

PRIOR AUTHORIZATION POLICY

POLICY: Neurology – Relyvrio Prior Authorization Policy

- Relyvrio™ (sodium phenylbutyrate and taurursodiol powder for oral suspension – Amylyx)

REVIEW DATE: 10/19/2022; selected revision 01/04/2023

OVERVIEW

Relyvrio, a combination product of sodium phenylbutyrate and taurursodiol, is indicated for the treatment of **amyotrophic lateral sclerosis (ALS)** in adults.¹

Guidelines

The American Academy of Neurology practice parameter on the care of patients with ALS (last updated 2009; reaffirmed 2020) does not yet address Relyvrio; Radicava is also not addressed.^{2,3} The practice parameter states that riluzole is safe and effective for slowing disease progression to a modest degree and should be offered to patients with ALS. However, riluzole may result in fatigue in some patients and if the risk of fatigue outweighs modest survival benefits, discontinuation of riluzole may be considered. Referral to a specialized multidisciplinary clinic should be considered for patients with ALS to optimize health care delivery, prolong survival, and enhance quality of life. Additionally, noninvasive mechanical ventilation may lengthen survival and can be considered to improve quality of life and slow forced vital capacity decline. The European Federation of Neurological Societies guidelines on the clinical management of ALS (2012) also recommend patients be offered treatment with riluzole as early as possible after diagnosis.⁴ However, patients with progressive muscular atrophy, primary lateral sclerosis, or hereditary spastic paraplegia should not be treated with riluzole.

POLICY STATEMENT

Due to the lack of clinical efficacy data, **approval is not recommended** for Relyvrio.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

None.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Relyvrio are not recommended in the following situations:

1. **Amyotrophic Lateral Sclerosis (ALS).** Approval is not recommended due to the unclear clinical benefit of Relyvrio and lack of clinical efficacy data.⁵ The preliminary evidence demonstrates a potentially minimal clinical benefit that is confounded to interpret (e.g., two-point difference in the ALS functional rating scale – revised [ALSFRRS-R] mean score). The efficacy data for Relyvrio are not convincing and have many limitations in analysis. Results from the ongoing Phase III trial (PHOENIX) are needed to determine whether Relyvrio provides clinically meaningful benefit in patients with ALS and to more clearly define an appropriate population for this therapy.

10/19/2022

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2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Relyvrio™ oral suspension [prescribing information]. Cambridge, MA: Amylyx; September 2022.
2. 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 2020);73(15):1227-1233.
3. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: drug, nutritional, and respiratory therapies (an evidence-based review). *Neurology*. 2009;73:1218-1226.
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. Paganoni S, Macklin EA, Hendrix S, et al. Trial of sodium phenylbutyrate-aurursodiol for amyotrophic lateral sclerosis. *N Engl J Med*. 2020 Sep 3;383(10):919-930.