

Sodium phenylbutyrate and taurursodiol (Relyvrio)

Notes:

- Quantity Limits: Yes

Non-Formulary **sodium phenylbutyrate and taurursodiol (Relyvrio)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-formulary **sodium phenylbutyrate and taurursodiol (Relyvrio)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a neurologist with expertise/interest in diagnosing and treating patients with amyotrophic lateral sclerosis (ALS)
- Prescribed for the treatment of ALS
- It has been less than 24 months from ALS symptom onset
- Patient has a forced vital capacity (FVC) of 60% or higher
- Current riluzole use or intolerance/contraindication to use

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously, criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:

Non-formulary **sodium phenylbutyrate and taurursodiol (Relyvrio)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a neurologist with expertise/interest in diagnosing and treating patients with amyotrophic lateral sclerosis (ALS)
- Prescribed for the treatment of ALS
- Patient does NOT require tracheotomy or non-invasive ventilation all day
- Patient has a FVC greater than 50% and blood gas PaCO₂ greater than 45 mmHg
- Patient is NOT enrolled in hospice

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Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication: Non-formulary **sodium phenylbutyrate and taurursodiol (Relyvrio)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a neurologist with expertise/interest in diagnosing and treating patients with amyotrophic lateral sclerosis (ALS)
- Patient does NOT require tracheotomy or non-invasive ventilation all day
- Patient has a FVC greater than 50% and blood gas PaCO₂ greater than 45 mmHg
- Patient has NOT experienced a significant clinical decline in ALSFRS-R and/or %FVC status
- Patient is NOT enrolled in hospice