

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

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

