tofersen (Qalsody)

Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

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