Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Medical Benefit Drugs
Hympavzi™ (marstacimab-hncq)

Effective: October 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
CareLink℠ – Refer to CareLink Procedures, Services 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 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 and B 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 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 B and include Hympavzi. Hympavzi is a tissue factor pathway inhibitor (TFPI) antagonist. Hympavzi works by reducing the amount, and therefore, the activity of, the naturally occurring anticoagulation protein TFPI. This results in increased amounts of thrombin, an enzyme that is critical in blood clotting.

Approval of Hympavzi was based on the BASIS trial which included 116 patients (aged 12 years and older and ≥35 kg) with severe hemophilia A (factor activity less than 1%) without FVIII inhibitors or moderately severe to severe hemophilia B (factor activity 1 to 2%) without FIX inhibitors. After a six-month observation phase, patients were enrolled to two cohorts based on the factor replacement treatment they were receiving prior to trial entry (on-demand or routine prophylaxis). Most patients were previously receiving routine prophylaxis. Patients who completed the observation phase received 12 months of Hympavzi. Treatment with Hympavzi experienced a reduction in annualized bleeding rate of 35% and 92% compared to routine prophylaxis and on-demand treatment, respectively.

Results from the Phase 3 BASIS trial (NCT03938792) supported the approval of Hympavzi in adults and adolescents 12 years and older with hemophilia A or B with inhibitors. The results demonstrated the superiority of Hympavzi in improving key bleeding outcomes including significantly reducing mean treated annualized bleeding rate (ABR) by 93% compared to on-demand (OD) intravenous treatment with bypassing agents (1.4 [95% CI: 0.9-2.3] vs.19.8 [95% CI: 16.1-24.3]; p<0.0001).

Food and Drug Administration (FDA) - Approved Indications:

Hympavzi (marstacimab-hncq) is a tissue factor pathway inhibitor (TFPI) antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding in episodes in adult and pediatric patients 6 years of age and older with hemophilia

A or hemophilia B, with or without inhibitors

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Hympavzi 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 6 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 6 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 Hympavzi as defined by a reduction in the frequency of bleeds

Limitations

- Coverage of Hympavzi will be authorized for 12 months
- Members new to the plan stable on Hympavzi should be reviewed against Reauthorization Criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J7172	Injection, marstacimab, 0. 5 mg

References

1. Hympavzi (marstacimab-hncq) [package insert]. San Francisco, CA; Genentech, Inc.: October 2024.
2. Mahlangu JN, et al. A phase 1b/2 clinical study of marstacimab, targeting human tissue factor pathway inhibitor, in haemophilia. Br J Haematol. 2023;200(2):229–239.
3. Mahlangu J, et al. Long-term safety and efficacy of the anti-tissue factor pathway inhibitor marstacimab in participants with severe haemophilia: Phase II study results. Br J Haematol. 2023;200(2):240–248.
4. 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 February 2025. Available at: https://elearning.wfh.org/resource/treatment-guidelines/.

Approval And Revision History

March 11, 2025: Reviewed by Pharmacy and Therapeutics Committee (P&T).

March 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 4/1/25)
Subsequent endorsement date(s) and changes made:

- July 2025 Administrative Updates: Added J Code, J7172 and removed C Code, C9304 update effective 7/1/25.
- September 2026: Joint Medical Policy and Health Care Services UM Committee review (effective 10/1/26): Updated criteria to reflect expanded indication for Hympavzi (marstacimab-hncq) to include the treatment of patients with hemophilia A or B

12 years and older with inhibitors and pediatric patients (ages 6 to 11 years) with or without inhibitors

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.