Neighborhood Health Plan OF RHODE ISLAND™
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Qfitlia ™ (fitusiran) (Subcutaneous)

Effective Date: 11/01/2025

Review Date: 09/17/2025, 01/27/2026, 07/21/2026

Pharmacy Scope: Medicaid

Medical Scope: Medicaid, Commercial, Medicare

I. Length of Authorization

Coverage will be provided for 6 months initially and may be renewed every 6 months thereafter.

II. Dosing Limits

A. Quantity limit (max daily dose) [Pharmacy Benefit]:

- Qfitlia 50 mg/0.5 mL prefilled pen: 0.5 mL every 60 days*
- Qfitlia 20 mg/0.2 mL single-dose vial: 0.2 mL every 60 days*
- *Note: Quantity limit exceptions may be granted to increase frequency for monthly dosing based on Antithrombin (AT) activity levels.

B. Max Units (per dose and over time) [HCPCS Unit]:

- 50 mg every month*

*(*Note: Requests for dose and/or frequency higher than max allowed will be reviewed on a case-by-case basis.)*

III. Summary of Evidence

Qfitlia (fitusiran) is a subcutaneously administered small interfering RNA (siRNA) therapeutic that targets antithrombin (AT) to rebalance hemostasis in patients with hemophilia A or B, with or without inhibitors. Qfitlia is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged ≥12 years. It functions by reducing AT levels, thereby enhancing thrombin generation and improving clot formation. The efficacy and safety of Qfitlia were established in multiple Phase 3 clinical trials. The ATLAS-INH and ATLAS-A/B trials were open-label, multicenter studies enrolling a combined 177 male patients with hemophilia A or B, with or without inhibitors. The primary endpoint was annualized bleeding rate (ABR). Due to thrombotic events observed with the 80 mg fixed dose, a revised antithrombin-based dosing regimen (AT-DR) was implemented in the ATLAS-OLE extension study targeting AT activity between 15%–35%. In ATLAS-OLE, 227 patients received individualized dosing with Qfitlia under the AT-DR protocol. In ATLAS-INH, Qfitlia prophylaxis reduced ABR by 73% compared to on-demand BPA treatment. Qfitlia reduced ABR by 71% compared to on-

demand CFCs. The most common adverse reactions included viral infections, nasopharyngitis, hepatic injury, injection site reactions, and headache.

IV. Initial Approval Criteria [1-3,8,10-11]

Coverage is provided in the following conditions:

- Member is at least 12 years of age; **AND**
- Member does not have a co-existing thrombophilic disorder or a history of, or risk factors predisposing to, thrombosis; **AND**
- Will not be used for the treatment of breakthrough bleeds *(Note: On-demand factor concentrates, or bypassing agents may be administered, with a reduced dose and frequency when occurring more than 7 days after initiation of Qfitlia, on an as needed basis for the treatment of breakthrough bleeds in members being treated with Qfitlia)*; **AND**

Universal Criteria

- Member has an antithrombin (AT) activity level of ≥ 60% prior to start of therapy and AT-activity will be monitored periodically, as outlined in the prescribing information, throughout therapy; **AND**
- Member does not have hepatic impairment (Child-Pugh Class A, B and C); **AND**
- Provider will consider alternative treatments in members with a history of symptomatic gallbladder disease, or interruption/discontinuation of therapy in members with acute/recurrent gallbladder disease; **AND**
- Will NOT be used in combination with any of the following *(Note: Members may continue their prior clotting factor concentrates (CFC) or bypassing agent (BPA) prophylaxis for the first 7 days of Qfitlia treatment. Discontinue CFC or BPA prophylaxis no later than 7 days after the initial dose of Qfitlia)***see chart below*:
    - Hemophilia bypassing agent prophylaxis (i.e., factor VIIa or anti-inhibitor coagulant complex); **OR**
    - Immune tolerance induction with clotting factor products (i.e., factor VIII or factor IX concentrates) as prophylactic therapy; **OR**
    - Hympavzi for hemophilia A or B without inhibitors; **OR**
    - Alhemo for hemophilia A or B with or without inhibitors; **OR**
    - Hemlibra for hemophilia A with inhibitors**; AND**

Hemophilia *(with or without factor VIII or IX inhibitors)* † Φ

- Member has a diagnosis of severe Hemophilia A (congenital factor VIII deficiency) or Hemophilia B (congenital factor IX deficiency aka Christmas Disease) as confirmed by blood coagulation testing *[Note:*

Severity defined as a FVIII level < 1% or FIX level ≤ 2%]; **AND**

- Must be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- Used as treatment in one of the following:
  - Primary prophylaxis in members with severe factor deficiency; **OR**
  - Secondary prophylaxis in members with at least TWO documented episodes of spontaneous bleeding into joints; **AND**
- For members with Hemophilia A, they must have had an inadequate response, intolerance, or contraindication to compliant use of at least one factor VIII product (e.g., Advate, Koate/Koate DVI, Hemofil, etc. with or without bypassing agent) AND Hemlibra AND one of the following: Alhemo, or Hympavzi; **OR**
- For Members with Hemophilia B, they must have had an inadequate response, intolerance, or contraindication to compliant use of at least one factor IX product (e.g., BeneFIX, Alprolix, Idelvion, Rebinyn, etc. with or without bypassing agent [i.e., Novoseven, FEIBA, etc.]) AND Alhemo

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); **Φ** Orphan Drug

***** Drugs to treat Hemophilia A or B***

Hemophilia A & B Drug Chart	
Factor VIIa (Hemophilia A or B)	
Novoseven RT	J7189
Sevenfact	J7212
Anti-Inhibitor Coagulant Complex (Hemophilia A or B)	
Feiba	J7198
Factor VIII (Hemophilia A)	
Advate	J7192
Kogenate FS	J7192
Helixate FS	J7192

Recombinate	J7192
Kovaltry	J7211
Eloctate	J7205
Koate / Koate-DVI	J7190
Hemofil M	J7190
Novoeight	J7182
Nuwiq	J7209
Obizur	J7188
Xyntha / Xyntha Solofuse	J7185
Afstyla	J7210
Adynovate	J7207
Jivi	J7208
Esperoct	J7204
Altuviiio	J7214
Humate-P	J7187
Alphanate	J7186
Wilate	J7183
Hemlibra	J7170
Factor IX (Hemophilia B)	
AlphaNine SD	J7193
Mononine	J7193
Alprolix	J7201
Profilnine	J7194
BeneFIX	J7194

Ixinity	J7213
Rixubis	J7200
Idelvion	J7202
Rebinyn	J7203
Tissue Factor Pathway Inhibitor (Hemophilia A or B)	
Alhemo	J7173
Hympavzi	J7172
Antithrombin-Directed Double-Stranded Small Interfering Ribonucleic acid (siRNA) (Hemophilia A or B)	
Qfitlia	J7174

V. Dispensing Requirements for Rendering Providers (Hemophilia Management Program)

- Prescriptions cannot be filled without an expressed need from the member, caregiver or prescribing practitioner. Auto-filling is not allowed.
- Monthly, rendering provider must submit for authorization of dispensing quantity before delivering factor product.
- The cumulative amount of medication(s) the member has on-hand should be taken into account when dispensing factor product.
- Dispensing requirements for renderings providers are a part of the hemophilia management program. This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide

VI. Renewal Criteria [1-3,8]

Coverage can be renewed based upon the following criteria:

- Member continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section IV;

AND

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hepatotoxicity, thromboembolic events, severe gallbladder disease, etc.; **AND**
    - Member has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline); **AND**
        - Member's latest AT-activity result is categorized as one of the following:*
            - Less than 15%; **AND**
                - Reduction in dose according to package labeling *(Note: Members already receiving 10 mg every 2 months must discontinue therapy);* **OR**
            - 15 % to 35 %; **AND**
                - Continue at the current dosage; **OR**
    - Member has not achieved satisfactory bleed control compared to baseline or the member's latest AT-activity result is categorized as greater than 35% after at least 6 months*; **AND**
        - Escalation in dose and frequency according to package labeling.

**Note: Patient AT-activity should be monitored at prescribed times following the initiation of therapy and after any dose modifications, using an FDA-cleared test.*

VII. Dosage/Administration [1]

Indication	Dose
Routine Prophylaxis in Congenital Hemophilia A or Hemophilia B	The starting dose of Qfitlia is 50 mg once subcutaneously every two months. Adjust the dose and/or dosing interval, if needed, to maintain AT activity between 15-35%. Measure AT activity using an FDA-cleared test at Weeks 4 (Month 1), 12 (Month 3), 20 (Month 5) and 24 (Month 6) following the starting dose and after any dose modification. – If any AT activity is <15%, a dose reduction is required. The lower dose should be initiated 3 months after the prior dose. AT measurements should be restarted after a dose reduction. – If AT activity is >35% after 6 months, or if the patient has not achieved satisfactory bleed control, dose escalation to 50 mg monthly should be considered. AT measurements should be restarted after a dose escalation.
• After Qfitlia is initiated, patients may continue their prior clotting factor concentrates (CFC) or bypassing agent (BPA) prophylaxis for the first 7 days of treatment. Discontinue CFC or BPA prophylaxis no later than 7 days after the initial dose of Qfitlia. • Once the patient's target dose is identified based on AT activity 15-35%, measure AT activity annually. Additional AT measurements can be considered if bleeding control is not adequate. After cessation of QFITLIA dosing, routine AT monitoring is not needed unless the patient is bleeding and treatment with CFC/BPA is required. Based on data from clinical studies, a majority of patients have AT activity >60% by 6 months after the last Qfitlia dose, after which standard doses of CFC/BPA may be used.	

VIII. Billing Code/Availability Information

HCPCS Code:

- J7174 – Injection, fitusiran, 0.04 mg

NDC:

- Qfitlia 50 mg single-dose (50 mg/0.5 mL) prefilled pen: 58468-0348-xx
- Qfitlia 20 mg (20 mg/0.2 mL) single-dose vial: 58468-0347-xx

IX. References

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6. Croteau SE1, Neufeld EJ. Transition considerations for extended half-life factor products. Haemophilia. 2015 May;21(3):285-8.
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8. MASAC Recommendation Concerning Prophylaxis for Hemophilia A and B with and without Inhibitors. Revised April 27, 2022. National Hemophilia Foundation. MASAC Document #267; April 2022. Available at: https://www.bleeding.org. Accessed May 2024.
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10. Malec, L. (2024). Hemophilia A and B: Routine management including prophylaxis. Shapiro AD, Tirnauer JS (Eds.), In *UptoDate*. Last updated: October 1, 2024. Accessed April 10, 2025. Available from https://www.uptodate.com/contents/hemophilia-a-and-b-routine-management-including-prophylaxis?search=hemophilia%20treatment&source=search_result&selectedTitle=1%7E150&usage_type=default&display_rank=1.
11. Young G, Srivastava A, Kavakli K, et al. Efficacy and Safety of Fitusiran Prophylaxis, an siRNA Therapeutic, in a Multicenter Phase 3 Study (ATLAS-INH) in People with Hemophilia A or B, with Inhibitors (PwHI). Blood, Volume 138, Supplement 1, 2021, Page 4, ISSN 0006-4971, https://doi.org/10.1182/blood-2021-150273..
12. Srivastava A, Rangarajan S, Kavakli K, et al. Fitusiran prophylaxis in people with severe haemophilia A or haemophilia B without inhibitors (ATLAS-A/B): a multicentre, open-label, randomised, phase 3 trial. The Lancet Haematology, Volume 10, Issue 5, e322 - e332

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D66	Hereditary factor VIII deficiency
D67	Hereditary factor IX deficiency