916
4. Qfitlia. Prescribing Information. Genzyme Corporation; March 2025, Accessed April 21, 2025. https://www.qfitlia.com/dam/Marketing/QfitliaUS/pdf/qfitlia_prescribing-information.pdf
5. Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. *Haemophilia*. 2020: 26(Suppl 6): 1-158. doi.org/10.1111/hae.14046
6. Young G, Srivastava A, Kavakli K, et al. Efficacy and safety of fitusiran prophylaxis in people with haemophilia A or haemophilia B with inhibitors (ATLAS-INH): a multicentre, open-label, randomised phase 3 trial. *The Lancet*. 2023;401:10386;P1427-1437. DOI: 10.1016/S0140-6736(23)00284-2