Reference number(s)
6930-A

Specialty Guideline Management
Qfitlia (fitusiran)

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Qfitlia	fitusiran

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

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.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

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

For initial requests: Chart notes, lab tests documenting all of the following (where applicable):

- Severe factor VIII (factor VIII level of <1%) or IX (factor IX level of ≤ 2%) deficiency.
- Baseline antithrombin (AT) activity (<60%).

- Baseline hepatic assessments.

For continuation requests: Chart notes documenting benefit from therapy (e.g., reduced frequency or severity of bleeds).

Prescriber Specialties

The medication must be prescribed by or in consultation with a hematologist.

Coverage Criteria

Hemophilia A and Hemophilia B[1]

Authorization of 12 months may be granted for hemophilia A and hemophilia B when all of the following criteria are met:

- Member is 12 years of age or older.
- Member has severe factor VIII deficiency (defined as factor VIII level of <1%) or severe factor IX deficiency (defined as factor IX level of ≤ 2%).
- Member must be using the requested medication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
- Member will not use the requested medication to treat breakthrough bleeding.
- Member does not have co-existing coagulation disorders (other than hemophilia A or B).
- 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).
- Member does not have a history of symptomatic gallbladder disease.
- Member does not have a history of or is planning to undergo immune tolerance treatment.
- Member does not have the following laboratory assessments at baseline:
    - Antithrombin (AT) activity < 60%.
    - Alanine transaminase (ALT) and/or aspartate aminotransferase (AST) greater than 1.5 times the upper limit of normal (ULN).
- Member does not have clinically significant liver disease.
- Member will not use the requested medication in combination with Alhemo, Hemlibra, or Hympavzi.
- Member has not previously received treatment with a gene therapy product (e.g., Beqvez, Hemgenix, Roctavian) for the treatment of hemophilia A or B.
- 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.
- Provider attests that AT activity and liver enzymes will be monitored per the protocol outlined in the prescribing information.

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Continuation of Therapy

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:

- Member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds).
- 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.

References

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