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

Effective Date: 11/01/2025
Review Date: 09/17/2025
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

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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**
- Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

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**

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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;
- 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 Hemlibra 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

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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
Factor IX (Hemophilia B)	
AlphaNine SD	J7193
Mononine	J7193
Alprolix	J7201
Profilnine	J7194
BeneFIX	J7194

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Ixinity	J7213
Rixubis	J7200
Idelvion	J7202
Rebinyn	J7203

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**

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

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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 member 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, members 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 member'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 member is bleeding and treatment with CFC/BPA is required. Based on data from clinical studies, a majority of members 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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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

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Appendix 1 – Covered Diagnosis Codes

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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:
Qfitlia was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use

Qfitlia according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

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