Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Altuviiio [antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl]

Effective: September 15, 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 – Approved Indications

Altuviiio [antihemophilic factor (recombinant), Fc-VWF-TEN fusion protein-ehtl] is a recombinant DNA-derived, Factor VIII concentrate indicated for use in for adults and children with Hemophilia A (congenital Factor VIII deficiency) for:

- Routine prophylaxis to reduce the frequency of bleeding episodes
- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding

Altuviiio is not indicated for the treatment of von Willebrand disease.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Altuviiio [antihemophilic factor (recombinant),Fc-VWF-XTEN fusion protein-ehtl] for Members when **ALL** the following clinical criteria is met:

Initial Authorization Criteria

1. Documented diagnosis of hemophilia A

AND

2. Documentation the requested medication is being prescribed for **one (1)** of the following:
    a. Routine prophylaxis to reduce the frequency of bleeding episodes
    b. On-demand treatment and control of bleeding episodes
    c. Perioperative management of bleeding

AND

3. Prescribed by or in consultation with a hematologist

Reauthorization Criteria

1. Prescribed by or in consultation with a hematologist

AND

2. Documentation the Member has experienced a therapeutic response from Altuviiio as defined by at least **one (1)** of the following:
    a. Reduced frequency of bleeds
    b. Reduced severity of bleeds

Limitations

- Coverage of Altuviiio for routine prophylaxis to reduce the frequency of bleeding episodes and on-demand treatment and control of bleeding episodes will be authorized for 12 months.
- Coverage of Altuviiio for perioperative management of bleeding will be authorized for three (3) months.
- Members new to the plan stable on Altuviiio should be reviewed against Reauthorization Criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J7214	Injection, Factor VIII/von Willebrand factor complex, recombinant (Altuviiio), per Factor VIII IU

References

1. Altuviiio [antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl] [package insert]. Waltham, MA; Bioverativ Therapeutics, Inc.: December 2025.
2. National Hemophilia Foundation. Hemophilia A. Accessed July 1, 2024. https://www.hemophilia.org/bleedingdisorders-a-z/types/hemophilia-a.
3. von Drygalski A, et al. Efanesoctocog Alfa Prophylaxis for Patients with Severe Hemophilia A. N Engl J Med 2023;388:310-318.

Approval And Revision History

May 9, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

- April 19, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)
- September 12, 2023: Updated diagnosis requirements and use requirements. Removed the requirement that the Member does not have von Willebrand disease. Added Reauthorization Criteria. Clarified the duration of approvals rules. Removed the following Limitation: “The Plan will cover Altuviiio when Plan Criteria, is met or if the Member has severe disease with frequent bleeding episodes and/or frequency hospitalization” (effective 12/1/23).
- October 1, 2023: Administrative update: Added new J Code J7214 to Medical Necessity Guideline
- August 13, 2024: No changes. Consolidated Tufts Health RITogether and Commercial Products coverage criteria into one Medical Necessity Guideline (eff 9/1/24).
- June 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template
- September 9, 2025: no changes.
- September 15, 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.