RX.PA.067.CCH RYPLAZIM (PLASMINOGEN INJECTION)

The purpose of this policy is to define the prior authorization process for Ryplazim (plasminogen injection) for the treatment of patients with plasminogen deficiency type 1 (hypoplasminogenemia).

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Ryplazim (plasminogen injection, is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed under the respective diagnosis:

- Must be ≥ 11 months of age
- Must have a diagnosis of plasminogen deficiency type 1 (hypoplasminogenemia) with documentation of ALL the following:
    - Plasminogen activity level ≤ 45% (NOTE: If member is receiving fresh frozen plasma, allow for a 7-day washout period before obtaining)
    - History of lesions and symptoms consistent with a diagnosis of congenital plasminogen deficiency (e.g., ligneous conjunctivitis, ligneous gingivitis, and/or pseudomembranous lesions on mucus membranes [middle ear, respiratory tract gastrointestinal tract])
- Must be prescribed by, or consulted with, a provider specialized in the patient's diagnosis (e.g., ophthalmologist, specialist from a hemophilia and thrombosis treatment center)
- Must not be initiated at a dosing frequency of less than every-3-days; more frequent dosing intervals are allowable following trough plasminogen activity levels

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation of the following:

- Must have chart documentation confirming a positive response to therapy as evidenced by at least ONE of the following:
  - Reduction in lesion number or size
  - Plasminogen activity trough level has increased at least 10% from baseline
  - Improvement in wound healing
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 12 months
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J2998	Ryplazim	Injection, plasminogen, human-tvmh, 1mg

References:

1. Ryplazim [package insert]. Fort Lee, NJ: Prometic Bioproduction Inc; November 2021.
2. Celkan T. Plasminogen deficiency. J Thromb Thrombolysis. 2017;43(1):132-138. doi:10.1007/s11239-016-1416-6

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	04/2024

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

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