Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Factor Products

Effective: June 1, 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

Hemophilia A (factor VIII [factor 8] deficiency) and hemophilia B (factor IX [factor 9] deficiency) are X-linked coagulation factor disorders associated with bleeding of variable severity, from life-threatening to clinically silent. The severity of bleeding manifestations in hemophilia generally correlates with the degree of the clotting factor deficiency. The primary clinical hallmarks of hemophilia are prolonged spontaneous and/or traumatic hemorrhages, most commonly within the musculoskeletal system and predominantly intra-articular bleeding into the large synovial joints. The aim of management of specific hemorrhages is to treat the bleed and prevent bleed recurrence, limit complications, and restore tissue and/or organ function to a pre-bleed state. The ideal is for patients to not experience any bleeds (i.e., achieve “zero” bleeds); therefore, all forms of prophylaxis provide superior benefits over episodic therapy. Prophylaxis in hemophilia consists of regular administration of therapeutic products aimed at maintaining hemostasis to prevent bleeding, especially joint hemorrhages, which would lead to arthropathy and disability. The severity of bleeding manifestations in hemophilia generally correlates with the degree of the clotting factor deficiency. For patients with hemophilia (clotting factor level <1% of normal) A or B with a severe phenotype (clotting factor level <1% of normal), it is recommended that such patients be on prophylaxis sufficient to prevent bleeds at all times. Prophylaxis should be individualized, taking into consideration patient bleeding phenotype, joint status, individual pharmacokinetics, and patient self-assessment and preference. All forms of prophylaxis provide superior benefits over episodic therapy. Per the World Health Federation, in order to optimize treatment and make economically sound clinical decisions, objective evidence of both short and long-term outcomes of hemophilia treatment regimens is required. Frequency of bleeding (particularly joint and muscle bleeds) and response to treatment have been the most important indicators of the effectiveness of hemostatic therapy and the best surrogate predictors of long-term musculoskeletal outcomes.

von Willebrand disease (VWD) is a common, inherited bleeding disorder. Patients with VWD experience excessive mucocutaneous bleeding, including heavy menstrual bleeding, epistaxis, easy bruising, prolonged bleeding from minor wounds and the oral cavity, and gastrointestinal bleeding, as well as bleeding after dental work, childbirth, and surgery, with musculoskeletal bleeding also seen in the most severe cases. Treatment includes adjunctive therapies, such as tranexamic acid, and therapies that directly increase the levels of VWF, such as desmopressin and VWF concentrates. Treatment is individualized based on specific diagnosis, bleeding phenotype, and specific clinical context.

Antihemophilic Coagulation Factor VIII (Recombinant) agents

- Advate, Adynovate, Afstyla®, Eloctate®, Esperoct®, Jivi®, Kovaltry®, Novoeight®, Nuwiq®, Obizur®, Recombinate, and Xyntha®

Antihemophilic Coagulation Factor VIII (Plasma-derived) agents

- Hemofil M, Koate® DVI, and Monoclate-P®

Antihemophilic Coagulation Factor VIII/von Willebrand factor Complex (Plasma-derived) agents

- Alphanate®, Humate-P®, and Wilate®

Coagulation Factor IX (Recombinant) agents

- Alprolix®, BeneFIX®, Idelvion®, Ixinity®, Rebinyn®, and Rixubis

Coagulation Factor IX (Plasma-derived) agents

- AlphaNine® SD and Mononine®

Factor IX Complex (Plasma-derived) agents

- Profilnine® SD

Coagulation Factor X (Plasma-derived) agent

- Coagadex®

Factor XIII Concentrate (Recombinant) agent

- Tretten®

Factor XIII Concentrate (Plasma-derived) agent

- Corifact®

Coagulation Factor VIIa (Recombinant) agent

- NovoSeven® RT, Sevenfact®

Anti-inhibitor Coagulant Complex (Plasma-derived) agent

- FEIBA NF

Von Willebrand factor (Recombinant) agent

- Vonvendi

Clinical Guideline Coverage Criteria

Initial Authorization Criteria

Factor Products (excluding Coagadex, Corifact, Jivi, Tretten, and Vonvendi)

The plan may authorize coverage of a Factor Product for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of hemophilia A, hemophilia B, or von Willebrand disease

AND

2. Documentation of **one (1)** of the following:
    a. Treatment and/or management of acute bleeding in Members with severe hemophilia, and maintenance therapy as needed to maintain trough factor levels at 1% or greater
    b. Treatment and/or management of acute bleeding episodes for Members with mild hemophilia (factor levels > 5% and <30%) or moderate hemophilia (factor levels of 1% - 5%), such as bleeding episodes associated with surgery or trauma
    c. Treatment and/or management of acute bleeding in Members with von Willebrand disease, and in clinical situations in which patients with von Willebrand disease are at increased risk of bleeding (i.e., surgery or trauma)
    d. Treatment and/or management of significant menorrhagia in women with von Willebrand disease

Coagadex (Coagulation Factor X [Human])

The plan may authorize coverage of Coagadex for Members when the following criteria are met:

1. Documented diagnosis of hereditary Factor X (FX) deficiency

AND

2. Documentation of **one (1)** of the following:
    a. Use as on-demand treatment and control of bleeding episodes
    b. Use as perioperative management of bleeding in patients with mild hereditary Factor X deficiency

Corifact (Factor XIII Concentrate [Human])

The plan may authorize coverage of Corifact for Members when the following criteria are met:

1. Documented diagnosis of congenital Factor XIII (FXIII) deficiency

AND

2. Documentation of **one (1)** of the following:
    a. Use as routine prophylactic treatment of congenital FXIII deficiency in clinical situations in which Members are at increased risk of bleeding (i.e., surgery)
    b. Use as perioperative management of surgical bleeding

Jivi (Factor VIII concentrate [recombinant])

The plan may authorize coverage of Jivi for Members when the following criteria are met:

1. Documented diagnosis of hemophilia A (congenital Factor VIII) deficiency

AND

2. Documentation of **one (1)** of the following:
    a. Use as on-demand treatment and control of bleeding episodes
    b. Use as perioperative management of bleeding
    c. Routine prophylaxis to reduce bleeding episodes

AND

3. The patient is at least 7 years of age or older

AND

4. The patient has been previously treated

NovoSeven or NovoSeven RT (Coagulation Factor VIIa [recombinant])

In addition to the above Factor Products criteria, the plan may authorize coverage of NovoSeven or NovoSeven RT for Members when the following criteria are met:

1. Documented diagnosis of acquired hemophilia or congenital factor VII deficiency

AND

2. Documented use as treatment and/or management of acute bleeding episodes or in clinical situations in which patients are at increased risk of bleeding (e.g., surgery, trauma)

Tretten (Coagulation Factor XIII A-Subunit [Recombinant])

The plan may authorize coverage of Tretten for Members when all of the following criteria are met:

1. Documented diagnosis of congenital factor XIII A-subunit deficiency

AND

2. Documented use as routine prophylaxis of bleeding

Vonvendi (von Willebrand Factor [Recombinant])

The plan may authorize coverage of Vonvendi for Members when all of the following criteria are met:

1. Documented diagnosis of von Willebrand disease

AND

2. The patient is at least 18 years old or older

AND

3. Documentation why treatment with Alphanate, Humate-P, and Wilate is not clinically appropriate

Reauthorization Criteria

The plan may authorize coverage of a Factor Product, Coagadex, Corifact, Jivi, NovoSeven/NovoSeven RT, and Tretten for Members when **ALL** of the following criteria are met:

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

Limitations

- Coverage of Factor Products 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 Factor Products for perioperative management of bleeding will be authorized for three (3) months.
- Members new to the plan stable on a Factor Product should be reviewed against Reauthorization Criteria.
- For Commercial Products and Tufts Health RITogether, the designated provider will contact a Health Plan Care Manager when they identify that a Member does not meet the Health Plan Clinical Criteria, or if the Member has severe disease with an inhibitor titer, frequent bleeding episodes and/or frequency hospitalization, or who may benefit from case management services.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J7175	Injection, factor X, (human), 1 IU (Coagadex)
J7179	Injection, Von Willebrand Factor (recombinant), (Vonvendi), 1 IU
J7180	Injection, factor XIII (antihemophilic factor, human), 1 IU
J7181	Injection, factor XIII A-subunit, (recombinant), per IU
J7182	Injection, factor VIII, (antihemophilic factor, recombinant), (Novoeight), per IU
J7183	Injection, von Willebrand factor complex (human), Wilate, 1 IU
J7185	Injection, factor VIII (antihemophilic factor, recombinant) (Xyntha), per IU
J7186	Injection, antihemophilic factor VIII/Von Willebrand factor complex (human), per factor VIII I.U.
J7187	Injection, Von Willebrand factor complex (Humate-P), per IU
J7188	Injection, factor VIII (antihemophilic factor, recombinant), (Obizur), per IU
J7189	Factor VIIa (antihemophilic Factor, recombinant), per 1mcg
J7190	Factor VIII (antihemophilic factor [human]) per IU
J7192	Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified
J7193	Factor IX (antihemophilic factor, purified, non-recombinant) per IU
J7194	Factor IX, complex, per IU
J7195	Factor IX (antihemophilic factor, recombinant) per IU
J7198	Anti-inhibitor, per IU
J7199	Hemophilia clotting factor, not otherwise classified
J7200	Injection, factor IX, (antihemophilic factor, recombinant), Rixubis, per IU
J7201	Injection, factor IX, Fc fusion protein (recombinant), Alprolix, per IU
J7202	Injection, factor IX, albumin fusion protein, (recombinant), Idelvion, 1 IU
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu
J7205	Injection, factor VIII, Fc fusion protein, (recombinant), per IU
J7207	Injection, factor VIII, (antihemophilic factor, recombinant), pegylated, 1 IU (Adynovate)
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u
J7209	Injection, factor VIII, (antihemophilic factor, recombinant), (Nuwiq), 1 IU
J7210	Injection, factor VIII, (antihemophilic factor, recombinant), (Afstyla), 1 IU
J7211	Injection, factor VIII, (antihemophilic factor, recombinant), (Kovaltry), 1 IU
J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram
J7213	Injection, coagulation factor IX (recombinant)
J7204	Injection, Factor VIII, antihemophilic factor (recombinant), (Esperoct), glycopegylated-exei, per IU

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Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T).

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).

Subsequent endorsement date(s) and changes made:

- September 12, 2023: Coverage for Senior Products and Tufts Health Unify apply to the Medical Necessity Guideline. Added Reauthorization Criteria to the Medical Necessity Guideline. Minor wording updates to clarify coverage. Removed the Limitations Coverage of Tretten will not be authorized for the diagnosis of congenital factor XIII B-subunit deficiency and Coverage of Coagadex will not be authorized for perioperative management of bleeding in major surgery in members with moderate and severe hereditary Factor X deficiency (effective 12/1/2023).
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- August 13, 2024: No changes. Administrative update to remove Medicare Products from the Medical Necessity Guideline (MNG). Medicare Products will have a separate MNG due to support CMS requirements (eff 10/1/24).

- April 2026: Administrative update: Added J code for Ixinity (J7213), effective 7/1/23.
- June 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template
- May 12, 2026: Effective June 1, 2026, Added expanded indication for Jivi, for pediatric patients age 7 and up and made administrative update to template to remove CareLink from the Medical Necessity Guideline template. Administrative update: updated template to read: “Tufts Health Together- MassHealth Accountable Care Partnership Plans; Fax 617-673-0939”, to reflect change.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be 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 the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy 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 Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

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.