Medical Necessity Guidelines
Medical Benefit Drugs
Qfitlia™ (fitusiran)

Effective: October 1, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Hemophilia is an inherited, lifelong bleeding disorder caused by a deficiency of coagulation factors. The two most common types of hemophilia are hemophilia A (Factor VIII deficiency) and B (Factor IX deficiency), and either type can lead to spontaneous bleeding and prolonged bleeding following an injury or surgical procedure. There are varying severities of hemophilia A and B depending on the level of factor produced by the patient. Severe hemophilia frequently results in bleeding even in the absence of trauma; moderate hemophilia is associated with less bleeding, and mild hemophilia usually results in bleeding only after obvious trauma. Historically hemophilia treatment involves replacing the deficient coagulation factor through episodic (on-demand) treatment or prophylaxis. Newer, easier-to-administer products have provided options for the management of patients with hemophilia A and B and include Qfitlia. Qfitlia is an antithrombin (AT)-directed small interfering ribonucleic acid (siRNA). Qfitlia works by reducing plasma AT levels which is expected to reduce or prevent the frequency of bleeding episodes. AT is a key protein involved in the clotting cascade.

Approval of Qfitlia was based on the ATLAS-A/B and ATLAS-INH clinical trials. The trials included adult and pediatric patients 12 years of age and older with hemophilia A or B with (ATLAS-INH) or without (ATLAS-A/B) inhibitors. A total of 57 patient were enrolled in ATLAS-INH and a total of 120 patients were enrolled in ATLAS-A/B. In both trials, patients were randomized 2:1 to receive Qfitlia prophylaxis at a fixed dose of 80 mg, administered subcutaneously monthly or bypassing agents or clotting factor concentrates (depending on the study) on demand for treatment of breakthrough bleeding episodes for 9 months. The primary efficacy endpoint was annualized bleeding rate (ABR) of treated bleeds. In patients with inhibitors (ATLAS-INH), Qfitlia reduced ABR by 73% compared with on demand treatment with bypassing agents. In patients without inhibitors (ATLAS-A/B), Qfitlia reduced ABR by 71% versus on demand treatment with clotting factor.

Food and Drug Administration - Approved Indications:

Qfitlia (fitusiran) 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.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Qfitlia for Members when **ALL** the following criteria is met:

Initial Authorization Criteria

1. Documented diagnosis of hemophilia A or B

AND

2. Documentation for use as prophylaxis to prevent or reduce the frequency of bleeding episodes

AND

3. Documentation of **one (1)** of the following:
    a. Less than 1% of endogenous factor VIII for hemophilia A
    b. Less than or equal to 2% of endogenous factor IX for hemophilia B

AND

4. The patient is at least 12 years of age or older

AND

5. Prescribed by or in consultation with a hematologist

Reauthorization Criteria

1. Documented diagnosis of hemophilia A or B

AND

2. The patient is at least 12 years of age or older

AND

3. Prescribed by or in consultation with a hematologist

AND

4. Documentation the Member has experienced a therapeutic response from Qfitlia as defined by a reduction in the frequency of bleeds

Limitations

- Coverage of Qfitlia will be authorized for 12 months
- Members new to the plan stable on Qfitlia should be reviewed against Reauthorization Criteria.

Codes

None

References

1. Qfitlia (fitusiran) [package insert]. Cambridge, MA; Genzyme Corporation: March 2025.
2. Srivastava A, 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. Lancet Haematol. 2023;10(5):e322–e332.
3. Young G, et al. Efficacy and safety of fitusiran prophylaxis in people with haemophilia A or haemophilia B with inhibitors (ATLAS-INH): a multicentre, open-label, randomised Phase 3 trial. Lancet. 2023;401(10386):1427–1437.
4. Young G, et al. Safety and efficacy of a fitusiran antithrombin-based dose regimen in people with hemophilia A or B: the ATLAS-OLE study. Blood. 2025.
5. Alok Srivastava et al on behalf of the WFH Guidelines for the Management of Hemophilia panelists and co-authors. World Federation of Hemophilia guidelines for the management of hemophilia. 3rd edition. 2020. Accessed February 2025. Available at: https://elearning.wfh.org/resource/treatment-guidelines/.

Approval And Revision History

July 8, 2025: Reviewed by Pharmacy and Therapeutics Committee (P&T).

September 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/25).

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.