HIGHMARK WHOLECARE

Updated: 07/2026
PARP Approved: 09/2026

Prior Authorization Criteria

Daybue (trofinetide)

All requests for Daybue (trofinetide) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of **Rett Syndrome** and the following criteria is met:

- Member must have a confirmed diagnosis of Rett syndrome according to the Rett Syndrome Diagnostic Criteria as follows:
  - Must have documentation of disease-causing mutation in the *MECP2* gene
  - Must have clinical features of Rett syndrome which include:
    - Partial or complete loss of acquired purposeful hand skills
    - Partial or complete loss of acquired spoken language
    - Gait abnormalities: impaired or absence of ability to walk
    - Hand wring/squeezing/clapping/tapping, mouthing and/or washing/rubbing that seems habitual or uncontrollable
  - Must have Rett Syndrome Clinical Severity Scale rating of 10–36
- Must be prescribed by or in consultation with a pediatric neurologist or neurologist
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines
- Does not have any contraindications to the requested medication
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
  - Documentation the member has had an improvement in clinical features of Rett syndrome
  - Documentation the member has had an improvement on the Rett Syndrome Clinical Severity Scale
- **Reauthorization Duration of approval: 12 months**

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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DAYBUE (TROFINETIDE) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

Does the member have documentation of disease-causing mutation in the *MECP2* gene? ☐ Yes ☐ No

Does the member have clinical features of Rett syndrome? ☐ Yes, please list in Supporting Information ☐ No

What is the member's Rett Syndrome Clinical Severity Scale rating?

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member had an improvement on the Rett Syndrome Clinical Severity Scale? ☐ Yes ☐ No

Has the member experienced an improvement in clinical features of Rett Syndrome with treatment? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date