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Section:	Prescription Drugs	**Effective Date:**	October 1, 2025
Subsection:	Hematological Agents	**Original Policy Date:**	May 2, 2025
Subject:	Qfitlia	**Page:**	1 of 4

Last Review Date: September 19, 2025

Qfitlia

Description

Qfitlia (fitusiran)

Background
Qfitlia (fitusiran) is an antithrombin-directed small interfering ribonucleic acid (siRNA) that causes degradation of antithrombin (AT) messenger RNA (mRNA) through RNA interference, reducing plasma AT levels (1).

Regulatory Status
FDA-approved indications: Qfitlia is an antithrombin-directed small interfering ribonucleic acid indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors (1).

Qfitlia carries boxed warnings for thrombotic events and acute and recurrent gallbladder disease. Serious thrombotic events have occurred in Qfitlia-treated patients. Antithrombin activity should be monitored with a target activity between 15-35% to reduce the risk of thrombosis. Interrupt Qfitlia prophylaxis in patients with a thrombotic event and manage as clinically indicated. Acute and recurrent gallbladder disease including cholelithiasis and cholecystitis have been associated with Qfitlia treatment. If gallbladder disease is suspected, appropriate imaging and clinical follow-up are indicated (1).

Qfitlia has been associated with hepatotoxicity. Obtain liver tests at baseline and then monthly for at least 6 months after initiating Qfitlia and after dose increases, and periodically thereafter as clinically indicated. Liver test elevations may require Qfitlia interruption or discontinuation (1).

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 (1).

The safety and effectiveness of Qfitlia in pediatric patients less than 12 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Qfitlia may be considered **medically necessary** if the conditions indicated below are met.

Qfitlia may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Hemophilia A
2. Hemophilia B

AND ALL of the following for **ALL** indications:

1. Used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
2. Prescriber agrees to monitor antithrombin activity prior to treatment and at weeks 4, 12, 20, and 24
3. Treatment will be interrupted or discontinued if gallbladder disease occurs
4. **NO** history of thrombophilia or thrombosis

Prior – Approval *Renewal* Requirements

Age 12 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Hemophilia A
2. Hemophilia B

AND ALL of the following for **ALL** indications:

1. Patient has had a clinical benefit from Qfitlia therapy (e.g., reduced bleeding episodes)
2. Used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
3. Prescriber agrees to monitor antithrombin activity prior to and after any dose modifications
4. Treatment will be interrupted or discontinued if gallbladder disease occurs

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 9 injections

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity 12 injections

Duration 12 months

Rationale

Summary
Qfitlia is an antithrombin-directed small interfering ribonucleic acid indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia A or B with or without factor VIII or IX inhibitors. Qfitlia carries boxed warnings for thrombotic events and acute and recurrent gallbladder disease. Qfitlia has also been associated with hepatotoxicity. The safety and effectiveness of Qfitlia in pediatric patients less than 12 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Qfitlia while maintaining optimal therapeutic outcomes.

References
1. Qfitlia [package insert]. Cambridge, MA: Genzyme Corporation; March 2025.

Policy History

Date	Reason
May 2025	Addition to PA
September 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.