Reference number(s)
4782-A

STANDARD MEDICARE PART B MANAGEMENT

RYPLAZIM (plasminogen, human-tvmh)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. Initial Requests: Medical records (e.g., chart notes, lab reports) documenting a baseline plasminogen activity level and a history of lesions and symptoms consistent with diagnosis.
B. Continuation Requests: Medical records (e.g., chart notes, lab reports) documenting disease stability or improvement.

III. CRITERIA FOR INITIAL APPROVAL

Plasminogen deficiency type 1 (hypoplasminogenemia)
Authorization of 12 months may be granted for treatment of plasminogen deficiency type 1 (hypoplasminogenemia) when all of the following criteria are met:
A. Member has a baseline plasminogen activity level of 45% or less at baseline.
B. Member has a documented history of lesions and symptoms consistent with a diagnosis of plasminogen deficiency type 1 (e.g., ligneous conjunctivitis, ligneous gingivitis or gingival overgrowth, vision abnormalities, respiratory distress and/or obstruction, abnormal wound healing).

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Ryplazim.

B. Ryplazim is being used to treat an indication enumerated in Section III.
C. The member is receiving benefit from therapy. Benefit is defined as:
   i. Disease stability while on the current regimen or
   ii. Disease improvement (e.g., improvement lesion number and/or size, absence of new lesion development, improvement in respiratory function, increased quality of life).

V. REFERENCES

1. Ryplazim [package insert]. Laval, Quebec, Canada: Prometic Bioproduction Inc; June 2021.
2. Shapiro AD, Nakar C, Parker JM, et al. Plasminogen replacement therapy for the treatment of children and adults with congenital plasminogen deficiency. *Blood*. 2018;131(12):1301-1310.
3. Celkan T. Plasminogen deficiency. *J Thromb Thrombolysis.* January 2017; 43(1):132-138.