

Medical Policy:

Qalsody (tofersen) intrathecal injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.387	February 24, 2025	July 6, 2023

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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. This 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).

EmblemHealth Inc. has reviewed the available Qalsody information regarding efficacy and safety and has consulted internal and external resources in making the coverage determination. The company will monitor and evaluate new scientific information as it becomes available.

Policy Statement

EmblemHealth will not cover Qalsody due to lack of conclusive evidence confirming clinical efficacy.

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	2/24/2025	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	1/12/2024	Annual Review: No Criteria changes
EmblemHealth & ConnectiCare	9/11/2023	Removed J-code J3490 – unclassified drugs. Added C9157- Injection, toferson 1mg
EmblemHealth & ConnectiCare	07/06/2023	New Policy

References

1. Product Information: QALSODY™ intrathecal injection, tofersen intrathecal injection. Biogen MA Inc (per FDA), Cambridge, MA, 2023.
2. US Food and Drug Administration. Peripheral and Central Nervous System Drugs Advisory Committee Meeting. March 22 2023. Available at: <https://www.fda.gov/advisory-committees/advisory-committee-calendar/updated-meeting-time-and-public-participation-information-march-22-2023-meeting-peripheral-and>. Accessed on April 24, 2023.
3. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: multidisciplinary care, symptom management, and cognitive/behavioral impairment (an evidence-based review). Neurology. 2009 (reaffirmed 2023);73(15):1227-1233.
4. Andersen PM, Abrahams S, Borasio GD, 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):360-375.
5. Shoesmith C, Abrahao A, Benstead T, et al. Canadian best practice recommendations for the management of amyotrophic lateral sclerosis. CMAJ. 2020;192(46):E1453-E1468.