Medical Policy:

Qalsody (tofersen) intrathecal injection

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

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.