QALSODY®
(tofersen) 100 mg/15 mL injection

# Starting QALSODY

## How to begin treatment with QALSODY and enroll in Biogen Support Services

**Please click for full Prescribing Information.**

INSTRUCTIONS FOR PATIENTS

QALSODY® (tofersen) 100 mg/15 mL injection

# How to begin treatment with QALSODY and enroll in Biogen Support Services*

*Please write legibly, sign where indicated, and provide all requested information. Be sure to include today's date. Partially completed forms may delay access to Biogen services.*

## 1 COMPLETE THE START FORM

**First, read the Consent Information on the next page.**
**Next, complete the first page of the Start Form.**

- Sign your name if you agree to the Authorization to Share Health Information in section 1 on the Start Form
- Sign your name if you agree to the Patient Services in section 2 and Marketing/Other Communications Authorization in section 3 on the Start Form
- Remember to include your email address in section 4 on the Start Form
  —When you share your email address with us, we can provide you with up-to-date information
- Make a copy of any insurance and pharmacy benefits cards and provide them to your doctor's office with your completed and signed Start Form

## 2 MEET YOUR QALSODY TEAM

**After the Start Form has been submitted to Biogen, the person receiving treatment will be enrolled in Biogen Support Services.**

- Biogen Support Services provides certain services that address nonmedical barriers to access. These include product education, insurance benefits investigations, and financial assistance.
- You will be assigned a Lead Case Manager (LCM) as part of your dedicated QALSODY care team. They will be there to help with initiation of therapy and to help you throughout the treatment journey
- Your LCM can provide information about the treatment center
  —If you have caller ID on your telephone, you may see a call from a 1-919 number, or a call that says Biogen

  Your LCM can also be reached at **1-877-QALSODY (1-877-725-7639)**, Monday through Friday, from 8:30 AM to 8:00 PM ET

## 3 ARRIVE AT YOUR QALSODY TREATMENT CENTER ON YOUR SCHEDULED DAY

*Biogen Support Services is intended for US residents only.

### What is QALSODY?

QALSODY® (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.

**Please see additional Important Safety Information throughout and click for full Prescribing Information.**

## I. AUTHORIZATION TO SHARE HEALTH INFORMATION

I understand that I have certain rights related to the collection, use, and disclosure of my medical and health information. This information is called "protected health information" (PHI) and includes demographic information (such as sex, race, date of birth, etc.), the results of physical examinations, clinical tests, blood tests, X-rays, and other diagnostic medical procedures that may be included in my medical records. Biogen will not use my PHI without my consent.

By signing this Authorization, I authorize my healthcare provider, my health insurance company and my pharmacy providers ("Healthcare Entities") to disclose to Biogen, and companies working with Biogen (collectively, "Biogen"), health information relating to my medical condition, treatment, and insurance coverage for Biogen to (i) provide me with support services (and related information and materials) related to any of Biogen's products, including but not limited to, online support, financial assistance services, compliance and persistency and other therapy support services, and (ii) conduct data analysis, market research and other necessary internal business activities, and (iii) provide me with information about Biogen's products, services, and programs for educational or other purposes. I understand that once I sign this Authorization, and my medical and health information is disclosed to Biogen by the Healthcare Entities, the Health Insurance Portability and Accountability Act (HIPAA) will no longer protect my information because Biogen is not covered by HIPAA. However, Biogen agrees to protect my health information by using and disclosing it only for purposes authorized in this Authorization or as required by law or regulations. I understand that my pharmacy provider may receive remuneration from Biogen in exchange for the health information and/or for any therapy support services provided to me.

I understand that I may refuse to sign this Authorization. I further understand that my treatment (including with a Biogen product), payment for treatment, insurance enrollment or eligibility for insurance benefits are not conditioned upon my agreement to sign this Authorization; but if I do not sign it or later cancel it, I will not be able to receive Biogen's therapy support services.

I may cancel this Authorization at any time by mailing a letter to: Biogen, ATTN: Patient Services, 5000 Davis Drive, PO Box 13919, Research Triangle Park, NC, 27709 or emailing privacy@biogen.com. Canceling this Authorization will end my consent to further disclosure of my health information to Biogen by my Healthcare Entities after they are notified of my cancellation but will not affect previous disclosures by them pursuant to this Authorization. Canceling this authorization will not affect my ability to receive treatment, payment for treatment, or my eligibility for health insurance.

This Authorization expires ten (10) years, or such shorter timeframe required by applicable law, from the day I sign it as indicated by the date next to my signature unless otherwise canceled earlier as set forth above.

**I have read and understand the Authorization to Share Health Information and agree to the terms.**

*Signature of patient or patient representative* _____ *Date* _____

## 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.
- **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.
- **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.

**Please see additional Important Safety Information throughout and click for full Prescribing Information.**

## II. PATIENT SERVICES AUTHORIZATION

By signing this Authorization, I authorize Biogen, and companies working with Biogen, to provide me with support services related to any of Biogen's products, including but not limited to: online support, financial assistance services, compliance and persistency and other therapy support services, as well as any information or materials related to such services. I understand and agree that personnel including but not limited to nurses, providing such support services on behalf of Biogen are not employed by my healthcare professional. I authorize Biogen, and companies working with Biogen, to contact me to provide such services and information by mail, email, fax, telephone call, text message (including calls and text messages made with an automatic telephone dialing system or a prerecorded voice), chat, push notifications and other forms of electronic messaging.

I also authorize Biogen, and companies working with Biogen, to use and disclose my medical and health information in connection with providing the services, including but not limited to, disclosing my information to vendors, processors, and service providers for business purposes associated with providing the services, sharing such information with my healthcare provider, insurance provider, or pharmacy, or disclosing my information where required by applicable laws or regulations. I also authorize the disclosure of my health information to specific individuals that I have designated.

**I have read and understand the Patient Services Authorization and agree to the terms.**

*Signature of patient or patient representative* *Date*

## III. MARKETING AUTHORIZATION

By signing this Authorization, I authorize Biogen, and companies working with Biogen, to contact me by mail, email, fax, telephone call, and text message for marketing purposes or otherwise provide me with information about Biogen's products, services, and programs or other topics of interest, conduct market research or otherwise ask me about my experience with or thoughts about such topics. I understand that Biogen may use auto-dialers, prerecorded messages and artificial voice messages to contact me at the telephone number I have provided on this form and that my mobile provider may charge me to receive these messages. I understand and agree that any information that I provide may be used by Biogen to help develop new products, services, and programs. I understand that Biogen will not sell or transfer my personal information to any unrelated third party for marketing purposes without my express permission. I understand that my consent to receive marketing communications is not required as a condition of purchasing or receiving any goods or services from Biogen. I understand that I may revoke this authorization and choose not to receive services or information from Biogen by mailing a letter to the address above or sending an email with the subject "Unsubscribe" to privacy@biogen.com.

**I have read and understand the Marketing Authorization and agree to the terms.**

*Signature of patient or patient representative* *Date*

Residents of certain US States (including but not limited to California) may have additional rights regarding the collection, use, maintenance, disclosure, and deletion of your personal information. To understand or exercise those rights, California residents please visit https://www.biogen.com/privacy-center/california-policy.html. For more information, visit https://www.biogen.com/privacy-center.html.

I understand that I have the right to receive a copy of the terms and conditions of my agreement with Biogen, and that I may request that copy at the time of signing or at a later date by contacting Biogen at: Biogen, ATTN: Patient Services, 5000 Davis Drive, PO Box 13919, Research Triangle Park, NC, 27709 or emailing privacy@biogen.com.

**Please see additional Important Safety Information throughout and click for full Prescribing Information.**

## IV. PATIENT INFORMATION

First name | Last name | Date of birth ☐ Male ☐ Female

Email | Home phone | Mobile phone

Address

City | State | Zip

Preferred language ☐ OK to leave message

### AUTHORIZING A CAREGIVER (OPTIONAL)

By providing caregiver information below, I authorize the disclosure of my health information to the following designated individual (optional).

☐ I also authorize this individual to take action on my behalf for the purposes of assessing my eligibility and enrolling me in Biogen services. I attest that the individual designated below has my permission and the knowledge and ability to accurately provide information about my insurance plans as well as provide details regarding my financial status.

Caregiver first name | Caregiver last name | Relationship

Address

City | State | Zip

Caregiver email | Caregiver phone

By providing the caregiver information above, I confirm that I have received permission from the designated individual listed above to share their contact information with Biogen.

***Healthcare provider section of form begins on next page.***

## IMPORTANT SAFETY INFORMATION (cont.)

### 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 additional Important Safety Information throughout and click for full Prescribing Information.**

ALL INFORMATION ON THIS PAGE MUST BE
**COMPLETED BY A HEALTHCARE PROVIDER**
IN ORDER TO RECEIVE BIOGEN SERVICES.

## PATIENT INFORMATION

First Name _____ Last Name _____

Date of birth _____ (MM/DD/YYYY)

## PRESCRIBER INFORMATION

First Name _____ Last Name _____

Address _____

City _____ State _____ Zip _____

Phone _____ Fax _____

Email _____

NPI # _____ State license # _____

Tax ID # _____ Clinic/hospital affiliation _____

## STATEMENT OF MEDICAL NECESSITY

Primary diagnosis: **ICD-10: G12.21** ☐ Date of ALS diagnosis: _____

Superoxide dismutase 1 (*SOD1*) mutation ☐ Yes ☐ No

## ADMINISTERING PHYSICIAN INFORMATION

First Name _____ Last Name _____

Specialty _____ Care coordinator contact _____

Phone _____ Fax _____

NPI # _____ State license # _____

## MEDICAL INSURANCE INFORMATION

***Include front and back copy of insurance card(s) along with this Start Form***

Primary insurance _____ Policy # _____

Group # _____ Insurance company phone _____

Policyholder's First Name _____ Policyholder's Last Name _____

Secondary insurance _____ Policy #/Group # _____

Medicaid/governmental payer _____ ☐ Genetic test on file

## TREATMENT

Name of prior or current treatment/medication (if applicable) _____

Date of next scheduled QALSODY treatment _____

☐ Check if patient is transitioning from clinical study

Participant number: _____

## SITE OF CARE

Facility Name _____

Address _____

City _____ State _____ Zip _____

Phone _____ Fax _____

NPI # _____ Tax ID # _____

## PLACE OF SERVICE (POS) CODE

☐ Physician office (11) ☐ Outpatient off-campus clinic (19)

☐ Inpatient (21)
Observation a possibility in lieu of inpatient admission? ☐ Yes ☐ No

☐ Outpatient on campus (ie, infusion, short stay, surgical suite) (22)

☐ Ambulatory surgical center (24) ☐ Other _____

## PROCUREMENT

☐ Specialty pharmacy—*complete prescription below*

☐ Direct buy—*Call 1-833-754-6457 or email OFT_specialtydistribution @optum.com*

☐ Unknown

## PRESCRIPTION FOR SPECIALTY PHARMACY (OPTIONAL)*

Administer QALSODY® (tofersen) intrathecally using a lumbar puncture. Initiate treatment with 3 loading doses administered at 14-day intervals. Administer maintenance doses every 28 days thereafter.

QALSODY (tofersen) injection 100 mg/15 mL in a single-dose vial:

☐ QALSODY treatment initiation with loading doses (1 vial, 13 refills)

☐ QALSODY annual maintenance (1 vial, 11 refills)

*Prescriber signature (dispense as written)* _____ *Prescriber signature (substitution allowed)* _____

*Name (print)* _____ *Date* _____

I authorize Biogen as my designated agent and on behalf of my patient to forward the above prescription, by fax or other mode of delivery, to the pharmacy chosen by the above-named patient.

*In New York, please attach copies of all prescriptions on Official New York State Prescription Forms.

## PRESCRIBER AUTHORIZATION (REQUIRED)

I authorize Biogen as my designated agent on behalf of my patient to furnish any information on this form to his/her insurer. I certify that the rationale for prescribing QALSODY® (tofersen) therapy is for a primary diagnosis of ICD-10: G12.21, and I will be supervising the patient's treatment accordingly.

***Prescriber signature***
Written signature only; stamps not acceptable.

***Date***

**Once completed, email to StartForm@Biogen.com or fax to 1-888-538-9781**

## INSTRUCTIONS FOR HEALTHCARE PROVIDERS

QALSODY® (tofersen) 100 mg/15 mL injection

# To help your patients enroll in Biogen Support Services* or begin QALSODY treatment, please follow these steps

**1** **Discuss the benefits and risks of treatment, and ask the patient to read the Consent Information and complete the indicated areas on the QALSODY Start Form**

**2** **Complete the Healthcare Provider section of the Start Form. Partially completed forms may delay access to Biogen services**

- **Specialty Pharmacy:** Fill out the Prescription section of the Start Form. Submitting the Start Form will enroll your patients in Biogen Support Services and a prescription will be filled by the specialty pharmacy
- **Direct Buy:** Follow your usual office procedure for procuring medication. Submitting the Start Form will only enroll your patients in Biogen Support Services
- **Transitioning from early access program (EAP):** Please check the corresponding box in the treatment section, if applicable
- **Unknown:** If your procurement methodology is unknown, please check the corresponding box and Biogen will follow up with you

**3** **Please make a photocopy of both sides of the covered individual's insurance card and pharmacy benefit card, if available**

**4** **Give the patient the Instructions and Consent Information pages to take home**

**5** **Send the completed Start Form and copies of insurance card and pharmacy benefit card to Biogen through Email or Fax:**

- **Email to StartForm@Biogen.com**
- **Fax to 1-888-538-9781**

*For questions, please contact Biogen at **1-877-QALSODY (1-877-725-7639)**.*

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Once the Start Form has been received by Biogen, the patient will be contacted by a QALSODY Lead Case Manager (LCM) to help navigate the process.

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**Biogen takes the confidentiality of personal information seriously. The benefits of granting consent include:**

- Expediting enrollment in Biogen Support Services, which includes help in areas such as insurance and financial assistance
- Giving Biogen access to the status of your prescription should assistance be required

*Biogen Support Services is intended for US residents only.

## INDICATION

QALSODY® (tofersen) is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (*SOD1*) gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain (NfL) observed in patients treated with QALSODY. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

**Please see additional Important Safety Information throughout and click for full Prescribing Information.**

## INDICATION

QALSODY® (tofersen) is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (*SOD1*) gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain (NfL) observed in patients treated with QALSODY. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

## IMPORTANT SAFETY INFORMATION

### Warnings and Precautions

#### Myelitis and/or Radiculitis

Serious adverse reactions of myelitis and radiculitis have been reported in patients treated with QALSODY. Six patients treated with QALSODY experienced myelitis or radiculitis in the clinical studies. Two patients discontinued treatment with QALSODY and required symptomatic management with full resolution of symptoms. In the remaining 4 patients, symptoms resolved without discontinuation of QALSODY. If symptoms consistent with myelitis or radiculitis develop, diagnostic workup and treatment should be initiated according to the standard of care. Management may require interruption or discontinuation of QALSODY.

#### Papilledema and Elevated Intracranial Pressure

Serious adverse reactions of papilledema and elevated intracranial pressure have been reported in patients treated with QALSODY. Four patients developed elevated intracranial pressure and/or papilledema. All patients received treatment with standard of care with resolution of symptoms, and no events led to discontinuation of QALSODY. If symptoms consistent with papilledema or elevated intracranial pressure develop, diagnostic workup and treatment should be initiated according to the standard of care.

#### Aseptic Meningitis

Serious adverse reactions of aseptic meningitis (also called chemical meningitis or drug-induced aseptic meningitis) have been reported in patients treated with QALSODY. One patient experienced a serious adverse reaction of chemical meningitis, which led to discontinuation of QALSODY. One patient experienced a serious adverse reaction of aseptic meningitis, which did not lead to discontinuation of QALSODY. In addition, nonserious adverse drug reactions of CSF white blood cell increased, and CSF protein increased have also been reported with QALSODY. If symptoms consistent with aseptic meningitis develop, diagnostic workup and treatment should be initiated according to the standard of care.

### Adverse Reactions

The most common adverse reactions (≥10% of patients treated with QALSODY and greater than placebo) were pain, fatigue, arthralgia, cerebrospinal fluid white blood cell increased, and myalgia.

**Please click for full Prescribing Information.**

For more information about QALSODY, visit **QALSODYhcp.com**.

For all other information, contact Biogen at **1-877-QALSODY (1-877-725-7639)**.

QALSODY® (tofersen) 100 mg/15 mL injection

Biogen


225 Binney Street, Cambridge, MA 02142 QAL-US-0021v2 11/23