Updated: 02/2025
PARP Approved: 03/2025

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.

HIGHMARK WHOLECARE

Updated: 02/2025
PARP Approved: 03/2025

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