blue of california

trofinetide (DAYBUE)

Diagnoses Considered for Coverage:

- Rett syndrome

Coverage Criteria:

For Rett syndrome:

Initial authorization

- Patient is at least 2 years old, **and**
- Prescribed by or in consultation with a neurologist, **and**
- Patient has a diagnosis of classic/typical Rett syndrome as confirmed by all the following:
  - Presence of the MECP2 gene mutation,
    and
  - Clinical evidence of disease, including all the following symptoms:
    i. Partial or complete loss of acquired purposeful hand skills, and
    ii. Partial or complete loss of acquired spoken language, and
    iii. Presence of gait abnormalities, and
    iv. Presence of stereotypic hand movements, such as hand wringing/squeezing, clapping/tapping, mouthing, and washing/rubbing automatisms,

  and
- Dose does not exceed FDA label maximum.

Coverage Duration: **3 months**

Reauthorization

- Symptoms have improved or been maintained while on Daybue (e.g., breathing, vocalizations, stereotypic hand movements, repetitive behaviors, mood, etc.), and
- Dose does not exceed FDA label maximum.

Coverage Duration: one year

Coverage Duration: See coverage criteria.

References:

1. Prescribing Information. Daybue. Acadia Pharmaceuticals, Inc. 2023.

Effective Date: 5/31/2023