



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:

- Through 12/31/2023: C9157 per 1 mg
- Effective 1/1/2024 and after: J1304 per 1 mg

How supplied

NDC: 64406-109-01: 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](#)

Special Instructions and pertinent Information

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

Covered under the Medical Benefit, please submit clinical information for prior authorization review

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice:

Amyotrophic lateral sclerosis (ALS) with SOD1 mutation (G12.21)

1. Being prescribed by or in consultation with a neurologist, AND
2. Presence of superoxide dismutase 1 gene mutation, AND
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 Authorization: 6 months

Reauthorization if meets below: 6 months

1. Patient has not progressed to become dependent on a ventilator

Additional Information:

Qalsody™ 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).

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.; 4/2023.

Policy Update

Date of Last Annual Review: 8/30/2023

Date of last revision: 1/3/2024

Changes from previous policy version:

- Added HCPCS J1304 per 1 mg, effective 1/1/2024 and after.

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