BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.85.065

Section:	Prescription Drugs	**Effective Date:**	July 1, 2026
Subsection:	Hematological Agents	**Original Policy Date:**	December 6, 2024
Subject:	Hympavzi	**Page:**	1 of 4

Last Review Date: June 11, 2026

Hympavzi

Description

Hympavzi (marstacimab-hncq)

Background
Hympavzi (marstacimab-hncq) is a human monoclonal IgG1 antibody directed against the Kunitz domain 2 (K2) of tissue factor pathway inhibitor (TFPI) to neutralize TFPI activity and enhance coagulation. TFPI is the primary inhibitor of the extrinsic coagulation cascade and negatively regulates thrombin generation within the extrinsic pathway of coagulation by inactivating the protease functions of FXa/FVIIa/TF complex. TFPI binds to and inhibits the factor Xa active site via its second Kunitz inhibitor domain (K2) (1).

Regulatory Status
FDA-approved indications: Hympavzi is a tissue factor pathway inhibitor (TFPI) antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with: (1)

- hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, or
- hemophilia B (congenital factor IX deficiency) without factor IX inhibitors.

Hympavzi has been associated with thromboembolic events, hypersensitivity reactions, and embryofetal toxicity. Hympavzi treatment may increase the risk of thromboembolic complications. Treatment should be interrupted if diagnostic findings consistent with thromboembolism occur and managed as clinically indicated. Hympavzi may cause

hypersensitivity reactions (including, but not limited to urticaria and pruritus). If a severe hypersensitivity reaction occurs, advise patients to discontinue Hympavzi and seek immediate emergency treatment. Hympavzi may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with Hympavzi and for 2 months after the last dose (1).

The safety and effectiveness of Hympavzi in pediatric patients less than 12 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Hympavzi may be considered **medically necessary** if the conditions indicated below are met.

Hympavzi may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Hemophilia A (congenital factor VIII deficiency)
   a. Severe factor VIII deficiency at baseline (factor VIII level < 1%)
   b. No detectable level or documented history of factor VIII inhibitors
2. Hemophilia B (congenital factor IX deficiency)
   a. Moderately severe to severe factor IX deficiency at baseline (factor IX level of ≤ 2%)
   b. No detectable level or documented history of factor IX inhibitors

AND ALL of the following for **ALL** indications:

1. Used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes

2. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Hympavzi and for 2 months after the last dose

Prior – Approval *Renewal* Requirements

Age 12 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Hemophilia A (congenital factor VIII deficiency)
   a. No detectable level or documented history of factor VIII inhibitors
2. Hemophilia B (congenital factor IX deficiency)
   a. No detectable level or documented history of factor IX inhibitors

AND ALL of the following for **ALL** indications:

1. Patient has had a clinical benefit from Hympavzi therapy (e.g., reduced bleeding episodes)
2. Used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
3. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Hympavzi and for 2 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 24 injections per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Hympavzi is a TFPI antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors or hemophilia B (congenital factor IX deficiency) without factor IX inhibitors. Hympavzi has been associated with thromboembolic events, hypersensitivity reactions, and embryofetal toxicity. The safety and effectiveness of Hympavzi in pediatric patients less than 12 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Hympavzi while maintaining optimal therapeutic outcomes.

References
1. Hympavzi [package insert]. New York, NY: Pfizer Inc.; December 2025.

Policy History

Date	Reason
December 2024	Addition to PA
March 2025	Annual review
June 2025	Annual review
June 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.