Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 11, 2023

RELYVRIO (sodium phenylbutyrate and taurursodiol)

LENGTH OF AUTHORIZATION: 6 Months

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Patient must have a documented diagnosis of amyotrophic lateral sclerosis (ALS) based on El Escorial revised diagnostic criteria.
- The medication is prescribed by or in consultation with a neurologist.
- ALS disease duration must be ≤ 18 months at the start of treatment.
- Trial of riluzole within previous 6 months.
- Baseline ALS Functional Rating Scale-Revised (ALSFRS-R) result must be provided. *(Scores must be ≥2 in all areas).*

CONTINUATION OF THERAPY:

- Patient met the above criteria; **AND**
- Documentation of slowed disease progression from baseline; **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 3 g sodium phenylbutyrate and 1 g taurursodiol single dose packets for oral suspension