| Reference number(s) |
| --- |
| 5915-A |

# Standard Medicare Part B Management Qalsody

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Qalsody | tofersen |

## 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 Indications[1]

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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

## Documentation

The following documentation must be available upon request for all submissions: Supporting chart notes,


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medical record documentation, and/or laboratory results as applicable to the coverage criteria and continuation of therapy sections.

- Initial Requests:
  - Weakness attributable to amyotrophic lateral sclerosis (ALS).
  - Genetic testing confirming superoxide dismutase 1 (SOD1) mutation.
- Continuation Requests:
  - Documentation of clinical benefit from therapy with the requested medication.

# Coverage Criteria

## Amyotrophic Lateral Sclerosis (ALS)[1]

Authorization of 12 months may be granted for treatment of amyotrophic lateral sclerosis (ALS) when all of the following criteria are met:

- Member is 18 years of age or older.
- Member has weakness attributable to ALS (e.g., medical history and/or diagnostic testing including nerve conduction studies, imaging and laboratory values to support the diagnosis).
- Member has an superoxide dismutase 1 (SOD1) mutation confirmed via genetic testing.

# Continuation Of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

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

- The member is currently receiving treatment with the requested medication.
- The requested medication is being used for the treatment of weakness associated with amyotrophic lateral sclerosis (ALS) in members who have a mutation in the superoxide dismutase 1 (SOD1) gene.
- Member has a documented clinical benefit from therapy with the requested medication.

# Summary Of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Qalsody.


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- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- EFNS guidelines on the Clinical Management of Amyotrophic Lateral Sclerosis (MALS) – revised report of an EFNS task force

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Qalsody are covered.

# Explanation Of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

# References

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


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