

Ryplazim® (plasminogen, human-tvmh)



Pharmacy Coverage Policy

Effective Date: April 27, 2022

Revision Date: April 27, 2022

Review Date: April 20, 2022

Line of Business: Commercial, Medicaid - Ohio

Policy Type: Prior Authorization

Page: 1 of 4

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to date version. Refer to http://apps.humana.com/tad/tad_new/home.aspx to verify that this is the current version before utilizing.

Disclaimer Description Coverage Determination	Background Medical Terms References
Disclaimer	<p>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. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise without permission from Humana.</p>
Description	<p>Ryplazim (plasminogen, human-tvmh) is a lyophilized preparation of human plasma-derived plasminogen.</p> <p>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 wound healing.</p> <p>Ryplazim (plasminogen, human-tvmh) is indicated for the treatment of patients with plasminogen deficiency type 1 (hypoplasminogenemia)</p> <p>Ryplazim (plasminogen, human-tvmh) is available in 68.6mg/50ml single use vials for intravenous administration.</p>
Coverage Determination	<p>Please note the following regarding medically accepted indications:</p> <p>All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those</p>

Ryplazim® (plasminogen, human-tvmh)

Effective Date: 4/27/2022

Revision Date: 4/27/2022

Review Date: 4/20/2022

Line of Business: Commercial, Medicaid - Ohio

Policy Type: Prior Authorization

Page: 2 of 4

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to date version. Refer to http://apps.humana.com/tad/tad_new/home.aspx to verify that this is the current version before utilizing.

uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Ryplazim (plasminogen, human -tvmh) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Plasminogen Deficiency Type 1 (Hypoplasminogenemia)

Member must meet ALL of the following criteria:

- Ryplazim (plasminogen) is prescribed by or in consultation with a hematologist
- Diagnosis of Plasminogen deficiency (PLGD) Type 1
- Baseline* plasminogen activity level of less than 45%
- Documentation of history of lesions or symptoms associated with hypoplasminogenemia (e.g., ligneous conjunctivitis, lesions in ear/mouth, respiratory tract, gastrointestinal, or urogenital location)

*Baseline level is defined as the plasminogen activity level before initiation of plasminogen

Ryplazim (plasminogen, human-tvmh) will be approved in plan year durations or as determined through clinical review.

See the [DISCLAIMER](#). All Humana member health plan contracts are NOT the same. All legislation/regulations on this subject may not be included. This document is for informational purposes only.

Ryplazim® (plasminogen, human-tvmh)

Effective Date: 4/27/2022

Revision Date: 4/27/2022

Review Date: 4/20/2022

Line of Business: Commercial, Medicaid - Ohio

Policy Type: Prior Authorization

Page: 3 of 4

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to date version. Refer to http://apps.humana.com/tad/tad_new/home.aspx to verify that this is the current version before utilizing.

Coverage Limitations

Ryplazim (plasminogen, human-tvmh) therapy is not considered medically necessary for members with the following concomitant conditions:

- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

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 membranes 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.

Provider Claims 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

See the [DISCLAIMER](#). All Humana member health plan contracts are NOT the same. All legislation/regulations on this subject may not be included. This document is for informational purposes only.

Ryplazim® (plasminogen, human-tvmh)

Effective Date: 4/27/2022

Revision Date: 4/27/2022

Review Date: 4/20/2022

Line of Business: Commercial, Medicaid - Ohio

Policy Type: Prior Authorization

Page: 4 of 4

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to date version. Refer to http://apps.humana.com/tad/tad_new/home.aspx to verify that this is the current version before utilizing.

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2022. URL: <http://www.clinicalpharmacology.com> Accessed April 2022
2. Lexi-Comp [database online]. Hudson, OH Lexi-comp, Inc.: URL <http://online.lexi.com> Accessed April 2022
3. Micromedex Healthcare Series: DRUGDEX. Thomson Micromedex, Greenwood Village, CO. 2022. Accessed April 2022
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.