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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Neuromuscular Agents	**Original Policy Date:**	May 19, 2023
Subject:	Qalsody	**Page:**	1 of 4

Last Review Date: December 13, 2024

Qalsody

Description

Qalsody (tofersen)

Background
Qalsody (tofersen) is an antisense oligonucleotide which degrades superoxide dismutase 1 (SOD1) mRNA through binding to SOD1 mRNA, which results in a reduction of SOD1 protein synthesis (1).

Regulatory Status
FDA-approved indication: Qalsody is an antisense oligonucleotide indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene (1).

Serious events such as myelitis, radiculitis, papilledema, elevated intracranial pressure, and aseptic meningitis have been reported. Monitor for symptoms; diagnostic workup and treatment should be initiated according to standard of care (1).

The safety and effectiveness of Qalsody in pediatric patients less than 18 years of age have not been established (1).

Related policies
Exservan, Radicava, Relyvrio

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Qalsody may be considered **medically necessary** if the conditions indicated below are met.

Qalsody may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Amyotrophic lateral sclerosis (ALS)

AND ALL of the following:

1. Mutation in the SOD1 gene
2. Baseline evaluation of the condition using the ALS Functional Rating Scale-Revised (ALSFRS-R)
3. Prescribed by or recommended by a neurologist

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Amyotrophic lateral sclerosis (ALS)

AND ALL of the following:

1. Documented stabilization, slowing of disease progression, or improvement of the condition using the ALS Functional Rating Scale-Revised (ALSFRS-R)
2. Prescribed by or recommended by a neurologist

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 8 single-dose vials

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity 3 single-dose vials per 84 days

Duration 12 months

Rationale

Summary

Qalsody (tofersen) is an antisense oligonucleotide indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the SOD1 gene. Serious events such as myelitis, radiculitis, papilledema, elevated intracranial pressure, and aseptic meningitis have been reported. The safety and effectiveness of Qalsody in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Qalsody while maintaining optimal therapeutic outcomes.

References

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

Policy History

Date	Action
April 2023	Addition to PA
June 2023	Annual review
September 2023	Annual review. Per SME, removed requirement to t/f or continue taking riluzole and added requirement for baseline ALSFRS-R in initiation and

	ALSFRS-R demonstrating improvement, slowing of disease progression or stabilization for renewal
September 2024	Annual review
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.