

Plasminogen, human-tvmh (Ryplazim®)

Place of Service
Office Administration
Infusion Center Administration
Home Infusion Administration
Outpatient Facility Infusion
Administration
HCPCS: J2998 per 1 mg

Condition listed in policy (see criteria for details)

- [Plasminogen deficiency type 1 \(hypoplasminogenemia\)](#)

AHFS therapeutic class: Enzyme

Mechanism of action: Plasma-derived human plasminogen

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Ryplazim® (plasminogen, human-tvmh) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, Medi-Cal, and when applicable, ASO/Shared Advantage/HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

ADMINISTRATION OF RYPLAZIM IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (Supporting Documentation must be submitted)

1. Patient is initiating therapy (allowed up to the first 15 doses) with Ryplazim or is being re-initiated on Ryplazim after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

Or

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Ryplazim based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Ryplazim based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.

4. Patient is clinically unstable based on documentation submitted.

5. Patient is physically or cognitively unstable based on documentation submitted.

Plasminogen deficiency type 1 (hypoplasminogenemia)

1. Diagnosis confirmed by one of the following:

- a. Mutations in the plasminogen (PLG) gene, OR
- b. Provider attestation of reduced levels of plasminogen activity at baseline

Covered Doses

6.6 mg/kg IV infusion every 2 to 4 days

Coverage Period

Indefinite

ICD-10:

E88.02

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Ryp plazim® (plasminogen, human-tvmh) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 68.8 mg lyophilized powder in a single-dose vial

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- Ryp plazim® (plasminogen, human-tvmh) [Prescribing information]. Fort Lee, New Jersey: Prometic Bioproduction Inc.; 2021.
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>

(7) Policy Update

Date of last review: 1Q2023

Date of next review: 1Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*