AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Daybue™ (trofinetide)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Recommended Dosage: Trofinetide should be administered orally or via gastrostomy (G) tube twice daily, in the morning and evening, with or without food. Dosing is weight-based, with the following recommended dosages:

- **Weight 9 kg to < 12 kg: 5,000 mg twice daily (25 mL twice daily)**
- **Weight 12 kg to < 20 kg: 6,000 mg twice daily (30 mL twice daily)**
- **Weight 20 kg to < 35 kg: 8,000 mg twice daily (40 mL twice daily)**
- **Weight 35 kg to < 50 kg: 10,000 mg twice daily (50 mL twice daily)**
- **Weight ≥ 50 kg: 12,000 mg twice daily (60 mL twice daily)**

Quantity Limit: 3600 mL (8 bottles) per 30 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

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- ❑ Member is ≥ 2 years of age
- ❑ Member has a diagnosis of Classical/typical Rett syndrome
- ❑ Prescribed by, or in consultation with, **ONE** of the following:
  - ❑ Geneticist
  - ❑ Pediatrician who specializes in childhood neurological or developmental disorders
  - ❑ Neurologist
- ❑ Diagnosis has been established by **BOTH** of the following:
  - ❑ Molecular genetic testing with heterozygous methyl-CpG-binding protein-2 (MECP2) pathogenic variant gene mutations
  - ❑ Diagnosis based on clinical presentation meeting **ALL** criteria to support diagnosis in chart below:

Diagnostic Criteria for Typical or Classical Rett Syndrome (RTT)
Required Findings for Typical/Classic RTT: ❑ Period of regression followed by recovery or stabilization ❑ All main criteria and all exclusion criteria
Main Findings (check all that apply): ❑ Partial or complete loss of acquired purposeful hand skills ❑ Partial or complete loss of acquired spoken language ❑ Gait abnormalities: Impaired (dyspraxic) or absence of ability ❑ Stereotypic hand movements such as hand wringing/squeezing, clapping/tapping, mouthing, and washing/rubbing automatisms
Exclusionary Findings (check all that apply): ❑ Brain injury secondary to trauma (peri- or postnatally), neurometabolic disease, or severe infection that causes neurological problems. ❑ Grossly abnormal psychomotor development in first 6 months of life

- ❑ Requested medication will **NOT** be used for other genetically related (allelic) disorders
- ❑ Physician has assessed baseline disease severity of behavior and/or functionality using an objective measure or tool (e.g., Rett Syndrome Behaviour Questionnaire (RSBQ), Clinical Global Impression-Severity (CGI-S), Motor-Behavior Assessment [MBA]) **(baseline assessment must be submitted)**
- ❑ Member does **NOT** have progressive weight loss prior to initiation of therapy
- ❑ Member does **NOT** have moderate or severe renal impairment (e.g., eGFR < 45 mL/min/1.73 m^2)

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Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member must continue to meet all initial authorization criteria
- ❑ Member must have a positive response to therapy from pre-treatment baseline with disease stability or improvement in core symptoms as evidenced on objective measure or tool (e.g., Rett Syndrome Behavior Questionnaire [RSBQ], Clinical Global Impression-Improvement [CGI-I] Score, MBA) **(documentation of improvement must be submitted)**
- ❑ Member has **NOT** experienced any treatment-restricting adverse effects (e.g., severe diarrhea or dehydration, significant weight loss)

Medication being provided by Specialty Pharmacy – AnovoRx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

***Approved by Pharmacy and Therapeutics Committee:** ~~5/25/2023;~~ **11/17/2023**
REVISED/UPDATED: ~~6/15/2023,~~ **12/11/2023**