MEDICAL MUTUAL®

Drug Policy

Policy:	**250501**	**Initial Effective Date:**
Code(s):	**HCPCS J3490, C9399**	**Annual Review Date:**
SUBJECT:	**Qfitlia ® (fitusiran)**	**Last Revised Date: 05/22/2025**

Subject to: ☐Site of Care
☐Medication Sourcing

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

I. Length of Authorization

Coverage will be provided for 6 months initially and may be renewed every 12 months thereafter.

II. Dosing Limits

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

Coverage is provided in the following conditions:

- Patient is at least 12 years of age; **AND**
- Patient 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 fitusiran, on an as needed basis for the treatment of breakthrough bleeds in patients being treated with fitusiran)*; **AND**

Universal Criteria

- Patient 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**
- Patient does not have hepatic impairment (Child-Pugh Class A, B and C); **AND**
- Provider will consider alternative treatments in patients with a history of symptomatic gallbladder disease, or interruption/discontinuation of therapy in patients with acute/recurrent gallbladder disease; **AND**
- Will NOT be used in combination with any of the following *(Note: Patients 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)*:
    - 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**
    - Emicizumab for hemophilia A with inhibitors; **AND**

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

- Patient 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 patients with severe factor deficiency; **OR**
    - Secondary prophylaxis in patients with at least TWO documented episodes of spontaneous bleeding into joints;

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

IV. Renewal Criteria [1-3,8]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hepatotoxicity, thromboembolic events, severe gallbladder disease, etc.; **AND**

- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline); **AND**
  - Patient's latest AT-activity result is categorized as one of the following:*
    - Less than 15%; **AND**
      - Reduction in dose according to package labeling *(Note: Patients already receiving 10 mg every 2 months must discontinue therapy);* **OR**
    - 15 % to 35 %; **AND**
      - Continue at the current dosage; **OR**
- Patient has not achieved satisfactory bleed control compared to baseline or the patient'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.*

V. 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.	

VI. Billing Code/Availability Information

HCPCS Code:

- J3490 – Unclassified drugs
- C9399 – Unclassified drugs or biologicals (hospital outpatient use)

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

VII. References

1. Qfitlia [package insert]. Cambridge, MA; Genzyme, Inc. March 2025. Accessed April 2025.
2. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. Revised April 11, 2024. National Hemophilia Foundation. MASAC Document #284; April 2024. Available at: https://www.bleeding.org. Accessed April 2025.
3. Guidelines for the Management of Hemophilia. 3rd Edition. World Federation of Hemophilia 2020. Available at: https://www1.wfh.org/publications/files/pdf-1863.pdf. Accessed May 2024.
4. Annual Review of Factor Replacement Products. Oklahoma Health Care Authority Review Board. Updated Dec 2020. Accessed May 2024.
5. Graham A1, Jaworski K. Pharmacokinetic analysis of anti-hemophilic factor in the obese patient. Haemophilia. 2014 Mar;20(2):226-9.
6. Croteau SE1, Neufeld EJ. Transition considerations for extended half-life factor products. Haemophilia. 2015 May;21(3):285-8.
7. Mingot-Castellano, et al. Application of Pharmacokinetics Programs in Optimization of Haemostatic Treatment in Severe Hemophilia a Patients: Changes in Consumption, Clinical Outcomes and Quality of Life. Blood. 2014 December; 124 (21).
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.
9. UKHCDO protocol for first line immune tolerance induction for children with severe haemophilia A: A protocol from the UKHCDO Inhibitor and Paediatric Working Parties. 2017. Available at: http://www.ukhcdo.org/guidelines. Accessed May 2024.

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

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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.