

# SENTARA HEALTH PLANS

## 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 1-800-750-9692.** 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:** (select ONE from below)

<input type="checkbox"/> <b>Daybue<sup>®</sup></b> (trofinetide)	<input type="checkbox"/> <b>Daybue<sup>®</sup> STIX</b> (trofinetide)
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**MEMBER & PRESCRIBER INFORMATION:** Authorization may be delayed if incomplete.

Member Name: \_\_\_\_\_

Member Sentara #: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

Prescriber Name: \_\_\_\_\_

Prescriber Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Office Contact Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

NPI #: \_\_\_\_\_

**DRUG INFORMATION:** Authorization may be delayed if incomplete.

Drug Form/Strength: \_\_\_\_\_

Dosing Schedule: \_\_\_\_\_ Length of Therapy: \_\_\_\_\_

Diagnosis: \_\_\_\_\_ ICD Code, if applicable: \_\_\_\_\_

Weight (if applicable): \_\_\_\_\_ Date weight obtained: \_\_\_\_\_

**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 or one 5,000 mg packet twice daily)**
- **Weight 12 kg to < 20 kg: 6,000 mg twice daily (30 mL twice daily or one 6,000 mg packet twice daily)**
- **Weight 20 kg to < 35 kg: 8,000 mg twice daily (40 mL twice daily or one 8,000 mg packet twice daily)**
- **Weight 35 kg to < 50 kg: 10,000 mg twice daily (50 mL twice daily or two 5,000 mg packets twice daily)**
- **Weight ≥ 50 kg: 12,000 mg twice daily (60 mL twice daily or two 6,000 mg packets twice daily)**

**Quantity Limit:**

- Daybue oral solution: 3600 mL (8 bottles) per 30 days
- Daybue Stix for oral solution:
  - 5,000 mg packets – 4 packets per day
  - 6,000 mg packets – 4 packets per day
  - 8,000 mg packets – 2 packets per day

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**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**

- Member is  $\geq 2$  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<sup>2</sup>)

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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**

*Not all drugs may be covered under every Plan*

*If a drug is non-formulary on a Plan, documentation of medical necessity will be required.*

*\*\*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.\**