Medical Necessity Guidelines

Medical Benefit Drugs

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

Effective: January 1, 2026

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

Applies to:

Public Plans Products

☒ 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

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 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 A 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 include Altuviiio. Altuviiio temporarily replaces the missing coagulation FVIII needed for effective hemostasis. Altuviiio is a recombinant FVIII analog fusion protein that is independent of endogenous von Willebrand factor (VWF) in order to overcome the half-life limit imposed by FVIII-VWF interactions

Approval of Altuviiio was based on the prospective, open-label XTEND-1 (adults and adolescents ≥12 years of age) and XTENDKids (children <12 years) trials. In both trials, patients have severe hemophilia A and are previously treated. In XTEND-1 133 of these patients received once-weekly Altuviiio as routine prophylaxis for 52 weeks, and 26 patients received Altuviiio as an on-demand treatment for 16 weeks, and then as routine prophylaxis for 26 weeks. Patients with at least 26 weeks of exposure to once-weekly Altuviiio prophylaxis, the median and mean annualized bleeding rates were 0 and 0.7, respectively. In XTEND-Kids, Altuviiio provided high, sustained FVIII levels throughout the weekly dosing interval, with a median annualized bleeding rate of 0 and an estimated mean annualized bleeding rate of 0.9. No FVIII inhibitors were observed any participant during the 52-week study period.

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 for Members when **ALL** the following criteria are 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 patient has experienced a positive 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 with 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.: Ma 2024.
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)

Subsequent endorsement date(s) and changes made:

- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024
- September 12, 2023: Updated diagnosis requirements and use requirements. Removed the requirement that the Member does not have von Willebrand disease. 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” Added Reauthorization Criteria. (effective 12/1/23).
- October 1, 2023: Administrative update: Addition of new HPHC code: Added new J Code J7214 to Medical Necessity Guideline.
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- August 13, 2024: No changes (eff 10/1/24)
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

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.