Medical Policy:
Ryplazim (human plasminogen), injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.346	January 9, 2024	February 10, 2022

Definitions

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

Length of Authorization

Coverage will be provided for 12 weeks initially and may be renewed. Continuation approval duration is 1 year.

Dosing Limits [Medical Benefit]

The recommended dose of Ryplazim is 6.6 mg/kg body weight given every 2 to 4 days (759 billable units (759 mg) every 2 days)

Guideline

I. INITIAL APPROVAL CRITERIA

1. **Plasminogen deficiency type I (hypoplasminogenemia).** Approve for 12 weeks if the patient meets all of the following (A, B, and C)
   A. Patient has a diagnosis of plasminogen deficiency type 1 confirmed by both of the following:
      i. Biallelic mutations in the *PLG* gene; **AND**
      ii. Baseline plasminogen activity level (prior to initiating Ryplazim) ≤ 45% of normal based on the reference range for the reporting laboratory; **AND**
   B. Patient has a history of lesions and symptoms consistent with a diagnosis of congenital plasminogen deficiency; **AND**
   C. Ryplazim is prescribed by or in consultation with a hematologist.

II. RENEWAL CRITERIA

1. **Patient is Currently Receiving Ryplazim**. Approve for 1 year if the patient meets all of the following (A **and** B):
   A. Patient meets one of the following (i. **or** ii.):
      i. Patient has had a clinical response to Ryplazim, as determined by the prescriber; **OR**
      Note: Examples of clinical response include resolution of active lesions, stabilization of current lesions, and prevention of new or recurrent lesions.
      ii. Patient has a trough plasminogen activity level ≥ 10% (absolute change in plasminogen activity) above the baseline trough level (prior to initiating Ryplazim); **AND**
   B. Ryplazim is prescribed by or in consultation with a hematologist.

Applicable Procedure Codes

Code	Description
J2998	Ryplazim 68.8mg Solution Reconstituted J2998 Injection, plasminogen, human-tvmh, 1 mg

Applicable NDCs

Code	Description
70573-0099-01	Ryplazim 68.8mg/vial, single dose vial
70573-0099-02	Ryplazim 68.8mg/vial, single dose vial
70573-0099-01	Ryplazim 68.8mg/vial, single dose vial

ICD-10 Diagnoses

Code	Description
E88.02	Plasminogen Deficiency

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/9/2024	Annual Review- no criteria changes

EmblemHealth & ConnectiCare	5/9/2023	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	1/11/2023	Transfer to New Template, Updated Procedure code to J2998, removed C9399 and J3590 (unclassified)
EmblemHealth & ConnectiCare	2/10/2022	New Policy

References

1. Ryplazim™ [package insert]. Rockville, MD, Prometric Biotherapeutics., Inc. Updated June 2021. Accessed January 6th 2022.