Hypoplasminogenemia
Ryplazim (plasminogen, human-tvmh) J2998
Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

- ☐ Patient has a diagnosis of plasminogen deficiency type 1 (hypoplasminogenemia); AND
- ☐ Documentation is provided that the diagnosis has been confirmed by the following:
  - ☐ Patient has a plasminogen activity level ≤ 45%; AND
  - ☐ Patient has a history of lesions and symptoms consistent with a diagnosis of congenital plasminogen deficiency.

- Ryplazim may NOT be approved for patients with plasminogen deficiency type 2

☐ **Continuation Requests: (Clinical documentation required for all requests)**

- ☐ Documentation is provided that there is clinically significant response to therapy as evidenced by:
  - ☐ Resolution or improvement of baseline lesions (if present) with no new or recurrent lesions; OR
  - ☐ Patient had achieved or maintained trough plasminogen activity level ≥10% above initial baseline level.
  - ☐ Individual experienced a clinically significant response to treatment, including a reduction in phototoxic reactions, or an increase in the pain-free period during direct sunlight exposure.

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Hypoplasminogenemia Drug PA

Drug Name(s):
RYPLAZIM PLASMINOGEN, HUMAN-TVMH

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.
- Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:
N/A

Prescriber Restrictions:
N/A

Coverage Duration:
Initial Approval will be for 6 months
Continuation will be for 12 months

FDA Indications:
Ryplazim

- Hypoplasminogenemia

Off-Label Uses:
N/A

Age Restrictions:
N/A

Other Clinical Consideration:
N/A

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?navitem=headerLogout#