Plasminogen, human-tvmh (Ryplazim®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

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 Indications

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

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- 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.
- Continuation Requests: Medical records (e.g., chart notes, lab reports) documenting disease stability or improvement.

PRESCRIBER SPECIALTIES

Must be prescribed by or in consultation with a hematologist.

COVERAGE CRITERIA

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:

- Member has a baseline plasminogen activity level of 45% or less.
- 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).

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section who are experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., improvement in lesion number and/or size, absence of new lesion development, improvement in respiratory function, increased quality of life).

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Ryplazim [package insert]. Fort Lee, NJ: Prometic Biotherapeutics Inc.; January 2024.
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.

EFFECTIVE DATE 7/31/2026

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