Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Qfitlia (fitusiran)

Effective: July 14, 2026

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

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 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

Food and Drug Administration (FDA) - 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** of the following criteria are 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

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J7174	Injection, fitusiran, 0.04 mg

References

1. Qfitlia (fitusiran) [package insert]. Cambridge, MA; Genzyme Corporation: September 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 June 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) (eff 8/1/25).

Subsequent endorsement date(s) and changes made:

- October 2025: Administrative update to HCPCs Codes: Added J Code, J7174 to guideline effective 10/1/25.
- July 14, 2026: Administrative updates: Template updated to remove CareLink from the Medical Necessity Guideline template. Template updated from “Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans” to “Tufts Health Together- MassHealth Accountable Care Partnership Plans.”

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is 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.