Reference number
5914-A

SPECIALTY GUIDELINE MANAGEMENT

QALSODY (tofersen)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Chart notes or medical record documentation supporting use as applicable in section IV and V.

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.

III. 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).

IV. CRITERIA FOR INITIAL APPROVAL

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.

V. 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.

VI. REFERENCES

1. Qalsody [package insert]. Cambridge, MA: Biogen MA, Inc.; April 2023.
2. 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
3. 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.