

POLICY: Neurology – Qalsody Utilization Management Medical Policy

- Qalsody™ (tofersen intrathecal injection – Biogen)

EFFECTIVE DATE: 08/15/2023

LAST REVISION DATE: 2/11/2026

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Qalsody, an antisense oligonucleotide, is indicated for the treatment of **amyotrophic lateral sclerosis (ALS)** in adults who have a **mutation** in the **superoxide dismutase 1 (SOD1) gene**.¹

Guidelines

The American Academy of Neurology (AAN) practice parameter on the care of patients with ALS (last updated 2009; reaffirmed 2023) does not address Qalsody, Relyvrio, Radicava ORS, or Radicava IV.^{2,3} The practice parameter states that riluzole is safe and effective for slowing disease progression to a modest degree and should be offered to patients with ALS. However, riluzole may result in fatigue in some patients and if the risk of fatigue outweighs modest survival benefits, discontinuation of riluzole may be considered. Referral to a specialized multidisciplinary clinic should be considered for patients with ALS to optimize health care delivery, prolong survival, and enhance quality of life.

The European Federation of Neurological Societies (EFNS) guidelines on the clinical management of ALS (2012) also recommend patients be offered treatment with riluzole as early as possible after diagnosis.⁴ Qalsody is not mentioned in these guidelines. The Canadian best practice recommendations for the management of ALS state that riluzole has demonstrated efficacy in improving survival in ALS and there is evidence that riluzole prolongs survival by a median duration of 3 months.⁵ Riluzole should be started soon after the diagnosis of ALS. In a select group of patients, Radicava has been shown to slow decline on the ALS Functional Rating Scale-Revised (ALSFRS-R) scores compared against intravenous (IV) placebo over a 6-month period. The following patients have demonstrated a benefit of Radicava: patients with a disease duration < 2 years, forced vital capacity > 80%, all ALSFRS-R subcomponent scores > 2, and patients who have demonstrated steady decline in the ALSFRS-R over a 3-month period. Evidence for benefit of Radicava IV at other stages of ALS have not been demonstrated. Risks and benefits as well as individualized goals should be considered and discussed before starting therapy with Radicava IV. Qalsody is not mentioned in these guidelines.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Qalsody. Approval is recommended for those who meet the Criteria and Dosing for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Qalsody

as well as the monitoring required for adverse events and long-term efficacy, approval requires Qalsody to be prescribed by, or in consultation with a neurologist with expertise in the diagnosis of ALS.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Qalsody is recommended in those who meet the following criteria:

FDA-Approved Indications

1. Amyotrophic Lateral Sclerosis (ALS). Approve for the duration noted if the patient meets ONE of the following criteria (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets EACH of the following (i through vi):

- i. Patient is ≥ 18 years of age; AND
- ii. The patient has a baseline measure of the plasma neurofilament light chain (NfL); AND
- iii. The patient has a diagnosis of clinically definite or probable amyotrophic lateral sclerosis (ALS) based on revised El Escorial criteria or Awaji criteria; AND
- iv. The patient has the presence of a superoxide dismutase 1 (SOD1) gene mutation; AND
- v. The patient has a slow vital capacity (%SVC) $\geq 65\%$; AND
- vi. Baseline documentation of retained functionality for most activities of daily living (i.e., score of ≥ 2 on each item of the ALS Functional Rating Scale – Revised [ALSFERS-R]) has been obtained

B) Patient is Currently Receiving Qalsody. Approve for 6 months if the patient meets EACH of the following (i through v):

- i. Patient is ≥ 18 years of age; AND
- ii. The patient has not experienced any unacceptable toxicity from treatment (e.g., serious myelitis and radiculitis, papilledema and elevated cranial pressure, aseptic meningitis); AND
- iii. The patient has had stabilization OR improvement in plasma NfL compared to baseline; AND
- iv. The patient has responded to therapy compared to pretreatment baseline with disease stability or mild progression indicating a slowing of decline on the ALSFRS-R (patient has not experienced rapid disease progression while on therapy); AND

Dosing. Approve the following dosing: 100 mg administered intrathecally every 14 days for three loading doses, followed by a maintenance dose of 100 mg administered intrathecally every 28 days thereafter.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Qalsody is not recommended in the following situations:

- 1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Qalsody™ intrathecal injection [prescribing information]. Cambridge, MA: Biogen; April 2023.
2. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: multidisciplinary care, symptom management, and cognitive/behavioral impairment (an evidence-based review). *Neurology*. 2009 (reaffirmed 2023);73(15):1227-1233.
3. 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.
4. Andersen PM, Abrahams S, Borasio GD, et al. EFNS guidelines on the clinical management of amyotrophic lateral sclerosis (MALS) – revised report of an EFNS task force. *Eur J Neurol*. 2012;19(3):360-375.
5. Shoesmith C, Abrahao A, Benstead T, et al. Canadian best practice recommendations for the management of amyotrophic lateral sclerosis. *CMAJ*. 2020;192(46):E1453-E1468.
6. Miller TM, Cudkowicz ME, Genge A, et al. Trial of antisense oligonucleotide tofersen for *SOD1* ALS. *N Engl J Med*. 2022;387:1099-110.
7. Qalsody. MN Department of Human Services. March 2025. Available at: <https://mn.gov/dhs/partners-and-providers/policies-procedures/minnesota-health-care-programs/provider/types/rx/pa-criteria/qalsody.jsp>. Accessed February 11, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	05/24/2023
Annual Revision	No criteria changes.	06/19/2024
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024
Annual Update	Updated policy to target all UCare plans. Prior to this the only target was Medicaid. Added requirement of baseline measurement of plasma neurofilament light chain (NfL) levels and attestation of improvement for continuation.	12/10/2024
Annual Revision	No criteria changes.	06/18/2025
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/15/2025
Annual Update	Amyotrophic Lateral Sclerosis: Initial criteria was update to remove diagnosis criteria based on validation of muscle weakness, predicted slowed vital capacity was updated from 50% to 65% and added the requirement the diagnosis is clinically definite or probable amyotrophic lateral sclerosis (ALS) based on revised El Escorial criteria or Awaji criteria. Continuation criteria was updated to remove the ALSFRS-R score requirement of above 3 (criteria now supports a slowing of decline on the ALSFRS-R scale) and added requirement there has no toxicity from treatment. Neurologist requirement and the patient <u>not</u> being dependent on invasive ventilation or tracheostomy was removed from both initial and continuation criteria.	02/11/2026