Clinical Policy Title:	sodium phenylbutyrate and taurursodiol
Policy Number:	RxA.781
Drug(s) Applied:	Relyvrio™
Original Policy Date:	01/17/2023
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Amyotrophic Lateral Sclerosis (must meet all):

1. Diagnosis of ALS;
2. Prescribed by or in consultation with a neurologist, neuromuscular specialist or physician specializing in terms of treatment of ALS;
3. Age ≥ 18 years;
4. Dose does not exceed 6 gm sodium phenylbutyrate/2 gm taurursodiol (2 packets) per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Amyotrophic Lateral Sclerosis (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy (e.g., no tracheostomy or permanent assisted ventilation);
3. If request is for a dose increase, new dose does not exceed 6 gm sodium phenylbutyrate/2 gm taurursodiol (2 packets) per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

References
Not Applicable

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/08/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023