Dosing and administration

QALSODY® (tofersen) 100 mg/15 mL injection

QALSODY should be administered intrathecally by healthcare professionals experienced in performing lumbar punctures.[1]

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.

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

Recommended dosing of QALSODY[1]

The recommended dosage is 100 mg (15 mL) of QALSODY per administration.

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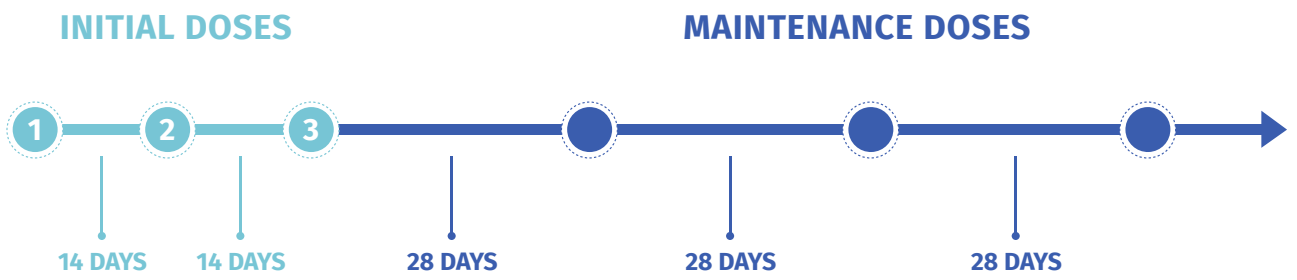
AFTER AN INITIAL DOSING PERIOD, QALSODY IS ADMINISTERED ONCE EVERY 28 DAYS



Missed second dose

If the second loading dose is missed, administer QALSODY as soon as possible, and give the third loading dose 14 days later.

Missed third dose

If the third loading dose is missed, administer QALSODY as soon as possible, and give the next dose 28 days later.

Missed maintenance dose

If a maintenance dose is missed, administer QALSODY as soon as possible, and give the next dose 28 days later.

Preparation instructions[1]

Use aseptic technique when preparing and administering QALSODY intrathecally

Vial preparation

- Allow refrigerated QALSODY to warm to room temperature (25°C/77°F) prior to administration, without using external heat sources
- Inspect the solution in the QALSODY vial prior to administration. Do not administer if particles are observed or the liquid in the vial is not clear and colorless to slightly yellow
- Do not shake the vial

Procedural preparation

- If indicated by the clinical condition of the patient, consider sedation
- If indicated by the clinical condition of the patient, consider imaging to guide intrathecal administration of QALSODY
- Prior to removing the vial's cap on the aluminum overseal, confirm readiness of the patient. An unopened QALSODY vial can be returned to the refrigerator
- Evaluate patients prior to and after intrathecal injection for the presence of potential conditions related to lumbar puncture, to avoid serious procedural complications

IMPORTANT SAFETY INFORMATION (cont.)

Warnings and Precautions (cont.)

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.

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Overview of administration[1]

1.

Prior to administration, remove approximately 10 mL of cerebrospinal fluid using a lumbar puncture needle. Remove the plastic cap and attach a needle to the syringe. Withdraw 15 mL (equivalent to 100 mg) from vial. Do not dilute QALSODY. External filters are not required.

2.

Administer QALSODY (100 mg/15 mL) using a lumbar puncture needle as an intrathecal bolus injection over 1 to 3 minutes.

3.

Once drawn into the syringe, the solution should be administered immediately (within 4 hours of removal from vial) at room temperature; otherwise, it must be discarded.

4.

Any unused contents of the single-dose vial should be discarded.

For complete dosing and administration details, click for full Prescribing Information.

Storage and handling guidelines[1]

Vials of QALSODY should be stored refrigerated, at a temperature between 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze.

If no refrigeration is available, QALSODY may be stored in its original carton, protected from light at or below 30°C (86°F) for up to 14 days.

If removed from the original carton, unopened vials of QALSODY can be removed from and returned to the refrigerator, if necessary, for not more than 6 hours per day at or below 30°C (86°F) for a maximum of 6 days (36 hours).

For complete preparation, storage, and handling details, click for full Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont.)

Warnings and Precautions (cont.)

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.

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

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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.

Biogen Support Services for your patients

Biogen is here to help your patients get started on treatment and provide additional support throughout their time on a Biogen therapy. Our Support Coordinators are committed to answering general disease and product questions, conducting a benefits investigation to determine patients' insurance coverage, and assessing eligibility for financial assistance. The Biogen team can be a resource for patients when they have questions about treatment.

BIOGEN SUPPORT SERVICES FOR PATIENTS

Call 1-877-725-7639

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

Reference: 1. QALSODY Prescribing Information, Cambridge, MA: Biogen.

Biogen