

DRUG POLICY

Qfitlia® (fitusiran)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Qfitlia is 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

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. For initial requests:
 - a. Chart notes
 - b. Lab tests documenting all of the following (where applicable):
 - i. Severe factor VIII (factor VIII level of <1%) or IX (factor IX level of ≤ 2%) deficiency
 - ii. Baseline antithrombin (AT) activity
 - iii. Baseline hepatic assessments
2. For continuation requests:
 - a. Chart notes documenting benefit from therapy (e.g., reduced frequency or severity of bleeds)

Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following:

1. Hematologist

Criteria for Initial Approval

Hemophilia A (congenital factor VIII deficiency) and Hemophilia B (congenital factor IX deficiency)

Authorization of 12 months may be granted for hemophilia A (congenital factor VIII deficiency) and hemophilia B (congenital factor IX deficiency) when all of the following criteria are met:

1. Member is 12 years of age or older
2. Member has severe factor VIII deficiency (defined as factor VIII level of <1%) or severe factor IX deficiency (defined as factor IX level of $\leq 2\%$)
3. Member must be using the requested medication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
4. Member will not use the requested medication to treat breakthrough bleeding
5. Member does not have co-existing coagulation disorders (other than hemophilia A or B)
6. Member does not have a history of arterial or venous thromboembolism, significant valvular disease or atrial fibrillation, or co-existing thrombophilic disorder (e.g., Factor V Leiden mutation)
7. Member does not have a history of symptomatic gallbladder disease
8. Member does not have a history of or is planning to undergo immune tolerance treatment
9. Member does not have the following laboratory assessments at baseline:
 - A. Antithrombin (AT) activity < 60%
 - B. Alanine transaminase (ALT) and/or aspartate aminotransferase (AST) greater than 1.5 times the upper limit of normal (ULN)
10. Member does not have clinically significant liver disease
11. Member will not use the requested medication in combination with Alhemo, Hemlibra, or Hymoviz
12. Member has not previously received treatment with a gene therapy product (e.g., Beqvez, Hemgenix, Roctavian) for the treatment of hemophilia A or B
13. Prophylactic use of bypassing agents, factor VIII products, and factor IX products will be discontinued no later than 7 days after the initial dose of Qfitlia
14. Provider attests that AT activity and liver enzymes will be monitored per the protocol outlined in the prescribing information

Continuation of Therapy

Hemophilia A (congenital factor VIII deficiency) and Hemophilia B (congenital factor IX deficiency)

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in coverage criteria section when all of the following are met:

1. Member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds)
2. Member is not using the requested medication in combination with bypassing agents, factor VIII products (e.g., Advate, Adynovate, Eloctate) or factor IX products (e.g., Alprolix, Ixinity, Rebinyn) for prophylactic use

Other

Qfitlia (fitusiran) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing		
Qfitlia (fitusiran) 20 mg/0.2 mL solution vial 50 mg/0.5 mL solution auto-injector pen	1 vial or pen per 28 days	Initial dose: 50 mg once subcutaneously every 2 months		
		Maintenance dosage:		
		Last Dosage Administered	Antithrombin Activity Level*	Dose Modification
		50 mg every 2 months	Less than 15%	20 mg every 2 months
			15 to 35%	Continue current dosage
			Greater than 35% after 6 months	50 mg every month
		20 mg every 2 months	Less than 15%	10 mg every 2 months
			15 to 35%	Continue current dosage
			Greater than 35% after 6 months	20 mg every month
		10 mg every 2 months	Less than 15%	Discontinue Qfitlia
			15 to 35%	Continue current dosage
			Greater than 35% after 6 months	10 mg every month

* 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 dosage reduction is required. The lower dose should be initiated 3 months after the prior dose. If AT activity is >35% after 6 months, or if the patient has not achieved satisfactory bleed control, dose escalation should be considered. AT measurements should be restarted after a dose reduction or escalation. 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.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J7174 – Injection, fitusiran, 0.04 mg (effective 10/1/2025)

REFERENCES

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

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.05.91

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Revised:

Current Effective Date: August 30, 2025