SENTARA HEALTH PLANS

MEDICAL 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 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Ryplazim® (plasminogen, human-tvmh) **(J2998) (Medical)**

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:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

Weight: _____ **Date:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

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Quantity Limits (maximum daily dose): 11 vials (68.8 mg per SDV) = 757 mg every 2 days

Indication	Dose
Type 1 Hypoplasminogenemia	The recommended dosage of Ryplazim is 6.6 mg/kg of body weight administered intravenously every 2 to 4 days. Initiate dosing at a frequency of every three days, then adjust as determined below: **Determination of Dosing Frequency** ❑ Obtain baseline plasminogen activity level (allow for a 7-day washout period if the member has been receiving fresh frozen plasma) ❑ Obtain trough plasminogen activity level 72 hours following the initial dose and prior to the second dose ❑ If plasminogen activity level is < 10% above baseline – Increase frequency of therapy to every 2 days ❑ If plasminogen activity level is ≥ 10 and ≤ 20% above baseline – Maintain therapy at frequency of every 3 days ❑ If plasminogen activity level is > 20% above baseline – Decrease frequency of therapy to every 4 days ❑ Maintain dosing frequency above for 12 weeks while treating active lesions ❑ If lesions have resolved – Continue therapy and re-assess in 12 weeks ❑ If lesions have not resolved, or there are new or recurrent lesions – Increase the dosing frequency in one-day increments every 4-8 weeks up to dosing every 2 days. If desired clinical effect is not seen in 12 weeks, assess trough plasminogen activity level ❑ If plasminogen activity level ≥ 10% above baseline – Consider other additional treatments (e.g., surgical removal) ❑ If plasminogen activity level < 10% above baseline – Repeat trough to confirm. If low trough is confirmed, consider discontinuing therapy if no clinical efficacy has been demonstrated

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 weeks

- ❑ Prescribed by or in consultation with a hematologist
- ❑ Member has a diagnosis of hypoplasminogenemia confirmed by a plasminogen level ≤ 45% of laboratory standard **(submit baseline plasminogen labs)**
- ❑ Member has presented at least **ONE** of the following clinical signs and symptoms of disease **(check all that apply)**:
  - ❑ Ligneous conjunctivitis
  - ❑ Gingivitis
  - ❑ Tonsillitis
  - ❑ Abnormal wound healing
  - ❑ Other _____

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- ❑ Member has non-visible lesions (located in areas such as the cervix, bronchus, colon, vagina or uterus) and the provider submits documentation confirmed by computed tomography, magnetic resonance imaging or ultrasound **(submit imaging results)**

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.

- ❑ **In members with complete response, coverage will be renewed annually thereafter**
- ❑ **In members with less than complete response, coverage will be renewed for an additional 12 weeks to optimize frequency of administration**

- ❑ Member has **NOT** experienced unacceptable toxicity from the drug (e.g., severe bleeding, respiratory distress, anaphylaxis and severe allergic reactions)
- ❑ Member has demonstrated a beneficial response to therapy (i.e., resolution of lesions) **(submit progress notes)**

OR

- ❑ Member meets **ONE** of the following:
  - ❑ Lesions have not resolved after an initial 12 weeks of therapy
  - ❑ New or recurrent lesions have developed

AND

- ❑ Provider will increase dosage frequency, in one day increments every 4-8 weeks up to the maximum dosing frequency (i.e., every two days) and re-assess trough plasminogen activity level **(please reference determination of dosing frequency table above)**

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____
  NPI or DEA # of administering location: _____

OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

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.

***Approved by Pharmacy and Therapeutic Committee:** 3/17/2022
REVISED/UPDATED: ~~5/9/2022; 6/15/2022;~~ **6/16/2022**