Ryplazim® (plasminogen, human-tvmh)

Humana

Pharmacy Coverage Policy

Effective Date: April 27, 2022
Revision Date: April 26, 2023
Review Date: April 19, 2023
Line of Business: Commercial, Medicaid - South Carolina, Medicaid - Ohio
Policy Type: Prior Authorization

Products Affected

Ryplazim intravenous solution

Listed Indications

Plasminogen Deficiency Type 1 (Hypoplasminogenemia)

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Does the member meet all of the following criteria?	
Criteria #1	Ryplazim (plasminogen) is prescribed by or in consultation with a hematologist
Criteria #2	Diagnosis of Plasminogen deficiency (PLGD) Type 1
Criteria #3	Baseline* plasminogen activity level of less than 45% *Baseline level is defined as the plasminogen activity level before initiation of plasminogen
Criteria #4	Documentation of history of lesions or symptoms associated with hypoplasminogenemia (e.g., ligneous conjunctivitis, lesions in ear/mouth, respiratory tract, gastrointestinal, or urogenital location)
Approval Duration	
Initial	Ryplazim (plasminogen, human-tvmh) will be approved in plan year durations or as determined through clinical review.

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Background

This is a prior authorization policy about Ryplazim (plasminogen, human-tvmh)
Plasminogen deficiency (hypoplasminogenemia) is an autosomal recessive, multisystem disorder characterized by formation of fibrinous pseudomembranes on mucous members throughout the body. The most commonly recognized manifestations of PLGD are lesions on the conjunctiva of the eye, termed ligneous conjunctivitis. These lesions can cause significant morbidity, and pseudomembranes affecting the respiratory system and central nervous system can cause fatal complications. Patients generally present for medical attention when they develop clinical symptoms and associated sequelae of pseudomembrane formation. Pseudomembranes are fibrin-rich lesions that form on mucous membranes and are described as "woody" (ligneous). Common sites of presentation include ligneous conjunctivitis (pseudomembrane formation in the conjunctive of the eye) which is the most easily recognizable and most common, but also includes ear and mouth, respiratory tract, gastrointestinal, and urogenital tracts.

Ryplazim (plasminogen, human-tvmh) is a lyophilized preparation of human plasma-derived plasminogen.

Ryplazim (plasminogen, human-tvmh) temporarily increases plasminogen levels in the blood. Plasminogen, its activators, and its receptors comprise pathways that play roles in various inflammation regulatory processes. These roles span functions in fibrinolysis, interaction with complement proteins, ECM degradation, inflammatory cell migration, and resolution of inflammation and would healing.

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

Ryplazim (plasminogen, human-tvmh) is available in 68.6mg/50ml single use vials for intravenous administration.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Ryplazim, plasminogen, hypoplasminogenemia, pharmacy, infusion, intravenous, plasminogen deficiency type 1

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2022. URL: http://www.clinicalpharmacology.com Updated periodically.
2. Lexi-Comp [database online]. Hudson, OH Lexi-comp, Inc.: URL http://online.lexi.com. Updated periodically.
3. Micromedex Healthcare Series: DRUGDEX. Thomson Micromedex, Greenwood Village, CO. 2022. Updated periodically.
4. Ryplazim [package insert]. Laval, Quebec, Canada: Prometic Bioproduction Inc. Tarrytown, NY: Regeneron Pharmaceuticals, Inc; Accessed from Package Insert - RYPLAZIM (fda.gov) on April 11, 2022.

Disclaimer	State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. 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. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically.