Tofersen (QALSODY)
Criteria for Use
May 2025

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive tofersen.

☐ Notably decreased respiratory function and dyspnea (a total score of 3 or less points on ALSFRS-R[1] items for dyspnea, orthopnea, or respiratory insufficiency [the sum of questions 10, 11 and 12 on the ALSFRS-R])

☐ Bilevel positive airway pressure (BiPAP) dependent (use 24 hours per day)

Inclusion Criteria

All of the following criteria must be met.

☐ Care provided by a VA neurologist or locally designated ALS expert

☐ Diagnosis of superoxide dismutase 1 (SOD1) ALS made or confirmed by a VA neurologist or locally designated ALS expert

☐ Laboratory documentation of a pathogenic SOD1 mutation in the electronic medical record

☐ Documentation of an itemized ALSFRS-R score in the electronic medical record

Footnotes

[1] Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised J Neurol Sci. 1999 Oct 31;169(1-2):13-21. doi: 10.1016/s0022-510x(99)00210-5.Tofersen has only been studied in patients with forced vital capacity (FVC) of 50% or higher, or FVC of 45 – 50% if the FVC had not declined more than 5% in the last 6 months.

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