Commercial/Healthcare Exchange PA Criteria

Effective: February 9, 2023

Prior Authorization: Relyvrio

Products Affected: Relyvrio™ (sodium phenylbutyrate and taurursodiol) powder for oral suspension

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

Covered Uses: None - Due to the lack of clinical efficacy data, **approval is not recommended** for Relyvrio.

Other Criteria:

Amyotrophic Lateral Sclerosis (ALS). Approval is not recommended due to the unclear clinical benefit of Relyvrio and lack of clinical efficacy data. 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 [ALSFRS-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.

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-taurursodiol for amyotrophic lateral sclerosis. *N Engl J Med*. 2020 Sep 3;383(10):919-930.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	02/09/2023