

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 1473-1
Program	Prior Authorization/Notification
Medication	Hypavzi™ (marstacimab-hncq)
P&T Approval Date	3/2025
Effective Date	7/1/2025

1. Background:

Hypavzi (marstacimab-hncq) 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:

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

2. Coverage Criteria^a:

A. Hemophilia A Without Inhibitors

1. Initial Authorization

a. Hypavzi will be approved based on **all** of the following criteria

1) Diagnosis of hemophilia A

-AND-

2) Patient is 12 years of age or older

-AND-

3) Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)

-AND-

4) Patient does not have a history of inhibitors to factor VIII

Authorization of therapy will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Hypavzi therapy

Authorization will be issued for 12 months.

B. Hemophilia B Without Inhibitors

1. Initial Authorization

<p>a. Hypavzi will be approved based on all of the following criteria</p> <p>1) Diagnosis of hemophilia B</p> <p style="text-align: center;">-AND-</p> <p>2) Patient is 12 years of age or older</p> <p style="text-align: center;">-AND-</p> <p>3) Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis)</p> <p style="text-align: center;">-AND-</p> <p>4) Patient does not have a history of inhibitors to factor IX</p> <p>Authorization of therapy will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p> <p>a. Documentation of positive clinical response to Hypavzi therapy</p> <p>Authorization will be issued for 12 months.</p> <p>^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</p>
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3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Medical Necessity may be in place.

4. References:

1. Hypavzi™ [package insert]. New York, NY: Pfizer Inc., October 2024.

Program	Prior Authorization/Notification - Hypavzi (marstacimab-hncq)
Change Control	
3/2025	New program.