RX.PA.096.CCH QALSODY (TOFERSEN)

The purpose of this policy is to define the prior authorization process for Qalsody (tofersen) 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).

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Qalsody (tofersen), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

- Must have all documentation submitted that supports the diagnosis of amyotrophic lateral sclerosis (ALS) (e.g., chart notes, imaging, nerve conduction studies, laboratory values)
- Must be age 18 years or older
- Must have a mutation in the superoxide dismutase 1 (*SOD1*) gene
- Must be prescribed by, or in consultation with, a neurologist, neuromuscular specialist, or physician specializing in the treatment of ALS
- Must have documentation of the member's baseline functional ability prior to initiating treatment (e.g., speech, walking, climbing stairs, etc.)
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation showing a positive clinical response as demonstrated by disease stability or mild progression, indicating a slowing of decline.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J1304	Qalsody	Injection, tofersen, 1 mg

References:

1. Qalsody (tofersen) [prescribing information]. Cambridge, MA: Biogen MA Inc; April 2023.
2. Miller TM, Cudkowicz ME, Genge A, et al; VALOR and OLE Working Group. Trial of antisense oligonucleotide tofersen for *SOD1* ALS. *N Engl J Med*. 2022;387(12):1099-1110. doi:10.1056/NEJMoa2204705[PubMed 36129998]

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	04/2024

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

Disclaimer

CountyCare medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of CountyCare and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

CountyCare reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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