AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Daybue (trofinetide)	Page:	1 of 2
Effective Date:	12/26/2023	Last Review Date:	10/5/2023

Applies to:	☒Illinois	☒Florida Kids	☐Michigan
	☒New Jersey	☒Maryland	☐Texas
	☒Pennsylvania Kids	☒Virginia	☐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

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:

Patient Weight	Dosage	Volume
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 March 16, 2023.