Qalsody® (tofersen)
(Intrathecal)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- Initial dose: 100 billable units (100 mg) every 14 days, for 3 doses only
- Subsequent doses: 100 billable units (100 mg) every 28 days thereafter

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**
- Member has a baseline measure of the plasma neurofilament light chain (NfL); **AND**

Amyotrophic Lateral Sclerosis (ALS) † Φ [1-3,5,7-9]

- Member has a diagnosis of clinically definite or probable ALS based on El Escorial revised criteria, Gold Coast criteria, or Awaji criteria; **AND**
- Member has the presence of a mutation in the superoxide dismutase 1 *(SOD1)* gene; **AND**
- Member has a slow vital capacity (%SVC) ≥ 65%; **AND**
- Baseline documentation of retained functionality for most activities of daily living [i.e., score of 2 or better on each* individual item of the ALS Functional Rating Scale – Revised (ALSFRS-R)]

  ***Note:** the ALSFRS-R is a 12-item questionnaire assessing functional disease progression across four domains including bulbar, fine motor, gross motor, and respiratory. Each item is scored on a five-point ordinal scale from 0 (loss or significant impairment) up to 4 (normal function) with a possible cumulative score of 48. A score of 2 or better on each item would correspond to a minimum ALSFRS-R score of 24.*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,3]

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet the indication-specific relevant criteria identified in section III; **AND**

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- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious myelitis and radiculitis, papilledema and elevated cranial pressure, aseptic meningitis, etc.; **AND**
- Member has improvement in the plasma neurofilament light chain (NfL) levels compared to baseline; **AND**
- Member has responded to therapy compared to pretreatment baseline with disease stability or mild progression indicating a slowing of decline on the ALSFRS-R (member has not experienced rapid disease progression while on therapy); **AND**
- Member does not have a cumulative score* on the ALSFRS-R of ≤ 3 (The cumulative possible score on the ALSFRS-R is 48; a cumulative score of 3 indicates loss/significant impairment [i.e., item score of zero] in nine or more items on the 12-item questionnaire)

***Note:** the ALSFRS-R is a 12-item questionnaire assessing functional disease progression across four domains including bulbar, fine motor, gross motor, and respiratory. Each item is scored on a five-point ordinal scale from 0 (loss or significant impairment) up to 4 (normal function) with a possible cumulative score of 48. A score of 2 or better on each item would correspond to a minimum ALSFRS-R score of 24.*

V. Dosage/Administration [1]

Indication	Dose
ALS	Administer 100 mg (15 mL) intrathecally as 3 loading doses at 14-day intervals. A maintenance dose should be administered once every 28 days thereafter.

VI. Billing Code/Availability Information

HCPCS Code:

- J1304 – Injection, tofersen, 1 mg; 1 billable unit = 1 mg

NDC:

- 100 mg/15 mL solution in a single-dose glass vial (preservative free): 64406-0109-xx

VII. References

1. Qalsody [package insert]. Cambridge, MA; Biogen MA Inc.; April 2023. Accessed June 2026.
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3. Cedarbaum JM, Stambler N, Malta E, et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. BDNF ALS Study Group (Phase III). J Neurol Sci. 1999 Oct 31;169(1-2):13-21.

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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. Neurology. 2009 Oct 13;73(15):1218-26.
5. Siddique N, Siddique T. Amyotrophic Lateral Sclerosis Overview. GeneReviews. Initial Posting: March 23, 2001; Last Revision: September 28, 2023; Accessed on June 3, 2026. http://www.ncbi.nlm.nih.gov/books/NBK1450/.
6. Hardiman O, van den Berg LH, Kiernan MC. Clinical diagnosis and management of amyotrophic lateral sclerosis. Nat Rev Neurol. 2011 Oct 11;7(11):639-49.
7. Costa J, Swash M, de Carvalho M. Awaji criteria for the diagnosis of amyotrophic lateral sclerosis: a systematic review. Arch Neurol. 2012 Nov;69(11):1410-6.
8. Pinto S, de Carvalho M. SVC Is a Marker of Respiratory Decline Function, Similar to FVC, in Patients With ALS. Front Neurol. 2019 Feb 28;10:109. doi: 10.3389/fneur.2019.00109. PMID: 30873101; PMCID: PMC6403463.
9. Elman L, McCluskey L. Diagnosis of amyotrophic lateral sclerosis and other forms of motor neuron disease. Shefner J, Goddeau Jr R (Eds.). *UpToDate.* Last updated: Aug 01, 2025. Accessed June 3, 2026. Available from: https://www.uptodate.com/contents/diagnosis-of-amyotrophic-lateral-sclerosis-and-other-forms-of-motor-neuron-disease .

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G12.21	Amyotrophic lateral sclerosis

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Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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