Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 26, 2024

Qalsody™ (tofersen)

LENGTH OF AUTHORIZATION: Up to 6 months

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age; AND
- Patient must have a diagnosis of clinically definite or probable amyotrophic lateral sclerosis (ALS) based on revised El Escorial criteria or Awaji criteria; AND
- Patient has a baseline measure of plasma neurofilament light chain (NfL); AND
- Patient has the presence of a superoxide dismutase 1 (SOD1) gene mutation; AND
- Patient has a slow vital capacity (%SVC) ≥ 65%; AND
- 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 [ALSFRS-R]) has been obtained

CONTINUATION OF THERAPY

- Patient met initial review criteria; AND
- Patient has not experienced any unacceptable toxicity from treatment (e.g., serious myelitis and radiculitis, papilledema and elevated cranial pressure, aseptic meningitis); AND
- Patient must have stabilization OR improvement in plasma NfL compared to baseline; AND
- 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
- Patient does not have a cumulative ALSFRS-R score ≤ 3
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Available as 100 mg/15 mL (6.7 mg/mL) solution in a single-dose vial.
- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/