Ryplazim (plasminogen, human-tvmh)

Override(s)	Approval Duration
Prior Authorization	Initial Approval: 6 months Continuation Approval: 1 year

Medications
Ryplazim (plasminogen, human-tvmh)

APPROVAL CRITERIA

Initial requests for Ryplazim (plasminogen, human-tvmh) may be approved if the following criteria are met:

I. Individual has a diagnosis of plasminogen deficiency type 1 (hypoplasminogenemia); **AND**
II. Documentation is provided that the diagnosis has been confirmed by the following (Shapiro 2018):
    A. Individual has a plasminogen activity level ≤ 45%; **AND**
    B. Individual has a history of lesions and symptoms consistent with a diagnosis of congenital plasminogen deficiency.

Continuation requests for Ryplazim (plasminogen, human-tvmh) may be approved if the following criteria are met:

I. Documentation is provided that there is confirmation of clinically significant response to therapy as evidenced by the following:
    A. Resolution or improvement of baseline lesions (if present) with no new or recurrent lesions; **OR**
    B. Individual had achieved or maintained trough plasminogen activity level ≥10% above initial baseline level.

Requests for Ryplazim (plasminogen, human-tvmh) may not be approved for the following:

I. Individual with plasminogen deficiency type 2; **OR**
II. When the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 11, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. Shapiro AD, Nakar C, Parker JM, et al. Plasminogen replacement therapy for the treatment of children and adults with congenital plasminogen deficiency. Blood. 2018 Mar 22;131(12):1301-1310. doi: 10.1182/blood-2017-09-806729.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.