

ALASKA MEDICAID
Prior Authorization Criteria

**Hypavzi™
(marstacimab-hncq)**

FDA INDICATIONS AND USAGE¹

Hypavzi™ 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, or
- hemophilia B (congenital factor IX deficiency) without factor IX inhibitors.

APPROVAL CRITERIA^{1,2,3}

1. Patient meets FDA labeled age **AND**;
2. Prescribed by or in consultation with a hematologist **AND**;
3. Patient has the diagnosis hemophilia A (without factor VIII inhibitors) or hemophilia B (without factor IX inhibitors) **AND**;
4. Hypavzi will not be used in combination with *prophylactic* factor replacement therapy **AND**;
5. One of the following applies for the patient:
 - a. Patient hemophilia is classified as severe (defined as factor activity <1%) **OR**
 - b. Patient has a documented history of 2 or more episodes of spontaneous bleeding into joints.

DENIAL CRITERIA¹

1. Failure to meet approval criteria **OR**;
2. Patient will use Hypavzi™ in combination with prophylactic factor therapy **OR**;
3. Hypavzi™ will be used to treat breakthrough bleeding episodes **OR**;
4. Dosing will be initiated at a maintenance level above 150mg once weekly in new-start patients

CAUTIONS¹

- Thromboembolic events may occur. Interrupt Hypavzi™ treatment if symptoms occur.
- Hypavzi™ may cause fetal harm.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- 8 prefilled 150mg/ml syringes or pens per 28 days

REFERENCES / FOOTNOTES:

Hypavzi™ Criteria
Version: 1
Original: 11/12/2024
Accepted 01/17/2025
Effective: 03/1/2025

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1. Hympavzi (marstacimab-hncq) [prescribing information]. New York, NY: Pfizer; October 2024
2. Study of the efficacy and safety PF-06741086 in adult and teenage participants with severe hemophilia A or moderately severe to severe hemophilia B. NCT03938792. Available at: <https://clinicaltrials.gov/study/NCT03938792>
3. Guidelines for the management of hemophilia. 3rd Edition. World Federation of Hemophilia 2020. Available at: <https://www1.wfh.org/publications/files/pdf-1863.pdf>