Relyvrio
(sodium phenylbutyrate and taurursodiol)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Relyvrio (sodium phenylbutyrate and taurursodiol) policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

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

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial Requests:
    1. Diagnosis of probable or definite ALS including documentation of symptom onset
    2. Forced Vital Capacity (FVC) >60% or Slow Vital Capacity (SVC) >60% of predicted value for gender, height, and age
B. Continuation Requests:
    1. Documentation of clinical benefit from Relyvrio therapy

Prescriber Specialties (initial approvals only)

This medication must be prescribed by or in consultation with a neurologist, neuromuscular specialist or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS).

Criteria for Initial Approval

Authorization of 12 months may be granted for treatment of ALS when all of the following criteria are met:

A. Diagnosis of probable or definite ALS
B. Member is 18 years of age or older
C. Forced Vital Capacity (FVC) >60% or Slow Vital Capacity (SVC) >60% of predicted value for gender, height, and age
D. Member does not have a tracheostomy
E. Onset of ALS symptoms within the preceding 18 months
F. Concomitant use of riluzole (at up to maximally indicated doses) unless contraindicated or clinically significant adverse effects are experienced

Continuation of Therapy

Authorization of 12 months may be granted for members continuing with Relyvrio therapy for the treatment of ALS when the following criteria are met:

A. Diagnosis of probable or definite ALS
B. There is a clinical benefit from Relyvrio therapy (e.g., slowed disease progression compared with the expected, natural course of ALS) supported by medical records
C. Member does not have a tracheostomy

Relyvrio is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Relyvrio – 2 packets per day

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Relyvrio [package insert]. Cambridge, MA: Amylyx Pharmaceuticals, Inc.; September 2022.
- EFNS Task Force on Diagnosis and Management of Amyotrophic Lateral Sclerosis; Andersen PM, et al. EFNS guidelines on the Clinical Management of Amyotrophic Lateral Sclerosis (MALS) – revised report of an EFNS task force. Eur J Neurol. 2012;19(3):360-75.
- Paganoni S, Macklin EA, Hendrix S, et al. Trial of sodium phenylbutyrate-taurursodiol for amyotrophic lateral sclerosis. N Engl J Med 2020; 383:919-30.
- Paganoni S, Hendrix S, Dickson SP, et al. Long-term survival of participants in the CENTAUR trial of sodium phenylbutyrate-taurursodiol in amyotrophic lateral sclerosis. Muscle Nerve 2021; 63:31-9.
- Paganoni S, Hendrix S, Dickson SP, et al. Effect of sodium phenylbutyrate/taurursodiol on tracheostomy/ventilation-free survival and hospitalization in amyotrophic lateral sclerosis: long-term results from the CENTAUR trial. J Neurol Neurosurg Psychiatry 2022.

POLICY HISTORY

Policy #: 05.04.86

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