Kedrion Connects™

Ryplazim® plasminogen, human-tvmh

After the healthcare provider and the patient have considered the benefits and risks of RYPLAZIM® and made the decision to prescribe RYPLAZIM, Kedrion Connects™ offers:

NEW START FORM

(to be completed by HCP)

Access Support for RYPLAZIM Patients

We help patients navigate their treatment journey by providing assistance with:

- ☑ Insurance benefit and drug coverage verification
- ☑ Prior authorization navigation
- ☑ Financial assistance for eligible co-pays

PATIENT CONSENT FORM

(to be completed by Patient)

Patient and Caregiver Education & Training

Our Kedrion Nurse Educators provide training and educational resources to help patients and caregivers:

- ☑ Learn RYPLAZIM proper reconstitution, administration, and safe handling
- ☑ Gain awareness on disease state, treatment
- ☑ Connect with resources, such as patient groups and advocacy organizations

Kedrion Connects™ provides access assistance, financial support, resources and training to help patients and caregivers feel confident in their treatment journey.

ENROLL TODAY!

To enroll in Kedrion Connects™, information included in the New Start Form and Patient Consent Form must be provided. **Please be sure to complete and return both documents.**

Fax completed forms to

408-419-1768

QUESTIONS? Call 888-262-8040. Kedrion Connects™ Support Services is available Monday to Friday, from 9 am to 7 pm ET (except holidays).

Kedrion Biopharma

1. SPECIALTY PHARMACY (please select preferred pharmacy)

Kedrion Connects™ will forward to preferred pharmacy, provided the specialty pharmacy is in-network according to the patient's plan.

☐ **Nufactor** ☐ **CVS** ☐ **Soleo**

2. PATIENT INFORMATION (required)

Patient name:

Date of birth: Sex: ☐ M ☐ F

Address:

City: State: Zip code:

Phone: Email:

Preferred method of contact: ☐ Phone ☐ Email

Best time to contact: ☐ Morning (8 AM—10 AM ET) ☐ Day (10 AM—5 PM ET) ☐ Evening (5 PM—8 PM ET)

If the patient is under 18

Primary contact/caregiver name:

Relationship to patient:

Phone:

Email:

3. INSURANCE INFORMATION (required)
Attach a copy of the front and back of all applicable insurance cards, if available

☐ Patient does not currently have insurance. ☐ Copy of the patient's insurance card(s) are attached.

Please complete the required information below only if not attaching a copy of the patient's insurance card(s) to this form.

Primary insurance type: ☐ Private/commercial ☐ Medicaid – State ☐ Other

Primary insurance name:

Beneficiary/cardholder name:

Cardholder relationship to patient:

Policy ID #

Prior authorization required? ☐ Yes ☐ No

Co-pay assistance eligibility? ☐ Yes ☐ No

Please see Important Safety Information on page 7.

4. CLINICAL INFORMATION (required)

☐ Check here if office visit notes are attached/included

E88.02 Plasminogen deficiency type 1: ☐ Yes ☐ No ☐ Unsure

Plasminogen activity level _____%

Other diagnosis and/or important clinical information? Please describe:

Has the patient ever been treated with RYPLAZIM?: ☐ Yes ☐ No ☐ Unsure

If yes, date of last treatment: If yes, next dose due:

What other treatments has the patient received? Please list:

Allergies? Please list:

Patient weight (kg): Date weight was recorded:

5. RYPLAZIM® PRESCRIBING INFORMATION

Recommended Dosing:

- Initiate RYPLAZIM dosing at a frequency of every three days (Q3D)
- Obtain a trough plasminogen activity level approximately 72 hours following the initial dose of RYPLAZIM and prior to the second dose (same time of day as initial dosing) and adjust according to Package Insert section 2.1

Scan the QR code to access the RYPLAZIM dose calculator and explore detailed guidance on long-term dosing and infusion frequency.

Prescribed dose of RYPLAZIM: ☐ 6.6 mg/kg ☐ Other: _____

Infusion frequency: ☐ Q3D ☐ Other: _____

Dispense quantity and duration: _____ vial(s) for _____ month(s)

Additional prescribing information:

Route of intravenous administration: ☐ Peripheral ☐ Other (please describe):

Start date:

6. OTHER DRUG ORDERS (dispense quantity sufficient for 1 month supply unless otherwise noted)

- ☐ Decline
- ☐ All ancillary supplies needed for the reconstitution and administration of RYPLAZIM.
- ☐ Other. Please write in any additional orders _____

7. THERAPY INITIATION AND SITE OF CARE

- ☐ Administration: _____ dose(s) to be administered in a clinical setting, followed by _____ dose(s) with in-home skilled nursing support, and subsequent self-administration at home.

  If the patient/caregiver will self-administer the first dose at home, enter "0" for both clinical setting and in-home skilled nursing support.
- ☐ Skilled Nurse needed: Nurse to administer medications per physician orders.
- ☐ Training Nurse needed: Instruct patient or caregiver to self-administer therapy

Specialty pharmacy to coordinate nursing? ☐ Yes ☐ No

Infusing Practice or facility name

Contact first and last name:

Phone: Fax: Email:

8. PRESCRIBER AUTHORIZATION (required)

☐ Dispense As Written / Brand Medically Necessary / Do Not Substitute / No Substitution / DAW / May Not Substitute
Prescriber's Signature: Date:

☐ May Substitute / Product Selection Permitted / Substitution Permissible
Prescriber's Signature: Date:

CA, MA, NC & PR: Interchange is mandated unless Prescriber writes the words "No Substitution"
ATTN: New York and Iowa providers, please submit electronic prescription

9. AUTHORIZING HEALTHCARE PROVIDER INFORMATION (required)

First name: Last name:

Address:

City: State: Zip code:

Practice phone: Practice fax:

Practice contact first and last name:

Practice contact phone: Practice contact email:

10. PHYSICIAN AUTHORIZATION (required)

I certify that RYPLAZIM is medically necessary for this patient and I will be supervising the patient's treatment accordingly. Non-approval of RYPLAZIM may result in further deterioration of the patient's health and/or hospitalization. By signing below, I certify that I have received the necessary patient authorization to release the information on this form relating to the above-referenced patient to Kedrion Biopharma Inc. and its third parties that work solely on behalf of the patient for the purpose of seeking reimbursement, verifying insurance coverage and/or the evaluation of the patient's eligibility for alternate sources of funding, patient support services, including materials fulfillment, and product fulfillment via specialty pharmacies.

Physician signature: Date:

Physician NPI #

Please see Important Safety Information on page 7.

KEDRION CONNECTS™ CONSENT FOR NURSE EDUCATOR PROGRAM

Patient Name (Last, First, Middle): _____

Phone Number: _____ Email Address: _____

Mailing Address: _____

By signing this form, I authorize the release of my information to Kedrion Biopharma Inc. and its subsidiaries and affiliates, including any service providers that work on its behalf ("Kedrion Biopharma") in connection with the Kedrion Connects™ Nurse Educator Program, as explained below (the "Program").

How will my information be used?

Kedrion Biopharma will use my information for the purpose of facilitating the Program. Specifically, I authorize Kedrion Biopharma and its Nurse Educators contact me or my caregiver to provide information and resources related to the Program, and educational materials and resources regarding the product and disease state; share my contact information with other patients for the purpose of forming a patient network; use my information to conduct internal analyses to improve its processes and communication; and as otherwise required or allowed by applicable laws. Additionally, I authorize Kedrion Biopharma to use my information for other purposes so long as it is deidentified so that it no longer identifies me.

What are my rights regarding my information?

1) I understand that I am entitled to a copy of this consent form and that I have the right to review, correct, amend, limit, and request the deletion of my personal information stored by Kedrion Biopharma. I understand that by signing below, I am consenting to Kedrion Biopharma's Privacy Notice (https://www.kedrion.us/privacy-statement/).
2) I may revoke my consent at any time for Kedrion Biopharma to use and disclose my information according to the instructions provided in Kedrion Biopharma's Privacy Notice. I understand that such revocation will not apply to any information already used or disclosed according to my previous consent.
3) I have the right to opt-out and discontinue receiving information from Kedrion Biopharma at any time.

I have read, understand, and agree to the release, use and disclosure of my information as described above (signature is required for a Kedrion Biopharma Nurse Educator to provide valuable information and resources).

X _____

PATIENT SIGNATURE/LEGAL REPRESENTATIVE SIGNATURE (indicate relationship) **DATE**

Once completed, please send a copy of the form to the following email address: **Rare.Disease@kedrion.com.**

Alternatively, you can **scan the QR code** below to securely complete and submit your consent online.

Please see Important Safety Information on page 7.

INDICATIONS AND SAFETY INFORMATION

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:

- 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 normal coagulation.
- Tissue Sloughing: Respiratory distress due to tissue sloughing may occur in patients with mucosal lesions in the tracheobronchial tree following RYPLAZIM administration. Please monitor appropriately.
- Transmission of Infectious Agents: RYPLAZIM is made from human plasma and therefore carries a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and theoretically, the Creutzfeldt-Jakob Disease (CJD) agent.
- Hypersensitivity Reactions: Hypersensitivity reactions, including anaphylaxis, may occur with RYPLAZIM. If symptoms occur, discontinue RYPLAZIM and administer appropriate treatment.
- 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 plasminogen activity trough levels in plasma.
- Laboratory Abnormalities: Patients receiving RYPLAZIM may have elevated blood levels of D-dimer. D-dimer levels will lack interpretability in patients being screened for venous thromboembolism (VTE).

ADVERSE REACTIONS:

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

To report SUSPECTED ADVERSE REACTIONS, contact KEDRION at 1-855-427-6378 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please scan the QR Code for Full Prescribing Information.