

Altuviiiio™ (antihemophilic factor [recombinant], Fc-VWF-XTEN fusion protein-eh1)

Effective: July 1, 2023

Prior Authorization Required If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
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Applies to:

Commercial Products

- Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
- Tufts Health Plan Commercial products; Fax 617-673-0988
CareLinkSM – Refer to CareLink Procedures, ServicesSM and Items Requiring Prior Authorization

Public Plans Products

- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
 - Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
 - Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
 - Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
- *The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products

- Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
- 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 X-linked recessive genetic disorder that primarily affects males, although in rare cases, females can have the disorder. It is caused by mutations in the genes that encode for coagulation factors. This causes bleeding into soft tissue, joints, and internal organs. It can also cause severe bleeding and death in traumatic incidences. Treatment is designed to replace the missing factor.

There are two types of hemophilia: hemophilia A is caused by a deficiency in coagulation factor VIII (FVIII), and hemophilia B is caused by a deficiency in coagulation factor IX (FIX) also known as fibrin stabilizing factor. Hemophilia A is four times as common as hemophilia B. In the United States, the estimated prevalence of hemophilia A is 12 cases per 100,000 males and the estimated incidence of hemophilia A is 1 case per 5617 live male births. The diagnosis is usually made in the first year or two of life. Hemophilia is a lifelong disorder with no cure at the present time. Studies using gene therapy are showing promising results, providing hope that a cure will be available in the future. The burden of illness is significant for patients with hemophilia, and the management of severe hemophilia can be complicated and extremely costly. The severity of the disease is determined by the amount of clotting factor in the blood and is typically separated into three categories:

- Mild disease: 5–40 IU/dL or 5%–40% of normal factor levels
- Moderate disease: 1–5 IU/dL or 1%–5% of normal factor levels
- Severe disease: <1 IU/dl or <1% of normal factor levels

Food and Drug Administration (FDA) Approved Indications:

- Altuviiiio is a novel recombinant DNA Factor VIII product indicated for use in for adults and children with Hemophilia A (congenital Factor VIII deficiency) for: (1) Routine prophylaxis to reduce the frequency of bleeding episodes; (2) On-demand treatment and control of bleeding episodes; and (3) Perioperative management of bleeding.

Clinical Guideline Coverage Criteria

The Plan may cover Altuviiiio when all the following clinical criteria is met:

1. The Member has a diagnosis of severe (<1%) congenital FVIII deficiency (hemophilia A)
OR
2. Member has mild to moderate disease as defined by Factor VIII levels greater than 2% to less than 40% of normal and has one of the following:
 - a. Currently been on other agents for prophylactic control
OR
 - b. On-demand treatment and control of bleeding episodes
OR
 - c. Perioperative management of bleeding
AND
3. Altuviiiio is being prescribed by or in consultation with a hematologist
AND
4. Member does not have von Willebrand disease

Limitations

- The Plan will cover Altuviiiio when Plan Criteria, is met or if the Member has severe disease with frequent bleeding episodes and/or frequency hospitalization.
- The Plan will cover Altuviiiio for 1 year for severe FVIII deficiency (<1%)
- The Plan will cover Altuviiiio for 1 year for mild to moderate FVIII deficiency (2%-40%)
- The Plan will cover Altuviiiio for management of surgical prophylaxis for a 3-month period.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

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

References:

1. Altuviiiio (Fc-VWF-XTEN) Payor & Provider Insights; Aventura, FI 03.23
2. Altuviiiio (Fc-VWF-XTEN) Medical professional Reference; New York NY <https://www.empr.com/home/news/altuviiiio-approved-as-once-weekly-factor-viii-therapy-for-hemophilia>
3. Altuviiiio (Fc-VWF-XTEN) [package insert] Up to date Clinical Manifestations and diagnosis of hemophilia;2023 <https://www.uptodate.com/contents/clinical-manifestations-and-diagnosis-of-hemophilia>
4. Altuviiiio (Fc-VWF-XTEN) [package insert]. town, state. Bioverativ Therapeutics Inc. April 2023.

Approval And Revision History

April 19, 2023: Reviewed by the Medical Policy Approval Committee (MPAC),

May 9, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T), effective July 1, 2023

Subsequent endorsement date(s) and changes made:

- October 1, 2023: Administrative update: Addition of new HPHC code: Added new J Code J7214 to Medical Necessity

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.