Therapeutic Class: Hemophilia Non-Factor Therapies

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: 6/15/2026

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

- Use solely for the treatment of breakthrough bleeding
- Concurrent use of more than one product in this policy.
- Concurrent use of any product in this policy with prophylactic factor VIII/IX concentrates or bypassing agents (ie, concurrent use of more than one product for routine prophylaxis).
    - Note that nonfactor therapy may be used alongside factor replacement products or bypassing agents when those agents are administered exclusively for the treatment of breakthrough bleeding episodes.
- 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	X	X
Hemlibra (emicizumab)	Any	X	X		
Hympavzi (marstacimab)	≥6 years	X	X	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:
    - Age ≥12 years: loading dose of 300 mg, then maintenance dose of 150 mg once weekly thereafter.
    - Age 6 to <12 years: loading dose of 150 mg, then maintenance dose of 75 mg once weekly thereafter.
- 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; July 2025, Accessed April 22, 2026. https://www.novo-pi.com/alhemo.pdf
2. Hemlibra. Prescribing Information. Genentech; July 2025, Accessed April 22, 2026. https://www.gene.com/download/pdf/hemlibra_prescribing.pdf
3. Hympavzi. Prescribing Information. Pfizer; December 2025, Accessed June 15, 2026. https://labeling.pfizer.com/ShowLabeling.aspx?id=20916
4. Qfitlia. Prescribing Information. Genzyme Corporation; March 2025, Accessed April 22, 2026. 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