

Qalsody™ (tofersen intrathecal injection)

When requesting Qalsody™ (tofersen), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Qalsody 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).

Coverage Guidelines

Treatment of Amyotrophic Lateral Sclerosis (ALS)

An individual must meet **all** of the following criteria for initial authorization:

- Patient is > 18 years of age;
- Has a confirmed SOD1 pathogenic variant;
- Has a weakness attributable to ALS
- Patient has adequate respiratory function and does not require invasive ventilation;
- Qalsody is prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS.

An individual must meet **all** of the following criteria for re-authorization:

- Has a confirmed SOD1 pathogenic variant;
- The patient continues to derive benefit from therapy;
- Does not require ventilation;
- Qalsody is prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS.

Approval duration (initial): 6 months

Approval duration (renewal): 6 months

Dosing Recommendation

Qalsody is administered intrathecally

- The recommended dosage is 100 mg (15 mL) of QALSODY per administration.
- Initiate QALSODY treatment with three (3) loading doses administered at 14-day intervals. Administer a maintenance dose every 28 days thereafter.

References

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13. Lu CH, Macdonald-Wallis C, Gray E, et al. Neurofilament light chain, a prognostic biomarker in amyotrophic lateral sclerosis. *Neurology*. 2015;84:2247-2257.
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16. 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). *Neurology*. 2009;73:1218-1226.