

DRUG POLICY

Qalsody® (Tofersen)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Qalsody (tofersen) 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 observed in patients with Qalsody. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Chart notes or medical record documentation supporting use as applicable below:

A. Initial Requests:

1. Member has weakness attributable to ALS confirmed by diagnostic testing (e.g., imaging, nerve conduction studies, laboratory results to support the diagnosis).
2. Genetic testing confirming SOD1 mutation.
3. Forced Vital Capacity (FVC) or Slow Vital Capacity (SVC) $\geq$ 45% of predicted value for gender, height and age.

B. Continuation Requests:

1. Documentation of clinical benefit from Qalsody therapy.

Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist, neuromuscular specialist or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS).

Criteria for Initial Approval

Amyotrophic Lateral Sclerosis

Authorization of 12 months may be granted for treatment of ALS when all of the following criteria are met:

- A. Member is 18 years of age or older.
- B. Member has weakness attributable to ALS confirmed by diagnostic testing (e.g., medical history and/or diagnostic testing including nerve conduction studies, imaging and laboratory values to support the diagnosis).
- C. Genetic testing confirming a SOD1 mutation.
- D. Forced Vital Capacity (FVC) or Slow Vital Capacity (SVC) $\geq$ 45% of predicted value for gender, height and age.
- E. Member does not have a tracheostomy.

Continuation of Therapy

Authorization of 12 months may be granted for members continuing with Qalsody therapy for the treatment of ALS when the following criteria are met:

- A. There is a clinical benefit from Qalsody therapy.
- B. Invasive ventilation or tracheostomy is not required.

Other

Qalsody (tofersen) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J1304 – Injection, tofersen, 1 mg (effective 1/1/2024)

REFERENCES

- Qalsody [package insert]. Cambridge, MA: Biogen MA, Inc.; April 2023.
- Miller TM, Cudkowicz ME, Genge A, et al. VALOR and OLE Working Group. Trial of Antisense Oligonucleotide Tofersen for SOD1 ALS. *N Engl J Med*. 2022 Sep 22;387(12):1099-1110
- EFNS Task Force on Diagnosis and Management of Amyotrophic Lateral Sclerosis; Andersen PM, 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):360-75.
- Van Damme P, Al-Chalabi A 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:e16264

POLICY HISTORY

Policy #: 05.05.04

Original Effective Date: October 5, 2023

Reviewed: June 2026

Revised: August 2024

Current Effective Date: October 17, 2024