STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOD PHENYLBUTYRATE-TAURURSODIOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOD PHENYLBUTYRAT /TAURURSODIOL	RELYVRIO	48081		GPI-10 (7450990270)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meet **ALL** the following?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or ALS specialist or being seen at an ALS Specialty Center or Care Clinic

   If yes, **approve for a total of 6 months by HICL or GPI-10. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 21 days with a quantity limit of #1 per day.**
   - **SECOND APPROVAL: Approve for the remaining days with a quantity limit of #2 per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOD PHENYLBUTYRATE-TAURURSODIOL (Relyvrio)** requires the following rule(s) be met for approval:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor) or ALS specialist or being seen at an ALS Specialty Center or Care Clinic

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SOD PHENYLBUTYRATE-TAURURSODIOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meet **ALL** of the following criteria?
   - The patient does not require invasive ventilation
   - The patient has improved or maintained baseline functional ability measured by functional assessments (e.g., Amyotrophic Lateral Sclerosis Functional Rating Scale [ALSFRS])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOD PHENYLBUTYRATE-TAURURSODIOL (Relyvrio)** requires the following rule(s) be met for renewal:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You do not require invasive ventilation (inserting a breathing tube into your throat)
   C. You have improved or maintained baseline functional ability measured by functional assessments (e.g., Amyotrophic Lateral Sclerosis Functional Rating Scale [ALSFRS: a tool for evaluating functional status])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Relyvrio.

REFERENCES

- Relyvrio [Prescribing Information]. Cambridge, MA: Amylyx Pharmaceuticals, Inc., September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/24/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 04/22