

RELYVRIO (sodium phenylbutyrate and taurursodiol)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Relyvrio (sodium phenylbutyrate and taurursodiol) is a powder for suspension indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS) (1). The mechanism by which this happens is not clearly known but the combination of sodium phenylbutyrate and taurursodiol may decrease neuronal cell death through reduction of endoplasmic reticulum stress and mitochondrial dysfunction (2).

Regulatory Status

FDA-approved indication: Relyvrio is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults (1).

In patients with disorders interfering with bile acid circulation, absorption of either components of Relyvrio may be decreased. Monitor for new or worsening diarrhea and consider consulting with a specialist (1).

Relyvrio has a high sodium content. In patients sensitive to sodium intake, consider the amount of sodium in each dose of Relyvrio and monitor as appropriate (1).

Studies have shown that riluzole is safe and effective for slowing disease progression to a modest degree in ALS. Riluzole is considered first-line therapy along with nutritional supplements for patients with ALS (3).

The safety and effectiveness of Relyvrio in pediatric patients less than 18 years of age have not been established (1).

Summary

Relyvrio (sodium phenylbutyrate and taurursodiol) is a powder for suspension indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS). Relyvrio has a high sodium content. In patients sensitive to sodium intake, the amount of sodium in each dose of Relyvrio should be considered and the patient should be monitored as appropriate. The safety and effectiveness of Relyvrio in pediatric patients less than 18 years of age have not been established (1).



**BlueCross
BlueShield**

Federal Employee Program.

**RELYVRIO
(sodium phenylbutyrate and taurursodiol)**

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Relyvrio while maintaining optimal therapeutic outcomes.

References

1. Relyvrio [package insert]. Cambridge MA: Amylyx Pharmaceuticals; September 2022.
2. Sodium phenylbutyrate and taurursodiol. Mechanism of Action. Clinical Pharmacology. Accessed on July 13, 2023.
3. Miller R, Jackson C, et al. Practice Parameter update: The care of the patient with amyotrophic lateral sclerosis: Drug, nutritional, and respiratory therapies (an evidence-based review): Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2009; 73; 1218-1226