# Medical Policy:

## Qalsody (tofersen) intrathecal injection- MEDICARE ONLY

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---|---|---|
| MG.MM.PH.417 | December 16, 2024 | December 16, 2024 |



The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## Definitions

Qalsody is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene. his indication is approved under accelerated approval based on reduction in plasma neurofilament light chain (NfL) observed in patients treated with Qalsody. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

## Length of Authorization

Coverage will be provided for 6 months and may be renewed.

## Dosing Limits [Medical Benefit]

The recommended dosage is 100 mg (15 mL) of QALSODY per administration.
Initiate QALSODY treatment with three (3) loading doses administered at 14-day intervals.
Administer a maintenance dose every 28 days thereafter.

## Guideline

**I. INITIAL CRITERIA**

**1. <u>Amyotrophic Lateral Sclerosis (ALS)</u>**

A. Member has confirmed diagnosis of ALS; **AND**

B. Member has a mutation in the superoxide dismutase 1 (SOD1) gene confirmed via genetic testing; **AND**

C. Patient ≥18 years of age; **AND**

D. Medication is prescribed by a neurologist, neuromuscular specialist, or physician specializing in the treatment of ALS; **AND**

E. FVC ≥50% as adjusted for sex, age, and height (from sitting position)

**II. RENEWAL CRITERIA**

**1. <u>Amyotrophic Lateral Sclerosis (ALS)</u>**

A. Member has had a documented clinical benefit from therapy with the requested medication; **AND**

B. Member has not demonstrated unacceptable toxicity from requested medication.

## Applicable Procedure Codes

| Code | Description |
|---|---|
| J1304 | Injection, tofersen, 1 mg |

## Applicable NDCs

| Code | Description |
|---|---|
| 64406-0109-01 | Qalsody 100 mg/15 mL |

## ICD-10 Diagnoses

| Code | Description |
|---|---|
| G12.21 | Amyotrophic lateral sclerosis |

## Revision History

| Company(ies) | DATE | REVISION |
|---|---|---|
| EmblemHealth & ConnectiCare | 12/16/2024 | New Policy |

## References

1. Product Information: QALSODY™ intrathecal injection, tofersen intrathecal injection. Biogen MA Inc (per FDA), Cambridge, MA, 2023.