

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Hypnavzi is an anti-tissue factor pathway inhibitor (anti-TFPI) product indicated for the routine prophylaxis to prevent or reduce frequency of bleeding episodes in adults and pediatric patients \geq 12 years of age with hemophilia A (congenital Factor VIII deficiency) without Factor VIII inhibitors or hemophilia B (congenital Factor IX deficiency) without Factor IX inhibitors.
Exclusion Criteria	None.
Required Medical Information	<p>For initial requests for Hemophilia A:</p> <p>Medical records supporting the request must be provided and include documentation of the following:</p> <p>Hypnavzi is being used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes;</p> <p>Patient has moderate or severe hemophilia A (a clotting factor level $<1\%$ or between 1%- 5%) without factors;</p> <p>Patient has tried with failure (defined as continuing to have spontaneous bleeds) or intolerance, or has a contraindication to factor VIII prophylaxis therapy or Hemlibra.</p> <p>For initial requests for Hemophilia B:</p> <p>Medical records supporting the request must be provided and include documentation of the following:</p> <p>Hypnavzi is being used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes;</p> <p>Patient has moderate or severe hemophilia B (a clotting factor level $<1\%$ or between 1%- 5%) without factors;</p> <p>Patient has tried with failure (defined as continuing to have spontaneous bleeds) or intolerance, or has a contraindication to factor IX prophylaxis therapy.</p> <p>For reauthorization of hemophilia A and B: (1) Patient continues to use Hypnavzi for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND (2) Documentation of clinical benefit (e.g., less bleeding episodes; less use of factor VIII replacement therapy or bypassing agents) has been provided.</p>
Age Restriction	Patient is at least 12 years of age.
Prescriber Restrictions	Must be prescribed by or in consultation with a hematologist or other specialist.
Coverage Duration	Initial and reauthorization: 12 months. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.

Other Criteria/Information	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.		
	HCPCS	Description	Billing Units/How Supplied
	J7172	Hypavzi (marstacimab-hncq), 0.5 mg injection	Billing unit: 0.5 mg 150 mg/ml SVD

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	5/15/2025	Pharmacy & Therapeutics (P&T) Committee	5/15/2025