Reference number(s)
5833-A

Specialty Guideline Management
Daybue

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Daybue	trofinetide

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

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

Documentation

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

- Genetic testing results confirming a pathogenic variant in the MECP2 gene.
- Medical records documenting clinical manifestations of disease.

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Prescriber Specialties

This medication must be prescribed by or in consultation with a physician who specializes in the treatment of Rett syndrome.

Coverage Criteria

Rett Syndrome[1-3]

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

- Member is 2 years of age or older.
- The diagnosis is confirmed by a pathogenic variant in the MECP2 gene.
- Member exhibits clinical manifestations of disease (e.g., hand wringing, apraxia, gait abnormalities, developmental delays).

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria who are experiencing benefit from therapy (e.g., stabilization or improvement in repetitive movements, mood dysfunction/disruptive behavior, vocalization, ambulation).

References

1. Daybue [package insert]. San Diego, CA: Acadia Pharmaceuticals, Inc.; September 2024.
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 10, 2025.