



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Daybue (trofinetide) Page: 1 of 2

Effective Date: 8/26/2024 Last Review Date: 7/2024

Applies to:	<input checked="" type="checkbox"/> Illinois	<input checked="" type="checkbox"/> Florida Kids	<input type="checkbox"/> Michigan
	<input checked="" type="checkbox"/> New Jersey	<input checked="" type="checkbox"/> Maryland	<input type="checkbox"/> Texas
	<input checked="" type="checkbox"/> Pennsylvania Kids	<input checked="" type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Daybue under the patient's prescription drug benefit.

### Description:

Daybue is indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older

### Applicable Drug List:

Daybue

### Policy/Guideline:

#### I. DOCUMENTATION

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

A. Initial requests:

1. Genetic testing results confirming a mutation in the *MECP2* gene
2. Medical records documenting clinical manifestations of disease

#### II. CRITERIA FOR INITIAL APPROVAL

##### Rett Syndrome

Authorization may be granted for treatment of Rett syndrome when all of the following criteria are met:

- A. Member is 2 years of age or older
- B. medication must be prescribed by or in consultation with a physician who specializes in the treatment of Rett syndrome
- C. The diagnosis is confirmed by a mutation in the *MECP2* gene
- D. Member exhibits clinical manifestations of disease (e.g., hand wringing, apraxia, gait abnormalities, developmental delays)

#### III. CRITERIA FOR CONTINUATION OF THERAPY

##### Rett Syndrome

Authorization may be granted for continued treatment of Rett syndrome when the following criteria are met:

- A. Medication is prescribed by or in consultation with a physician who specializes in the treatment of Rett syndrome



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- B. Member is experiencing benefit from therapy (e.g., stabilization or improvement in repetitive movements, mood dysfunction/disruptive behavior, vocalization, ambulation)

### Approval Duration and Quantity Restrictions:

**Initial and Renewal Approval Duration:** 12 months

**Quantity Level Limit:** 3600 mL per 30 days

Recommended dosage is twice daily (morning and evening) with or without food based on patient weight:

<u>Patient Weight</u>	<u>Dosage</u>	<u>Volume</u>
9 kg to < 12 kg	5,000 mg twice daily	25 mL twice daily
12 kg to < 20 kg	6,000 mg twice daily	30 mL twice daily
20 kg to < 35 kg	8,000 mg twice daily	40 mL twice daily
35 kg to < 50 kg	10,000 mg twice daily	50 mL twice daily
50 kg or more	12,000 mg twice daily	60 mL twice daily

### References:

1. Daybue [package insert]. San Diego, CA: Acadia Pharmaceuticals, Inc.; March 2023.
2. Neul JL, Percy AK, Benke TA, et al. Design and outcome measures of LAVENDER, a phase 3 study of trofinetide for Rett syndrome. *Contemp Clin Trials*. 2022;114:106704.
3. Neul JL, Eskind AS. Rett syndrome: NORD. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/rett-syndrome/#complete-report> Published March 15, 2023. Accessed February 2, 2024.