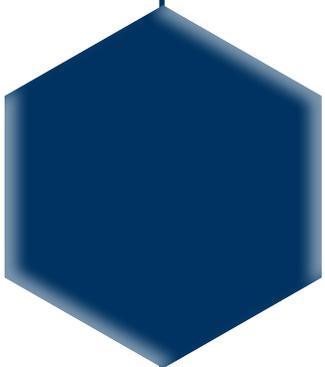


For People  
Living With  
Amyotrophic  
Lateral  
Sclerosis



BHV-0223  
**Expanded  
Access  
Protocol**



# What is Expanded Access?

Under its expanded access programs, the US Food and Drug Administration (FDA) works with companies to allow access to investigational drugs outside of a clinical trial. This program is for patients with serious or life-threatening illness for whom there are no comparable or satisfactory alternate therapies.



Investigational Therapies



To Patients in Need

## About Protocol BHV0223-401

This study involves a drug called riluzole, which is approved by the FDA for the treatment of amyotrophic lateral sclerosis (ALS). Riluzole is usually given in a tablet form to be taken with water and swallowed whole. In this study, an investigational formulation of the drug riluzole will be used. This new investigational formulation is an orally dissolving tablet that is placed entirely under your tongue; wait until the entire tablet dissolves completely (a few seconds).

# Who is eligible for the BHV-0223 Expanded Access Program (EAP)?

## **INCLUSION CRITERIA**

- ALS diagnosis of any type or duration
- Current or previous treatment with oral riluzole tablets, no prior treatment with riluzole tablets, or successful completion of a clinical trial with BHV-0223
- Swallowing difficulties, People with ALS (PALS) or caregiver report of choking one or more times per week, or investigator decision to treat with sublingual BHV-0223 because (s)he deems the PALS cannot be adequately treated with oral riluzole
- Adequate hepatic function

## **EXCLUSION CRITERIA**

- PALS with history of a severe hypersensitivity reaction to riluzole
- Presence of acute or chronic liver disease

For more information about the inclusion and exclusion criteria for this program visit: **[www.ClinicalTrials.gov](http://www.ClinicalTrials.gov)** under NCT number **NCT03537807**.

If you meet the above criteria,  
you may be eligible for this  
Expanded Access Program

# Frequently Asked Questions

## **Can PALS request expanded access?**

People with ALS (PALS) interested in participating in the BHV-0223 EAP should discuss with his/her doctor if BHV-0223 is an appropriate treatment option. All requests for expanded access to BHV-0223 must come through a treating doctor.

## **I am a doctor and believe my PALS may be a candidate for the BHV-0223 EAP. Where can I find more information about participating?**

Doctors can email [BHV0223ExpandedAccess@earlyaccesscare.com](mailto:BHV0223ExpandedAccess@earlyaccesscare.com) for further details. These channels are specifically for US-based doctors who may have eligible PALS.

## **How long after expanded access is requested does it take to receive the drug?**

If the doctor is already participating in the BHV-0223 EAP, the first visit will be to obtain informed consent and assess eligibility. Once eligibility is confirmed, the drug will be shipped to the doctor within 10 business days.

# Frequently Asked Questions

## **Do PALS participating in the EAP have to pay for the drug?**

No, People with ALS (PALS) in the US who receive the drug through an expanded access program for ALS will not pay for BHV-0223 while they are participating in the program.

## **How long will PALS be provided with the investigational drug?**

PALS in the EAP will receive the drug until the drug is approved by the US FDA.

## **How often do PALS need to visit the doctor's office?**

PALS will generally visit their doctor approximately once a month for the first 3 months of treatment, and then once every 3 months.

## **Can PALS outside of the US receive BHV-0223?**

Currently expanded access for BHV-0223 is only available for PALS in the US.

Call **Early Access Care** regarding this protocol at **1-888-315-5797 (Option 6)** or email us at **[BHV0223ExpandedAccess@earlyaccesscare.com](mailto:BHV0223ExpandedAccess@earlyaccesscare.com)**

# Expanded Access Protocol for ALS BHV0223-401

## FDA Reviewed, IRB Approved

### Information for Physicians

If you are interested in participating in the **Expanded Access Program for BHV-0223**, contact **Early Access Care** at [BHV0223ExpandedAccess@earlyaccesscare.com](mailto:BHV0223ExpandedAccess@earlyaccesscare.com) or call **1-888-315-5797 (Option 6)**

#### ELIGIBILITY CHECKLIST AND CDA

- Once contacted, Early Access Care will send the physician an Eligibility Checklist to ensure the person living with ALS meets all criteria for the Expanded Access Program (EAP).
- If the person living with ALS qualifies as eligible for the EAP, Early Access Care will customize a Confidentiality Disclosure Agreement (CDA) to be signed by the physician prior to receiving the protocol and other essential documents

#### ESSENTIAL DOCUMENTS

Upon receipt of the signed CDA, Early Access Care will forward the following essential documents:

- Protocol
- 1572
- Informed Consent Form (ICF)
- Investigator's Brochure (IB)
- Site Contract

#### PROTOCOL TO IRB

- The physician submits the protocol and informed consent to a local Investigational Review Board (IRB) for approval if needed
- Once approved the physician will discuss eligibility with the person living with ALS

#### INFORMED CONSENT

The physician will inform the person living with ALS on known and potential risks of BHV-0223 and any procedures that are required to monitor the progress of the person living with ALS. This is called informed consent.

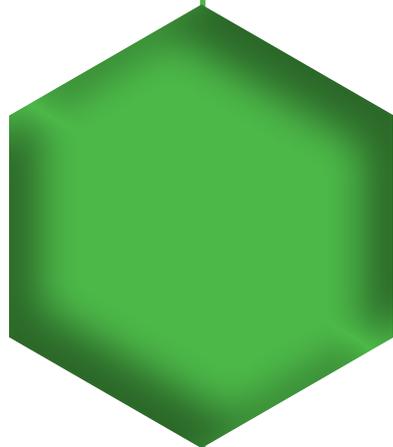
#### COSTS

- Expanded Access for BHV-0223 is offered at no charge
- IRB fees are covered by Biohaven Pharmaceuticals
- Potential hospital costs related to visits and safety monitoring may apply

#### LOGISTICS

- Early Access Care will ensure that BHV-0223 is shipped to the physician in the most expedient manner

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Amyotrophic Lateral Sclerosis



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**Expanded Access**  
Protocol



[www.biohavenpharma.com](http://www.biohavenpharma.com)