

PLASMINOGEN DEFICIENCY



FOUNDATION

Insurance Approval Toolkit

Updated April 2022

Plasminogen Deficiency Foundation

plgd.org

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Overview

Ryplazim is the only FDA-approved treatment for Plasminogen Deficiency Type 1 (PLGD), an ultra-rare, chronic clotting factor deficiency. As this drug was recently approved, and the condition is so rare, most insurance companies will require special review (prior authorization) before approving the medication for patients. This guide is intended to help you navigate the insurance review process.

Goals

1. To assist patients in understanding the insurance approval process, and in advocating for themselves with their insurer
2. To assist providers in quickly and efficiently obtaining insurance approval for this medication

Steps in the Insurance Approval Process

I. Contact Kedrion, the Pharmaceutical Company for Ryplazim

Currently, there is a shortage of supply of Ryplazim (as of April 2022). In order to get started on this medication, **your doctor should contact the company** and let them know that you are in need of treatment with Ryplazim. Your physician will provide your weight (so your dosage of Ryplazim can be calculated) and you will be added to the candidate list for the medication; your doctor will be notified as soon as Ryplazim is available for you. Eventually, once there is enough supply of the medication for everyone who needs it, this step will not be necessary.

Kedrion Contact Information for Ryplazim Candidate List: p.underland@kedrion.com

II. Insurance Approval Process: Prior Authorization

Your insurance company will likely require a special review process before Ryplazim can be approved, known as a Prior Authorization (PA). Your provider can help to navigate this process with your insurance company. Here is a list of tips and resources you may find useful when navigating through this process:

- a. In most cases, it is better to submit the Prior Authorization as a **medical benefit**. If the authorization is denied under the medical benefit, your provider can submit an authorization request under your pharmacy benefit.
- b. Include a **Letter of Medical Necessity** to send to the insurance company with the Prior Authorization. A sample Letter is included in this Toolkit; your doctor can edit it with the details of your medical history as appropriate (**Appendix A**)
- c. Include the **medical information about Ryplazim**, including information from the clinical trials and safety data. This information is included in this Toolkit (**Appendix B**)
- d. Search for your **insurer's policy on coverage of Ryplazim**. Many insurers are already aware of this medication and have written a policy about how they will cover it for their patients; your doctor can reference this information when applying for

coverage. We have compiled policy documents from several major insurance companies and included them in this Toolkit (**Appendix C**)

- e. Find out what length of time the drug will be approved for by the insurance company; sometimes a Prior Authorization for a medication starts when the application is submitted, and sometimes it starts when the patient receives the first dose of the medication. The length of time that the drug is approved will vary by insurance company; when the approval time is nearing the end, your doctor will have to re-submit the Prior Authorization so you can continue on the medication. This information can be found in the insurance company's approval paperwork once they have agreed to cover the medication.
- f. During the approval process, the insurance company may direct you to the pharmacy that is approved to dispense Ryplazim. This may be your Hemophilia Treatment Center (HTC) pharmacy, The Alliance Pharmacy, Nufactor, or another commercial specialty pharmacy.
- g. The Hemophilia Alliance is available to assist with your insurance questions. You can contact Jeff Blake at Jeff@HemoAlliance.org.

III. Ryplazim Distribution and Dispensing

Once the Prior Authorization is approved, your doctor will **submit a prescription for Ryplazim to the Dispensing Pharmacy** that your insurance company has approved. The Dispensing Pharmacy will then work with a Distributor to obtain the medication. **The Alliance Pharmacy** and **Nufactor Specialty Pharmacy** are the 2 organizations that can distribute Ryplazim to the pharmacy that will be dispensing Ryplazim. You will work with the Dispensing Pharmacy to arrange delivery to your home of the medication and any supplies you will need. In some cases, the drug may also be shipped to your doctor's office, where they will dispense it to you.

Understanding DISTRIBUTING vs DISPENSING Pharmacies:

There may be multiple pharmacy organizations involved in getting Ryplazim to you.

The Alliance Pharmacy (TAP) and Nufactor are currently the only 2 organizations that can DISTRIBUTE this medication. This means that they will send the doses of Ryplazim to the specific dispensing pharmacy that your insurance company approves.

Other specialty pharmacies, including HTC pharmacies, receive Ryplazim from TAP or Nufactor, and can then DISPENSE the medication to you. The pharmacy that dispenses the medication to you is determined by the insurance company.

In some cases, The Alliance Pharmacy or Nufactor may be both the DISTRIBUTING and the DISPENSING pharmacy, if your insurance company approves TAP/Nufactor to send the medication directly to you. In other cases, The Alliance Pharmacy or Nufactor will be the

DISTRIBUTING pharmacy, and a separate specialty pharmacy, like your local HTC pharmacy, will be the DISPENSING pharmacy and will mail the drug to you.

IV. Financial Assistance

Kedrion currently has a **Co-Pay Assistance program** for patients with private insurance, to help with the cost of co-pays for this medication. This program can be accessed online and the specialty pharmacy can assist your doctor in enrolling you if you are eligible. The enrollment instructions are included in this Toolkit (**Appendix D**).

If you have Medicaid or Medicare, you are not eligible for the Co-Pay Assistance Program. Your doctor or your HTC may be able to help you find additional resources.

If you are denied coverage, your HTC can assist you in an appeal process. If you do not have any medical insurance, your HTC may be able to assist you in getting an insurance policy that would give you coverage of this medication.

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