

# There for Rare: Provides guidance along the treatment journey



There for Rare\* is a patient support program for Loargys® (pegzilarginase-nbln) designed to provide you and your patients with:



Coverage support



Product support



Access and  
reimbursement support



Financial support



Information from a nurse or  
pharmacist about LOARGYS



Support for your patients from  
a Patient Access Manager  
throughout their LOARGYS journey

Call 1-844-982-5691 and select Option 2, Monday–Friday, 8 am–8 pm Eastern time with a pharmacist available 24/7, or visit [www.LOARGYS.com](http://www.LOARGYS.com) for more information

\*There for Rare is not part of a patient's treatment team and does not provide medical advice or case management services. There for Rare does not administer Immedica medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

## IMPORTANT SAFETY INFORMATION

### WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

*See full prescribing information for complete boxed warning*

Initiate LOARGYS in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue LOARGYS, and immediately initiate appropriate medical treatment, including use of epinephrine.

## WARNINGS AND PRECAUTIONS

**Hypersensitivity Reactions Including Anaphylaxis:** Life-threatening hypersensitivity reactions, including anaphylaxis, have occurred in patients treated with enzyme replacement therapies, including LOARGYS. Hypersensitivity reactions that were mild to moderate in severity occurred in 13% (6/48) of LOARGYS-treated subjects in clinical trials. Hypersensitivity reactions have included facial swelling, rash, flushing and dyspnea. The reactions generally occurred with the first few doses but may occur later in treatment.

Please see additional Important Safety Information on following pages and full [Prescribing Information](#).



# There for Rare: Provides access and reimbursement support to help patients receive their medication



Upon receipt of a completed Patient Enrollment Form and verification of eligibility, the following coverage may be provided:



## Comprehensive benefits verification

There for Rare performs a comprehensive benefits verification for each new patient to determine how Loargys® (pegzilarginase-nbln) will be covered and which acquisition options are available, as well as the patient's eligibility for financial assistance. You will receive a detailed summary of benefits for all patients that explains their health plan's benefits and coverage.



## Prior Authorization (PA) support

There for Rare may be able to help identify payer requirements needed to submit a PA request for LOARGYS.



## Appeal and exception support

If a patient's coverage is denied, or they require an exception, a Patient Access Manager may be able to help navigate the appeal or medical exception process.

## Access and reimbursement resources

### Coding & Billing Guide for LOARGYS

The Coding & Billing Guide for LOARGYS can help with the reimbursement process.

### Product Acquisition Guide for LOARGYS

The Product Acquisition Guide can help with ordering LOARGYS.

To obtain reimbursement information and resources, such as sample letters, visit [www.loargys.com/resources](http://www.loargys.com/resources)

## IMPORTANT SAFETY INFORMATION (cont'd) WARNINGS AND PRECAUTIONS (cont'd)

Administration of LOARGYS should be supervised by a healthcare provider knowledgeable in the management of hypersensitivity reactions including anaphylaxis in a healthcare setting with appropriate medical monitoring and support measures. Premedication with an antihistamine and/or corticosteroid should be considered in patients who previously have developed a hypersensitivity reaction. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue LOARGYS and immediately initiate appropriate medical treatment, including use of epinephrine. Consider the risks and benefits of re-administering LOARGYS in patients who have experienced a severe hypersensitivity reaction. Caution should be exercised upon rechallenge. Inform patients of the symptoms of life-threatening hypersensitivity reactions and to seek immediate medical attention should symptoms occur. If a mild or moderate reaction occurs, consider treatment with antihistamines and/or corticosteroids.

Please see additional Important Safety Information on following pages and full [Prescribing Information](#).



## IMPORTANT SAFETY INFORMATION (cont'd)

### ADVERSE REACTIONS

The most common adverse reactions are vomiting, pyrexia, infusion associated reactions and constipation.

### USE IN SPECIFIC POPULATIONS

**Pregnancy:** There are no available data on LOARGYS use in pregnant females to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes.

**Lactation:** There is no data on the presence of LOARGYS in either human or animal milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LOARGYS and any potential adverse effects on the breast-fed infant from LOARGYS or from the underlying maternal condition.

**Pediatric:** The safety and effectiveness of LOARGYS have been established for the reduction of plasma arginine in pediatric patients 2 years and older with ARG-1 D, in conjunction with dietary protein restriction. The safety and effectiveness of LOARGYS have not been established for the reduction of plasma arginine in pediatric patients aged less than 2 years with ARG-1 D.

**Geriatric:** Clinical studies of LOARGYS did not include subjects 65 years of age and older to determine whether they respond differently from younger adult subjects.

### INDICATION

LOARGYS is an arginine specific enzyme indicated for the treatment of hyperargininemia in adult and pediatric patients 2 years of age and older with Arginase 1 Deficiency (ARG1-D), in conjunction with dietary protein restriction.

This indication is approved under accelerated approval based on reduction of plasma arginine. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Please see full [Prescribing Information](#).