Reference number(s)
5915-A

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

II. DOCUMENTATION

The following documentation must be available upon request for all submissions: Supporting chart notes or medical record as applicable to 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.

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

Amyotrophic Lateral Sclerosis (ALS)
Authorization of 12 months may be granted for treatment of ALS when both 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.

V. 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:
A. The member is currently receiving treatment with Qalsody.
B. Qalsody is being used for the treatment of weakness associated with ALS in members who have a mutation in the SOD1 gene.
C. There is a clinical benefit from Qalsody therapy.

VI. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Qalsody.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology

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

VII. EXPLANATION OF RATIONALE

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

VIII. REFERENCES

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