SENTARA COMMUNITY PLAN
(MEDICAID)

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Hympavzi™ (marstacimab-hncq)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Recommended Dosing:

- Loading dose: **SUBQ:** 300 mg single loading dose (as two 150 mg injections).
- Maintenance dose (begin 1 week after the loading dose): **SUBQ:** 150 mg once weekly (on the same day each week at any time of the day).

Quantity Limits: 4 syringes/pens per 28 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

- ❑ Member is ≥ 12 years of age
- ❑ Member's weight is ≥ 35 kg
- ❑ Medication prescribed by a specialist familiar with treating patients with hemophilia (factor VIII or IX deficiency)

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- ❑ Provider will initiate the member on marstacimab therapy at 150 mg once weekly
- ❑ Female patients of reproductive potential are **NOT** pregnant prior to initiating therapy with marstacimab
- ❑ Marstacimab will **NOT** be used in combination with clotting factor replacement products (i.e., factor VIII or factor IX concentrates), or Hemlibra® (emicizumab-kxwh) in those with hemophilia A as prophylactic therapy
- ❑ Marstacimab will **NOT** be used for the treatment of breakthrough bleeds (**NOTE**: Factor VIII or Factor IX products may be administered on an as needed basis for the treatment of breakthrough bleeds in patients being treated with marstacimab)
- ❑ Member does **NOT** have a history of, or is on current treatment for, coronary artery diseases, venous or arterial thrombosis, or ischemic disease
- ❑ Member meets **ONE** of the following diagnosis conditions:
  - ❑ Member has a diagnosis of **Hemophilia A** (congenital factor VIII deficiency) and meets **ALL** the following:
    - ❑ Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing
    - ❑ A level of severe hemophilia A is documented by a factor VIII activity level < 1 IU/dL (in the absence of exogenous factor VIII) **(Assay results for activity level documentation required)**
    - ❑ Member has been tested and found negative for active factor VIII inhibitors (i.e., results from a Bethesda assay or Bethesda assay with Nijmegen modification of less than 0.6 Bethesda Units (BU) has been performed within the past 30 days and submitted) and is **NOT** receiving a bypassing agent (e.g., Feiba, Sevenfact)
    - ❑ Member has **NOT** received prior gene therapy for hemophilia A (e.g., Roctavian® (valoctocogene roxaparvovec-rvox))
    - ❑ Member meets **ONE** of the following:
      - ❑ Member has a history of life-threatening hemorrhage requiring on-demand use of Factor VIII therapy
      - ❑ Member has a history of repeated, serious spontaneous bleeding episodes requiring on-demand use of Factor VIII therapy was required for these serious spontaneous bleeding episodes
  - ❑ Member has a diagnosis of **Hemophilia B** (congenital factor IX deficiency) and meets **ALL** the following:
    - ❑ Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing
    - ❑ A level of moderately severe to severe hemophilia B is documented by a factor IX activity level ≤ 2 IU/dL (in the absence of exogenous factor IX) **(Assay results for activity level documentation required)**
    - ❑ Member has been tested and found negative for active factor IX inhibitors (i.e., results from a Bethesda assay or Bethesda assay with Nijmegen modification of less than 0.6 Bethesda Units (BU) has been performed within the past 30 days and submitted) and is **NOT** receiving a bypassing agent (e.g., Feiba, Sevenfact)
    - ❑ Member has **NOT** received prior gene therapy for hemophilia B (e.g., Hemgenix® (etranacogene dezaparvovec-drlb), Beqvez™ (fidanacogene elaparvovec-dzkt))

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- ❑ Member meets **ONE** of the following:
  - ❑ Member has a history of life-threatening hemorrhage requiring on-demand use of Factor IX therapy
  - ❑ Member has a history of repeated, serious spontaneous bleeding episodes requiring on-demand use of Factor IX therapy was required for these serious spontaneous bleeding episode

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, dosing recommendations, etc. identified in the Initial Criteria section
- ❑ Member has **NOT** experienced any unacceptable toxicity from the drug (e.g., thromboembolic events, hypersensitivity)
- ❑ Member has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline, in severity of bleeding episodes, and/or in the number of spontaneous bleeding events) [**NOTE:** providers must submit well-documented, quantitative assessment of bleeding events since initiating marstacimab therapy]
- ❑ If titration to 300 mg once weekly dosing is medically necessary, **ALL** the following must be met:
  - ❑ Member's current weight is greater than or equal to 50 kg
  - ❑ Control of bleeding events has been inadequate (**NOTE:** providers must submit well-documented, quantitative assessment of two or more breakthrough bleeding events while on maintenance therapy at the lower dose of 150 mg in the past six months)
  - ❑ Member has been fully adherent to maintenance therapy for at least six months at the lower dose **(verified by chart notes and/or pharmacy paid claims)**

Medication being provided by Specialty Pharmacy – Proprium Rx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*