

## tofersen (Qalsody)

### Medical Benefit Drug Policy

#### Place of Service

Office Administration

Outpatient Facility Administration

Infusion Center Administration

#### **Drug Details**

**USP Category:** CENTRAL NERVOUS SYSTEM AGENTS

**Mechanism of Action:** Antisense oligonucleotide specific for SOD1 mRNA

#### **HCPCS:**

J1304:Injection, tofersen, 1 mg

#### **How Supplied:**

100 mg/15 mL (6.7 mg/mL) 1 single-dose vial

#### **Condition(s) listed in policy** *(see coverage criteria for details)*

- Amyotrophic Lateral Sclerosis (ALS) with SOD1 Mutation

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

#### **Special Instructions and Pertinent Information**

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

#### **Coverage Criteria**

**The following condition(s) require Prior Authorization/Preservice.**

#### **Amyotrophic Lateral Sclerosis (ALS) with SOD1 Mutation**

**Meets medical necessity if all the following are met:**

1. Being prescribed by or in consultation with a neurologist
2. Presence of superoxide dismutase 1 gene mutation
3. Patient has received concurrent or prior treatment with riluzole or has medical reason why riluzole cannot be used

#### **Covered Doses:**

100 mg as an intrathecal injection every 14 days for 3 doses, followed by maintenance of 100 mg every 28 days thereafter

#### **Coverage Period:**

Initial: 6 months

Reauthorization: 6 months if patient has not progressed to become dependent on a ventilator

**ICD-10:**

G12.21

**References**

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Qalsody (tofersen) [prescribing information]. Cambridge, MA: Biogen MA Inc; April 2023.
4. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: drug, nutritional, and respiratory therapies (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology [published correction appears in *Neurology*. 2009 Dec 15;73(24):2134] [published correction appears in *Neurology*. 2010 Mar 2;74(9):781]. *Neurology*. 2009;73(15):1218-1226. Reaffirmed on January 25, 2023. Available at: <https://www.aan.com/Guidelines/home/GuidelineDetail/370>
5. Van Damme P, Al-Chalabi A, Andersen PM, et al. European Academy of Neurology (EAN) guideline on the management of amyotrophic lateral sclerosis in collaboration with European Reference Network for Neuromuscular Diseases (ERN EURO-NMD). *Eur J Neurol*. 2024;31(6):e16264. Available at: <https://onlinelibrary.wiley.com/doi/10.1111/ene.16264>.

**Review History**

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- No clinical change following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity  
Reviewed by P&T Committee*