

Medical Policy: Ryplazim (human plasminogen), injection

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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) \leq 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 \geq 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.