

## Getting started with QALSODY

# Your guide to how QALSODY is administered



### What is QALSODY?

QALSODY<sup>®</sup> (tofersen) is a prescription medicine used to treat adults with amyotrophic lateral sclerosis (ALS) who have a mutation, or change, in the superoxide dismutase 1 (*SOD1*) gene. QALSODY is approved under accelerated approval based on reduction in neurofilament light chain (NfL) in the blood observed in patients treated with QALSODY. Continued approval of QALSODY may require verification of clinical benefit in a confirmatory study.

### IMPORTANT SAFETY INFORMATION

#### What is the most important information that I should know about QALSODY?

QALSODY can cause serious side effects, including:

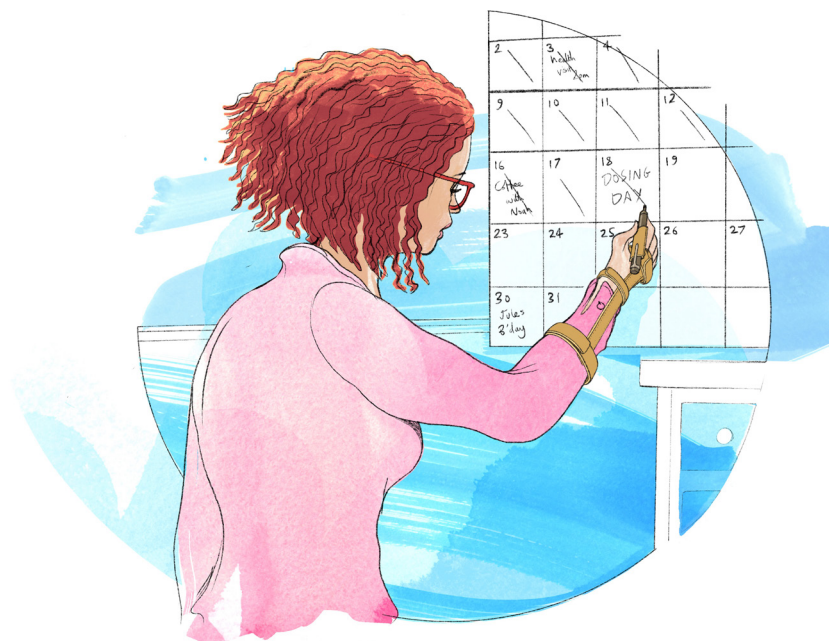
- Inflammation of the spinal cord (myelitis) and/or irritation of the nerve roots (radiculitis), including serious cases, have been reported in patients treated with QALSODY. Six patients treated with QALSODY experienced inflammation of the spinal cord or irritation of the nerve roots in the clinical studies. Two patients stopped treatment with QALSODY and their symptoms resolved with treatment. In the remaining 4 patients, symptoms resolved without stopping QALSODY. If you experience common symptoms such as abnormal sensations (pins and needles), numbness, or weakness, please contact your healthcare provider. Your healthcare provider can help you determine how to address symptoms, and may recommend that you stop taking QALSODY.

Please see additional Important Safety Information throughout and click for full [Prescribing Information](#).

## QALSODY is an intrathecal injection—an injection into the spinal fluid

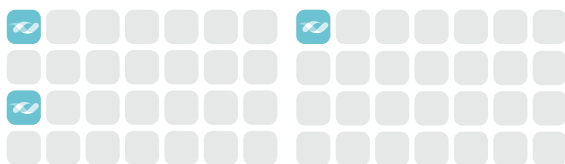
QALSODY is administered by healthcare providers experienced in performing lumbar punctures

- A healthcare provider inserts a needle into the fluid of the spine
- Approximately 10 mL of spinal fluid is removed to create space for QALSODY
- QALSODY is then injected into the remaining spinal fluid over 1 to 3 minutes



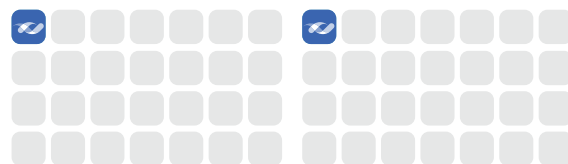
After an initial dosing period,  
QALSODY is administered once every 28 days

### INITIAL DOSES



Loading doses are administered at **14-day intervals**  
(Doses 1 through 3)

### MAINTENANCE DOSES



Maintenance doses are given once **every 28 days** thereafter  
(Dose 4 and onward)

## IMPORTANT SAFETY INFORMATION (cont.)

### What is the most important information that I should know about QALSODY? (cont.)

QALSODY can cause serious side effects, including:

- **Swelling of the optic nerve (papilledema) and increased pressure inside the skull (elevated intracranial pressure)**, including serious cases, have been reported in patients treated with QALSODY. The optic nerve connects the eyes with the brain and is responsible for vision. Four patients developed increased pressure inside the skull and/or swelling of the optic nerve. All patients received treatment from their healthcare provider that resolved these symptoms, and no events led to stopping QALSODY. If you experience common symptoms of swelling of the optic nerve such as blurred vision, double vision, or vision loss, please contact your healthcare provider. If you experience symptoms of increased pressure inside the skull, such as headache, vomiting, or numbness or weakness, please contact your healthcare provider.

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## Making your treatment experience as seamless as possible

There may be steps you can take to help make your QALSODY treatment day go even smoother. Here are some questions you may want to consider asking your healthcare provider before your appointment:



Do I need to bring my respiratory equipment or ventilator for during the lumbar puncture?

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Do I need to wear any specific kind of clothing?

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Do I need to bring anything warm with me like a blanket or cozy socks?

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Is it possible to listen to music or a podcast during the injection process?

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Are there any specific instructions I need to know for before or after the injection?

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Do I need to make time to rest after the injection?

## IMPORTANT SAFETY INFORMATION (cont.)

### What is the most important information that I should know about QALSODY? (cont.)

QALSODY can cause serious side effects, including:

- **Inflammation of the brain linings (aseptic meningitis, also called chemical meningitis or drug-induced aseptic meningitis)**, including serious cases, have been reported in patients treated with QALSODY. One patient experienced a serious side effect of inflammation of the brain linings, which led to the patient stopping QALSODY. One patient experienced a serious side effect of inflammation of the brain linings, which did not lead to the patient stopping QALSODY. In addition, nonserious side effects that can be signs of inflammation or infection have also been reported with QALSODY, including increased white blood cells and increased protein in the cerebrospinal fluid (the fluid around the spinal cord and the brain). If you experience symptoms such as headache, fever, vomiting, neck stiffness, nausea or vomiting, please contact your healthcare provider.

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### What should I tell my healthcare provider before I start using QALSODY?

Before taking QALSODY, tell your healthcare provider if you are pregnant, plan to become pregnant, or are breastfeeding or plan to breastfeed.

### What are the possible side effects of QALSODY?

QALSODY can cause serious side effects. See “What is the most important information I should know about QALSODY?” above.

The most common side effects reported in patients treated with QALSODY were pain (back pain, pain in arms or legs), feeling tired, joint pain, increased white blood cell count in the cerebrospinal fluid (CSF), and muscle pain.

These are not all the possible side effects of QALSODY. Please talk to your healthcare provider if you experience any of these symptoms, or other new symptoms that concern you.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

This information is not intended to replace discussions with your healthcare provider.

**Please see full Prescribing Information.**

— BIOGEN —  
**SUPPORT SERVICES**  
— FOR PATIENTS —

For financial, insurance, or treatment education, call Biogen Support Services at **1-877-725-7639**

**Monday-Friday, 8:30 AM to 8:00 PM ET**

Visit [QALSODY.com](https://www.QALSODY.com)