Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 258.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Ryplazim (plasminogen, human-tvmh)

I. Policy:
Ryplazim (plasminogen, human-tvmh)

II. Purpose/Objective:
To provide a policy of coverage regarding Ryplazim (plasminogen, human-tvmh).

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Ryplazim (plasminogen, human-tvmh) functions by temporarily increasing plasminogen levels in the blood, providing a temporary correction of the plasminogen deficiency and reduction or resolution of extravascular fibrinous lesions.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Ryplazim (plasminogen, human-tvmh) will be considered medically necessary for all lines of business when all of the following criteria are met:

- Medical record documentation of a diagnosis of plasminogen deficiency type 1 (hypoplasminogenemia) confirmed by medical record documentation of all of the following:
    - Documentation of a plasminogen activity level less than or equal to 45% **AND**
    - Documentation of a history of external and/or internal lesions and symptoms consistent with a diagnosis of congenital plasminogen deficiency type 1 (PLGD) **AND**
    - Documentation of the presence of biallelic mutations in the plasminogen (PLG) gene

AUTHORIZATION DURATION: Approval will be given for an **initial duration of three (3) months** or less if the reviewing provider feels it is medically appropriate. After the initial three (3) month approval, subsequent approvals will be for a **duration of six (6) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- Medical record documentation of resolution or improvement in documented lesions AND medical record documentation of no new or recurrent lesions **OR**
- Medical record documentation of trough plasminogen level greater than or equal to 10% above baseline trough plasminogen level

Ongoing subsequent approvals will be for a **duration of six (6) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- Medical record documentation of continued positive response to Ryplazim therapy including no new or recurrent lesions **OR**
- Medical record documentation of trough plasminogen level greater than or equal to 10% above baseline trough plasminogen level

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:
1. Ryplazim [prescribing information]. Fort Lee, NJ: Prometic Biotherapeutics Inc; June 2023.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 5/17/22

Revised: 5/11/23 (LOB carve out, Medicaid business segment), 12/28/23 (references added)

Reviewed: 5/10/24

MA UM Committee approval: 12/31/23