POLICY NUMBER: RX.PA.067.MPC
REVISION DATE: 02/2023
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RX.PA.067.MPC Ryplazim (plasminogen, human-tvmh)

The purpose of this policy is to define the prior authorization process for Ryplazim® (plasminogen, human-tvmh)

Ryplazim® (plasminogen, human-tvmh) is a plasma-derived human plasminogen indicated for the treatment of patients with plasminiogen deficiency type 1 (hypoplasminogenemia).

PROCEDURE

A. Initial Authorization Criteria:

1. Plasminogen Deficiency Type 1 (must meet all of the following):

- Member is ≥ 11 months of age
- Prescribed by or in consultation with a hematologist
- Diagnosis of hypoplasminogenemia confirmed by ALL of the following:
  - Plasminogen (PLG) gene mutation
  - Plasminogen activity levels ≤ 45%
  - Documentation history of visible or non-visible lesions and symptoms consistent with plasminogen deficiency type 1
    - Abnormal wound healingOR
    - Respiratory distress/obstruction
- Member has healing of lesions/wounds suspected as a source of a recent bleeding event
- Prescriber attests that members using concomitant antiplatelet, anticoagulants or other therapies that impact normal coagulation processes will be monitored for at least 4 hours following Ryplazim infusion

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Ryplazim will be considered investigational or experimental for any other use and will not be covered.

D. 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 all of the following:

- MPC Renewal:
  - Chart documentation confirming positive response to therapy as evidenced by:
    - Reduction in lesion number or size
    - Plasminogen activity trough level has increased at least 10% from baseline
    - Improvement in wound healing
  - Prescribed by or in consultation with a hematologist
  - Prescriber attests that members using concomitant antiplatelet, anticoagulants or other therapies that impact normal coagulation processes will be monitored for at least 4 hours following Ryplazim infusion

- Non- MPC Renewal:
  - Members who have previously been taking Ryplazim and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria).
  - Member has not been receiving samples for Ryplazim;
  - Prescribed by or in consultation with a hematologist
  - Provider has documented positive clinical response of the member's treatment:
    - Reduction in lesion number or size
    - Plasminogen activity trough level has increased at least 10% from baseline
    - Improvement in wound healing

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	3 months
Reauthorization	12 months

Codes:

Code	Description
J2998	Injection, plasminogen, human-tvmh, 1mg

REFERENCES

1. Ryplazim [package insert]. Fort Lee, NJ: Prometic Bioproduction Inc; November 2021.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/2023*
P&T Review	*11/2022*
New Policy	*10/2022*