Ryplazim[®] plasminogen, human-tvmh

CODING INFORMATION

This guide contains the information necessary to bill payers for RYPLAZIM® [plasminogen, human-tvmh]. The provider is responsible for submitting accurate and appropriate diagnostic and billing codes to obtain reimbursement.

The coding information provided herein is extracted from a variety of medical coding systems. While it is meant to assist you, it is ultimately the healthcare professional's responsibility for certifying and confirming the codes that best define the patient's diagnosis and treatment, which should be based on the patient's condition and the services provided, while verified by the medical record documentation. The codes listed below are intended for informational purposes, are subject to change, and should not be considered as a complete list of possible codes.

NATIONAL DRUG CODES (NDCs) ¹			
NDC Number	Strength	Diluent Volume*	
70573-099-01 or 70573-099-02†	68.8 mg	12.5 mL	

*Diluent not included in package

[†]Pricing for RYPLAZIM can be found in Price Compendia databases under NDC 70573-099-02.

HEALTHCARE C	OMMON PROCEDURAL CODING SYSTEM (HCPCS) ²		
HCPCS Code	Description		
J2998‡	Injection, plasminogen, human-tvmh, 1 mg		
*Effective 7/1/22			
INTERNATIONAL CLASSIFICATION OF DISEASES, TENTH REVISION (ICD-10) ³			
ICD-10 Code	Description		
E88.02	Plasminogen deficiency		
H67	Otitis media in diseases classified elsewhere		
H67.1	Otitis media in diseases classified elsewhere, right ear		

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H67.2	Otitis media in diseases classified elsewhere, left ear
H67.3	Otitis media in diseases classified elsewhere, bilateral
H67.9	Otitis media in diseases classified elsewhere, unspecified ear

G91.4	Hydrocephalus
H10.51	Ligneous conjunctivitis
H10.511	Ligneous conjunctivitis, right eye
H10.512	Ligneous conjunctivitis, left eye
H10.513	Ligneous conjunctivitis, bilateral
100	Peopiratory disorder in diseases classified classybers

J99 Respiratory disorder in diseases classified elsewhere

CURRENT PROCEDUREAL TERMINOLOGY (CPT®) CODE48		
CPT [®] Code	Description	
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	

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HOME INFUSION THERAPY CODES (OR ADMINISTRATION CODES) ²		
Code	Description	
S9338 or S9345	Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	

INDICATIONS AND USAGE

RYPLAZIM® (plasminogen, human-tvmh) is a plasma-derived human plasminogen indicated for the treatment of patients with plasminogen deficiency type 1 (hypoplasminogenemia).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:

RYPLAZIM is contraindicated in patients with known hypersensitivity to plasminogen or other components of RYPLAZIM.

WARNINGS AND PRECAUTIONS:

- normal coagulation.
- the tracheobronchial tree following RYPLAZIM administration. Please monitor appropriately.
- Transmission of Infectious Agents: RYPLAZIM is made from human plasma and therefore carries a risk theoretically, the Creutzfeldt-Jakob Disease (CJD) agent.
- symptoms occur, discontinue RYPLAZIM and administer appropriate treatment.
- plasminogen activity trough levels in plasma.
- levels will lack interpretability in patients being screened for venous thromboembolism (VTE).

ADVERSE REACTIONS:

The most frequent (incidence \geq 10%) adverse reactions in clinical trials were abdominal pain, bloating, nausea, fatigue, extremity pain, hemorrhage, constipation, dry mouth, headache, dizziness, arthralgia, and back pain.

1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the accompanying Full Prescribing Information.

FOR MORE INFORMATION, PLEASE VISIT **KEDRION.COM**

For questions or to place an order, please contact your Kedrion Biopharma representative or Kedrion Biopharma Customer Service.

References: 1. RYPLAZIM [prescribing information]. Fort Lee, NJ. Kedrion Biopharma Inc. 2021. 2. US Department of Health & Human Services, Centers for Medicare & Medicaid Services. First Quarter, 2022 HCPCS Coding Cycle. Available at: https://www.cms.gov/Medicare/ Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update. Accessed June 21, 2022. 3. American Medical Association. ICD-10-CM 2022. The Complete Official Codebook. Optum360, LLC. 2021. 4. American Medical Association. Current Procedural Terminology (CPT®) 2022 Professional Edition. Revised 2021. Chicago, IL: American Medical Association; 2021

· Bleeding: RYPLAZIM administration may lead to bleeding at active mucosal disease-related lesion sites or worsen active bleeding not related to disease lesions. Discontinue RYPLAZIM if serious bleeding occurs. Monitor patients during and for 4 hours after infusion when administering RYPLAZIM to patients with bleeding diatheses and patients taking anticoagulants, antiplatelet drugs, or other agents which may interfere with

• Tissue Sloughing: Respiratory distress due to tissue sloughing may occur in patients with mucosal lesions in

of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and

Hypersensitivity Reactions: Hypersensitivity reactions, including anaphylaxis, may occur with RYPLAZIM. If

• Neutralizing Antibodies: Neutralizing antibodies (inhibitors) may develop, although they were not observed in clinical trials. If clinical efficacy is not maintained (e.g., development of new or recurrent lesions), determine

· Laboratory Abnormalities: Patients receiving RYPLAZIM may have elevated blood levels of D-dimer. D-dimer

To report SUSPECTED ADVERSE REACTIONS, contact KEDRION at 1-855-427-6378 or the FDA at

KEDRION BIOPHARMA CUSTOMER SERVICE

Website: kedrion.us Email:

Phone: 855.353.7466 | Fax: 855.751.7951 US CustomerService@kedrion.com Hours: Mon – Fri I 7:00AM – 7:00PM CT

