UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2296-2
Program	Prior Authorization/Medical Necessity
Medication	Relyvrio® (sodium phenylbutyrate and taurursodiol)
P&T Approval Date	12/2022, 12/2023
Effective Date	3/1/2024

1. Background:

Relyvrio® is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults.[1]

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Relyvrio** will be approved based on **all** of the following criteria:

   a. Submission of medical records (e.g., chart notes, previous medical history, diagnostic testing including: imaging, nerve conduction studies, laboratory values) to support the diagnosis of amyotrophic lateral sclerosis (ALS)[2, 3]

   -AND-

   b. Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS

   -AND-

   c. Provider attestation that the patient's baseline functional ability has been documented prior to initiating treatment (e.g., speech, walking, climbing stairs, etc.)

   -AND-

   d. Patient is not dependent on invasive ventilation or tracheostomy

   Authorization will be issued for 6 months.

B. Reauthorization

1. **Relyvrio** will be approved based on **all** of the following criteria:

   a. Diagnosis of ALS

   -AND-

   b. Prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS

   -AND-

c. Patient is currently receiving **Relyvrio** therapy

-AND-

d. Provider attestation that the patient has slowed disease progression from baseline

-AND-

e. Patient is not dependent on invasive ventilation or tracheostomy

Authorization will be issued for 6 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Relyvrio [package insert]. Cambridge, MA: Amylyx Pharmaceuticals, Inc. September 2022.
2. Subcommittee on Motor Neuron Diseases of World Federation of Neurology Research Group on Neuromuscular Diseases, El Escorial "Clinical Limits of ALS" Workshop Contributors. El Escorial World Federation of Neurology criteria for the diagnosis of amyotrophic lateral sclerosis. J Neurol Sci 1994; 124: 96–107.
3. Brooks BR, Miller RG, Swash M, Munsat TL; World Federation of Neurology Research Group on Motor Neuron Diseases. El Escorial revisited: revised criteria for the diagnosis of amyotrophic lateral sclerosis. Amyotroph Lateral Scler Other Motor Neuron Disord. 2000;1(5):293-299. doi:10.1080/146608200300079536
4. Paganoni S, Macklin EA, Hendrix S, et al. Trial of Sodium Phenylbutyrate-Taurursodiol for Amyotrophic Lateral Sclerosis. N Engl J Med. 2020;383(10):919-930. doi:10.1056/NEJMoa1916945

Program	Prior Authorization/Medical Necessity – Relyvrio® (sodium phenylbutyrate and taurursodiol)
Change Control	
12/2022	New program.
12/2023	Annual review without changes to clinical coverage criteria.