Clinical Policy: Fitusiran (Qfitlia)

Reference Number: CP.PHAR.706
Effective Date: 03.28.25
Last Review Date: 02.26
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Fitusiran (Qfitlia®) is a small interfering ribonucleic acid (siRNA) targeting antithrombin.

FDA Approved Indication(s)

Qfitlia is indicated for the routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with hemophilia A (factor VIII [FVIII] deficiency) or B (factor IX [FIX] deficiency) with or without factor VIII or IX inhibitors.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Qfitlia is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Congenital Hemophilia A or B (must meet all)**:**

1. Prescribed for routine prophylaxis of bleeding episodes in members with one of the following (a or b):
   a. Congenital hemophilia A (FVIII deficiency);
   b. Congenital hemophilia B (FIX deficiency);
2. Prescribed by or in consultation with a hematologist;
3. Age ≥ 12 years;
4. Antithrombin (AT) activity ≥ 60%;
5. For members who are new to Qfitlia therapy and have not previously used bypassing agents, FVIII, or FIX products for routine prophylaxis: Member meets one of the following (a, b, or c):
   a. For hemophilia A: Member has severe hemophilia, defined as a FVIII level ≤ 1%;
   b. For hemophilia B: Member has moderately severe to severe hemophilia, defined as a FIX level ≤ 2%;
   c. Member has experienced at least one serious spontaneous bleed (*see Appendix D*);
6. Member meets one of the following (a or b):^
   ^For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395
   a. Failure of a bypassing agent, FVIII, or FIX* product (*see Appendix B)* used for routine prophylaxis as assessed and documented by prescriber (*see Appendix D*);
   b. Member had ≥ 6 acute bleeding episodes in the previous 6 months treated with a bypassing agent, FVIII, or FIX product;

**Prior authorization may be required for bypassing agents, FVIII, and FIX products*

7. Qfitlia is not prescribed concurrently with another hemophilia prophylaxis agent (e.g., Alhemo®, Hemlibra®, Hympavzi™, bypassing agents, FVIII or FIX products as prophylactic therapy*);
   **On-demand usage of a FVIII or FIX product may be continued*
8. Dose does not exceed 50 mg per month.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Congenital Hemophilia A or B (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy (e.g., reduction in the number of all bleeds, joint bleeds, and/or target joint bleeds over time);
3. Qfitlia is not prescribed concurrently with another hemophilia prophylaxis agent (e.g., Alhemo, Hemlibra, Hympavzi, bypassing agents, FVIII or FIX products as prophylactic therapy*);
   **On-demand usage a FVIII or FIX product may be continued*
4. If request is for a dose increase, new dose does not exceed 50 mg per month.

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AT: antithrombin
FDA: Food and Drug Administration
FVIII: factor VIII
FIX: factor IX
siRNA: small interfering ribonucleic acid

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen
FVIII products for control and prevention of bleeding episodes and/or for routine prophylaxis - examples	
Advate®, Adynovate®, Afstyla®, Altuviiio®, Eloctate®, Esperoct®, Hemofil M®, Jivi®, Kogenate FS®, Koate-DVI®, Kovaltry®, Novoeight®, Nuwiq®, Recombinate®, Xyntha®	See individual Prescribing Information for dosing regimen
FIX products for control and prevention of bleeding episodes and/or for routine prophylaxis - examples	
Alprolix®, AlphaNine® SD, BeneFIX®, Idelvion®, Ixinity®, Rebinyn®, Rixubis®	See individual Prescribing Information for dosing regimen

Drug Name	Dosing Regimen
Bypassing products for control and prevention of bleeding episodes and/or for routine prophylaxis - examples	
NovoSeven® RT, SevenFact®, Feiba®	See individual Prescribing Information for dosing regimen

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): thrombotic events, acute and recurrent gallbladder disease

Appendix D: General Information

- Examples of member responding positively to therapy may include: reduction in number of all bleeds over time, reduction in number of joint bleeds over time, or reduction in number of target joint bleeds over time.
- There are no strict criteria for failing a bypassing agent, FVIII, or FIX product for routine prophylaxis; however, the following reasons are acceptable to fulfill the criteria:
  - Prescriber has documented clinical criteria which support his or her assessment that the member has failed factor therapy.
  - Clinically significant bleeding, hemarthroses, life-threatening bleeding episodes, joint swelling, upcoming surgery/procedure not responding to current therapy, or other clinical assessment as determined by prescriber.
- Serious bleeding episodes include bleeds in the following sites: intracranial; neck/throat; gastrointestinal; joints (hemarthrosis); muscles (especially deep compartments such as the iliopsoas, calf, forearm); or mucous membranes of the mouth, nose and genitourinary tract.
- A spontaneous bleed is defined as a bleeding episode that occurs without apparent cause and is not the result of trauma.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Routine prophylaxis of bleeding episodes	Starting dose: 50 mg SC every two months Adjust the dose and/or dosing interval, if needed to maintain AT activity between 15-35%	50 mg/month

VI. Product Availability

- Single-dose prefilled pen: 50 mg/0.5 mL
- Single-dose vial for injection: 20 mg/0.2 mL

VII. References

1. Qfitlia Prescribing Information. Cambridge, MA: Genzyme Corporation; March 2025. Available at: https://www.qfitlia.com. Accessed October 23, 2025.
2. Srivastava A, Santagostino E, Dougall A, et al. WFH guidelines for the management of hemophilia. *Haemophilia*. 2020;26(suppl 6):1-158.

3. Medical and Scientific Advisory Council (MASAC) of the National Bleeding Disorders (formerly National Hemophilia Foundation): Database of treatment guidelines. Available at: https://www.bleeding.org/healthcare-professionals/guidelines-on-care/masac-documents. Accessed November 24, 2025.
4. Rezende SM, Neumann I, Angchaisuksiri P, et al. International Society on Thrombosis and Haemostasis clinical practice guideline for treatment of congenital hemophilia A and B based on the Grading of Recommendations Assessment, Development, and Evaluation methodology. J Thromb Haemost. 2024;22(9):2629-2652.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J7174	Injection, fitusiran, 0.04 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	12.03.24	02.25
Drug is now FDA approved – criteria updated per FDA labeling: maximum dosing revised; for initial approval criteria, clarified factor level limits apply only to members who are new to Qfitlia and have not previously used bypassing agents, FVIII, or FIX products for routine prophylaxis; added Commercial approval duration of 6 months or to the member's renewal date, whichever is longer to both initial and continued therapy criteria; revised continued approval duration for Medicaid & HIM to 12 months; references reviewed and updated.	04.09.25	
HCPCS code added [J7174], HCPCS codes removed [C9399, J3490].	09.11.25	
1Q 2026 annual review: revised provider confirmation of discontinuation of bypassing agents and factor products as prophylaxis to exclusion for concurrent use of hemophilia prophylaxis agent with more examples; added step therapy bypass for IL HIM per IL HB 5395; for Medicaid and HIM, revised initial approval duration from 6 months to 12 months; references reviewed and updated.	10.23.25	02.26

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional

organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.