

plasminogen human-tvmh (Ryplazim)

Medical Benefit Drug Policy

Place of Service

Office Administration

Infusion Center Administration

Home Infusion Administration

Outpatient Facility Infusion Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT

Mechanism of Action: Plasma-derived human plasminogen

HCPCS:

J2998:Injection, plasminogen, human-tvmh, 1 mg

How Supplied:

68.8 mg single-dose lyophilized powder for reconstitution

Condition(s) listed in policy *(see coverage criteria for details)*

- Plasminogen Deficiency Type 1 (Hypoplasminogenemia)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Plasminogen Deficiency Type 1 (Hypoplasminogenemia)

Meets medical necessity if all the following are met:

1. Diagnosis confirmed by ONE of the following:
 - a. Mutations in the plasminogen (PLG) gene
 - b. Provider attestation of reduced levels of plasminogen activity at baseline

Covered Doses:

Up to 6.6 mg/kg given intravenously every 2 to 4 days

Coverage Period:

Indefinite

ICD-10:

E88.02

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. Ryplazim (plasminogen, human-tvmh) Prescribing Information. Kedrion Biopharma, Inc., Fort Lee, New Jersey: 1/2024.
3. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>

Review History

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- No clinical change following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*