Drug Coverage Policy

Effective Date.....11/15/2025
Coverage Policy Number.....IP0742
Policy Title.....Qfitlia

Hemophilia – Non-Factor Routine Prophylaxis Products – Qfitlia

- Qfitlia™ (fitusiran subcutaneous injection – NovoNordisk)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview
Qfitlia, an antithrombin-directed small interfering ribonucleic acid, is indicated for the routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatric patients ≥ 12 years of age with hemophilia A or B with or without Factor VIII or Factor IX inhibitors.[1]

Qfitlia is given by subcutaneous (SC) injection only.[1] The initial dose is 50 mg SC once every 2 months (Q2M). Monitor antithrombin activity utilizing an FDA-cleared test. Maintain antithrombin activity between 15% to 35% by adjusting the dose and/or frequency of administration. Other dose regimens include: 50 mg SC once monthly (QM); 20 mg SC Q2M; 20 mg SC QM; 10 mg SC Q2M; and 10 mg SC QM. Qfitlia may be given by the patient and/or caregiver after proper training. In pediatric patients 12 to 17 years of age, Qfitlia should be given by or under supervision of an adult.

Disease Overview
Hemophilia A and B are genetic bleeding disorders caused by a dysfunction or deficiency of coagulation Factor VIII and Factor IX, respectively.[2-7] Because hemophilia is an X-linked condition, males are primarily impacted. Patients who have these types of hemophilias are not able to properly form clots in the blood and may bleed for a longer time than normal following injury or surgery. Patients may also experience spontaneous bleeding in muscles, joints, and organs. Bleeds may be life-threatening. A main morbidity is hemophilic arthropathy, which limits mobility. It is estimated that 33,000 males are living with hemophilia in the US; hemophilia A accounts for around 80% of the cases (approximately 26,400 patients) and hemophilia B comprises 20% of cases (around 6,600 patients). Hemophilias are often classified as mild, moderate, or severe based on reduced Factor VIII or IX levels. Approximately 50% and 30% of patients with hemophilia A and hemophilia B, respectively, have severe disease. The formation of inhibitors (antibodies) to factor products is a challenging complication as it causes Factor VIII and Factor IX therapies to be ineffective, which increases bleeding frequency and severity. Inhibitors develop in around 30% and 10% of patients with severe hemophilia A and hemophilia B, respectively.

Coverage Policy

Policy Statement
Prior Authorization is required for benefit coverage of Qfitlia. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Qfitlia as well as the monitoring required for adverse events and long-term efficacy, approval requires Qfitlia to be prescribed by or in consultation with a hemophilia specialist.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but not limited to, chart notes, laboratory tests, claims records, and/or other information.

Qfitlia is considered medically necessary when ONE of the following is met (1, 2, 3, or 4):

FDA-Approved Indications

1. **Hemophilia A without Factor VIII Inhibitors.** Approve for 1 year if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, iv, v, vi, and vii):
- **i.** Patient is ≥ 12 years of age; AND
- **ii.** Patient is using Qfitlia for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND
- **iii.** Patient has moderately severe to severe hemophilia A as evidenced by a baseline (without Factor VIII replacement therapy) Factor VIII level of ≤ 2% **[documentation required]**; AND
- **iv.** Patient meets ONE of the following (a or b):
  - **a)** Patient meets BOTH of the following [(1) and (2)]:
    - **(1)** Factor VIII inhibitor titer testing has been performed within the past 30 days **[documentation required]**; AND
    - **(2)** Patient does not have a positive test for Factor VIII inhibitors of ≥ 1.0 Bethesda units/mL **[documentation required]**; OR
  - **b)** Patient has not received Factor VIII therapy in the past; AND
- **v.** According to the prescriber, prophylactic use of Factor VIII products will be discontinued no later than 7 days following the initial Qfitlia dose; AND
  Note: Use of Factor VIII products for the treatment of breakthrough bleeding is permitted.
- **vi.** The medication is prescribed by or in consultation with a hemophilia specialist;
- **vii.** Preferred product criteria is met for the product(s) as listed in the below table(s) [Employer Plans]; OR

B) Patient is Currently Receiving Qfitlia. Approve if the patient meets ALL of the following (i, ii, iii, and iv):
- **i.** Patient is using Qfitlia for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND
- **ii.** According to the prescriber, prophylactic use of Factor VIII products will not occur while receiving Qfitlia; AND
  Note: Use of Factor VIII products for the treatment of breakthrough bleeding is permitted.
- **iii.** The medication is prescribed by or in consultation with a hemophilia specialist; AND
- **iv.** According to the prescriber, patient experienced a beneficial response to therapy.
  Note: Examples of a beneficial response to therapy include a reduction in bleeding events, in the severity of bleeding episodes, in the number of bleeding events that required treatment, and/or in the number of spontaneous bleeds.

2. Hemophilia A with Factor VIII Inhibitors. Approve for 1 year if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, iv, v, vi and vii):
- **i.** Patient is ≥ 12 years of age; AND
- **ii.** Patient is using Qfitlia for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND
- **iii.** Patient meets BOTH of the following (a and b):
  - **a)** Factor VIII inhibitor titer testing has been performed within the past 30 days **[documentation required]**; AND
  - **b)** Patient has a positive test for Factor VIII inhibitors of ≥ 0.6 Bethesda units/mL **[documentation required]**; AND
- **iv.** According to the prescriber, prophylactic use of bypassing agents will be discontinued no later than 7 days following the initial Qfitlia dose; AND

Note: Use of bypassing agents for the treatment of breakthrough bleeding is permitted. Examples of bypassing agents include NovoSeven RT (coagulation Factor VIIa [recombinant] intravenous infusion), Sevenfact (Factor VIIa [recombinant]-jncw intravenous infusion), and FEIBA (anti-inhibitor coagulant complex intravenous infusion).

v. Patient is not undergoing immune tolerance induction therapy; AND

vi. The medication is prescribed by or in consultation with a hemophilia specialist; AND

vii. Preferred product criteria is met for the product(s) as listed in the below table(s) [Employer Plans]; OR

B) Patient is Currently Receiving Qfitlia. Approve if the patient meets ALL of the following (i, ii, iii, iv, and v):

i. Patient is using Qfitlia for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND

ii. According to the prescriber, prophylactic use of bypassing agents will not occur while receiving Qfitlia; AND

Note: Use of bypassing agents for the treatment of breakthrough bleeding is permitted. Examples of bypassing agents include NovoSeven RT (coagulation Factor VIIa [recombinant] intravenous infusion), Sevenfact (Factor VIIa [recombinant]-jncw intravenous infusion), and FEIBA (anti-inhibitor coagulant complex intravenous infusion).

iii. Patient is not undergoing immune tolerance induction therapy; AND

iv. The medication is prescribed by or in consultation with a hemophilia specialist; AND

v. According to the prescriber, patient experienced a beneficial response to therapy.

Note: Examples of a beneficial response to therapy include a reduction in bleeding events, in the severity of bleeding episodes, in the number of bleeding events that required treatment, and/or in the number of spontaneous bleeds.

3. Hemophilia B without Factor IX Inhibitors. Approve for 1 year if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, iv, v, vi, and vii):

i. Patient is ≥ 12 years of age; AND

ii. Patient is using Qfitlia for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND

iii. Patient has moderately severe to severe hemophilia B as evidenced by a baseline (without Factor IX replacement therapy) Factor IX level of ≤ 2% **[documentation required]**; AND

iv. Patient meets ONE of the following (a or b):

a) Patient meets BOTH of the following [(1) and (2)]:

(1) Factor IX inhibitor titer testing has been performed within the past 30 days **[documentation required]**; AND

(2) Patient does not have a positive test for Factor IX inhibitors of ≥ 1.0 Bethesda units/mL **[documentation required]**; OR

b) Patient has not received Factor IX therapy in the past; AND

v. According to the prescriber, prophylactic use of Factor IX products will be discontinued no later than 7 days following the initial Qfitlia dose; AND

Note: Use of Factor IX products for the treatment of breakthrough bleeding is permitted.

vi. The medication is prescribed by or in consultation with a hemophilia specialist; AND

vii. Preferred product criteria is met for the product(s) as listed in the below table(s) [Employer Plans]; OR

B) Patient is Currently Receiving Qfitlia. Approve if the patient meets ALL of the following (i, ii, iii, and iv):
- **i.** Patient is using Qfitlia for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND
- **ii.** According to the prescriber, prophylactic use of Factor IX products will not occur while receiving Qfitlia; AND
  Note: Use of Factor IX products for the treatment of breakthrough bleeding is permitted.
- **iii.** The medication is prescribed by or in consultation with a hemophilia specialist; AND
- **iv.** According to the prescriber, patient experienced a beneficial response to therapy.
  Note: Examples of a beneficial response to therapy include a reduction in bleeding events, in the severity of bleeding episodes, in the number of bleeding events that required treatment, and/or in the number of spontaneous bleeds.

4. Hemophilia B with Factor IX Inhibitors. Approve for 1 year if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, iv, v vi, and vii):
- **i.** Patient is ≥ 12 years of age; AND
- **ii.** Patient is using Qfitlia for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND
- **iii.** Patient meets BOTH of the following (a and b):
  - **a)** Factor IX inhibitor titer testing has been performed within the past 30 days **[documentation required]**; AND
  - **b)** Patient has a positive test for Factor IX inhibitors of ≥ 0.6 Bethesda units/mL **[documentation required]**; AND
- **iv.** According to the prescriber, prophylactic use of bypassing agents will be discontinued no later than 7 days following the initial Qfitlia dose; AND
  Note: Use of bypassing agents for the treatment of breakthrough bleeding is permitted. Examples of bypassing agents include NovoSeven RT (coagulation Factor VIIa [recombinant] intravenous infusion), Sevenfact (Factor VIIa [recombinant]-jncw intravenous infusion), and FEIBA (anti-inhibitor coagulant complex intravenous infusion).
- **v.** Patient is not undergoing immune tolerance induction therapy; AND
- **vi.** The medication is prescribed by or in consultation with a hemophilia specialist; AND
- **vii.** Preferred product criteria is met for the product(s) as listed in the below table(s) [Employer Plans]; OR

B) Patient is Currently Receiving Qfitlia. Approve if the patient meets ALL of the following (i, ii, iii, iv, and v):
- **i.** Patient is using Qfitlia for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND
- **ii.** According to the prescriber, prophylactic use of bypassing agents will not occur while receiving Qfitlia; AND
  Note: Use of bypassing agents for the treatment of breakthrough bleeding is permitted. Examples of bypassing agents include NovoSeven RT (coagulation Factor VIIa [recombinant] intravenous infusion), Sevenfact (Factor VIIa [recombinant]-jncw intravenous infusion), and FEIBA (anti-inhibitor coagulant complex intravenous infusion).
- **iii.** Patient is not undergoing immune tolerance induction therapy; AND
- **iv.** The medication is prescribed by or in consultation with a hemophilia specialist; AND
- **v.** According to the prescriber, patient experienced a beneficial response to therapy.

Note: Examples of a beneficial response to therapy include a reduction in bleeding events, in the severity of bleeding episodes, in the number of bleeding events that required treatment, and/or in the number of spontaneous bleeds.

Employer Plans:

Product	Criteria
Qfitlia (fitusiran subcutaneous injection)	Patient meets ONE of the following (A, B, C or D): **A.** For Hemophilia A without Factor VIII inhibitors. **1.** Approve if the patient has tried Hemlibra **[documentation required]**; OR **2.** Approve if the patient has already been started on therapy with Qfitlia. **B.** For Hemophilia A with Factor VIII inhibitors. **1.** Approve if the patient has tried Hemlibra **[documentation required]**; OR **2.** If, according to the prescriber, there is concern for a drug-drug interaction with Hemlibra (e.g., drug-drug interaction between Hemlibra and Feiba), approve; OR **3.** Approve if the patient has already been started on therapy with Qfitlia. **C.** For Hemophilia B without Factor IX inhibitors. **1.** Approve if the patient has tried at least one of Alhemo or Hympavzi **[documentation required]**; OR **2.** Approve if the patient has already been started on therapy with Qfitlia. **D.** For Hemophilia B with Factor IX inhibitors. **1.** Approve if the patient has tried Alhemo **[documentation required]**; OR **2.** Approve if the patient has already been started on therapy with Qfitlia.

Conditions Not Covered

Qfitlia for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concurrent Use with Alhemo (concizumab-mtci subcutaneous injection), Hemlibra (emicizumab-kxwh subcutaneous injection), or Hympavzi (marstacimab-hncq subcutaneous injection.** These are also non-factor products used for routine prophylaxis in hemophilia A and/or B.[8-10] There is no evidence to support concomitant use of Qfitlia with Alhemo, Hemlibra, or Hympavzi.

Coding Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J7174	Injection, fitusiran, 0.04 mg (Code effective date 10/01/2025)

References

1. Qfitlia™ subcutaneous injection [prescribing information]. Cambridge, MA: Genzyme/Sanofi; March 2025.
2. Chowdary P, Carcao M, Kenet G, Pipe SW. Haemophilia. *Lancet*. 2025;405(10480):736-750.
3. Franchini M, Mannucci PM. The more recent history of hemophilia treatment. *Semin Thromb Hemost*. 2022;48(8):904-910.
4. Croteau SE. Hemophilia A/B. *Hematol Oncol Clin North Am*. 2022;36(4):797-812.
5. Centers for Disease Control and Prevention. Data and statistics on hemophilia. Available at: https://www.cdc.gov/hemophilia/data-research/. Accessed on June 6, 2025.
6. National Bleeding Disorders Foundation. Hemophilia A: An overview of symptoms, genetics, and treatments to help you understand hemophilia A. Available at: https://www.bleeding.org/bleeding-disorders-a-z/types/hemophilia-a. Accessed on June 6, 2025.
7. National Hemophilia Foundation. Hemophilia B. An overview of symptoms, genetics, and treatments to help you understand hemophilia B. Available at: https://www.hemophilia.org/bleeding-disorders-a-z/types/hemophilia-b. Accessed on June 6, 2025.
8. Alhemo® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; May 2025.
9. Hemlibra® subcutaneous injection [prescribing information]. South San Francisco, CA and Tokyo, Japan: Genentech/Roche and Chugai; January 2024.
10. Hympavzi™ subcutaneous injection [prescribing information]. New York, NY: Pfizer; October 2024.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	07/15/2025
Annual Revision	"Non-Factor Routine Prophylaxis Products" was added to the title of the Policy. In addition, the following changes were made: **Hemophilia A without Factor VIII Inhibitors:** For Initial Therapy, the requirement that "Patient has severe hemophilia A as evidenced by a baseline (without Factor VIII replacement therapy) Factor VIII level of < 1%" was changed to "Patient has moderately severe to severe hemophilia A as evidence by a baseline (without Factor VIII replacement therapy) Factor VIII level of ≤ 2%".	8/15/2025

	The requirement regarding prophylactic use of Factor VIII products was changed from "will not occur 7 days after the initiation of Qfitlia therapy" to "will be discontinued no later than 7 days following the initial Qfitlia dose". For a Patient Currently Receiving Qfitlia, regarding prophylactic use of Factor VIII products, the word "using" was changed to "receiving." **Hemophilia A with Factor VIII Inhibitors:** For Initial Therapy, regarding prophylactic use of bypassing agents, the phrase "will not occur 7 days after the initiation of Qfitlia therapy" was changed to "will be discontinued no later than 7 days following the initial Qfitlia dose". For a Patient Currently Receiving Qfitlia, the word "products" was removed after "bypassing agents" and "using" was changed to "receiving" regarding prophylactic use. For both Initial Therapy and for a Patient Currently Receiving Qfiltia, a requirement was added that the patient is not undergoing immune tolerance induction therapy. Previously, this was addressed in Conditions Not Recommended for Approval. **Hemophilia B without Factor IX Inhibitors:** For Initial Therapy, the requirement that patients have "moderately severe or severe hemophilia B" was changed to "moderately severe to severe hemophilia B." The requirement regarding prophylactic use of Factor IX products was changed from "will not occur 7 days after the initiation of Qfitlia therapy" to "will be discontinued no later than 7 days following the initial Qfitlia dose". For a Patient Currently Receiving Qfitlia, regarding prophylactic use of Factor IX products, the word "using" was changed to "receiving." In the Note that addresses a beneficial response, the phrase "to therapy" was added and "spontaneous bleeding events" was changed to "spontaneous bleeds." **Hemophilia B with Factor IX Inhibitors:** In Initial Therapy, regarding prophylactic use of bypassing agents, the phrase "will not occur 7 days after the initiation of Qfitlia therapy" was changed to "will be discontinued no later than 7 days following the initial Qfitlia dose". For a Patient Currently Receiving Qfitlia, the word "products" was removed after "bypassing agents" and "using" was changed to "receiving" regarding prophylactic use. For both Initial Therapy and for a Patient Currently Receiving Qfiltia, a requirement was added that the patient is not undergoing immune tolerance induction therapy while receiving Qfitlia. Previously, this was	

	addressed in Conditions Not Recommended for Approval. **Conditions Not Recommended for Approval:** Regarding Concurrent Use of Non-Factor Routine Prophylaxis Products, all agents are now listed together in one criterion. Patient Receiving Immune Tolerance Induction Therapy was removed as this is now addressed in approval criteria in patients with inhibitors.	
Selected Revision	**Added** preferred product table for Employer Plans **Coding Information:** **Added HCPCS Coding Table** with HCPCS Code J7174 with a code effective date of 10/1/2025	10/01/2025
Selected Revision	**Hemophilia A without Factor VIII Inhibitors:** For Initial Therapy, "no later than 7 days following the initial Qfitlia dose" was added to the requirement regarding prophylactic use of Factor VIII products.	11/01/2025
Selected Revision	**Updated** policy template **Updated** preferred product table for Employer Plans	11/15/2025

The policy effective date is in force until updated or retired.