Print Reset

AETNA BETTER HEALTH® OF VIRGINIA REQUEST FORM

DUR MEDICATION DAYBUE™ (trofinetide)

Fax back to: 1-855-799-2553

If the following information is not complete, correct, or legible, the PA process can be delayed. Please use one form per member.

MEMBER INFORMATION

Last Name: _____

First Name: _____

Medicaid ID Number: _____

Date of Birth: _____

Weight in Kilograms: _____

PRESCRIBER INFORMATION

Last Name: _____

First Name: _____

NPI Number: _____

Phone Number: _____

Fax Number: _____

DRUG INFORMATION

Drug Name/Form: _____

Strength: _____

Dosing Frequency: _____

Length of Therapy: _____

Quantity per Day: _____

(Form continued on next page).

Member's Last Name: **Member's First Name:**

DIAGNOSIS AND MEDICAL INFORMATION

For initial approval, complete the following questions to receive a 1-year approval:

1. Is Daybue prescribed by or in consultation with a neurologist?
   ☐ Yes ☐ No

2. Is the member 2 years of age or older?
   ☐ Yes ☐ No

3. Does the member have a diagnosis of classical/typical or variant/atypical Rett syndrome, as established by *both* of the following:

   - Molecular genetic testing with heterozygous methyl-CpG-binding protein-2 (*MECP2*) pathogenic variant gene mutations; **AND**
   - Diagnosis based on clinical presentation meeting ALL criteria to support diagnosis*****?

   ☐ Yes ☐ No

4. Does the member have severe renal impairment?
   ☐ Yes ☐ No

5. Has the physician assessed baseline disease severity of behavior and/or functionality using an objective measure or tool (e.g., Clinical Global Impression-Improvement [CGI-I] score, Motor-Behavior Assessment [MBA], Interval History Form, Clinical Severity Scale, Rett Syndrome Gross Motor Scale)?
   ☐ Yes ☐ No

For renewal, complete the following questions to receive a 1-year approval:

6. Does the member continue to meet criteria numbers 1–4?; **AND**
   ☐ Yes ☐ No

7. Does the member have 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], CGI-I, MBA, Interval History Form, Clinical Severity Scale, Rett Syndrome Gross Motor scale)?
   ☐ Yes ☐ No

(Form continued on next page).

Member's Last Name: **Member's First Name:**

***Diagnostic Criteria for Typical or Classical Rett Syndrome (RTT)[i,ii]**

Consider diagnosis when postnatal deceleration of head growth is observed

Required Findings for Typical/Classic RTT	Required Findings for Atypical/Variant RTT
– Period of regression followed by recovery or stabilization[†] – All main criteria and all exclusion criteria – Supportive criteria are not required, although often present in typical RTT	– Period of regression followed by recovery or stabilization[†] – At least 2 out of 4 main criteria – At least 5 out of 11 supportive criteria

Main Findings

- 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

- 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[¶]

Supportive Findings (NOT required[‖])

- Breathing disturbances when awake
- Bruxism when awake
- Impaired sleep pattern
- Abnormal muscle tone
- Peripheral vasomotor disturbances
- Scoliosis/kyphosis
- Growth retardation
- Small cold hands and feet
- Inappropriate laughing/screaming spells
- Diminished response to pain
- Intense eye communication "eye pointing"

† Because *MECP2* mutations are now identified in some individuals prior to any clear evidence of regression, the diagnosis of "possible" RTT should be given to those individuals < 3 years of age who have not lost any skills but otherwise have clinical features suggestive of RTT. These individuals should be reassessed every 6–12 months for evidence of regression. If regression manifests, the diagnosis should then be changed to definite RTT. However, if the child does not show any evidence of regression by 5 years of age, the diagnosis of RTT should be questioned.

‡ Loss of acquired language is based on best acquired spoken language skill, not strictly on the acquisition of distinct words or higher language skills. Thus, an individual who had learned to babble but then loses this ability is considered to have a loss of acquired language.

§ There should be clear evidence (neurological or ophthalmological examination and MRI/CT) that the presumed insult directly resulted in neurological dysfunction.

¶ Grossly abnormal to the point that normal milestones (acquiring head control, swallowing, developing social smile) are not met. Mild generalized hypotonia or other previously reported subtle developmental alterations during the first six months of life are common in RTT and do not constitute an exclusionary criterion.

‖ If an individual has or ever had a clinical feature listed, it is counted as a supportive criterion. Many of these features have an age dependency, manifesting and becoming more predominant at certain ages. Therefore, the diagnosis of atypical RTT may be easier for older individuals than for younger. In the case of a younger individual (< 5 years of age) who has a period of regression and ≥ 2 main criteria but does not fulfill the requirement of 5/11 supportive criteria, the diagnosis of "probably atypical RTT" may be given. Individuals who fall into this category should be reassessed as they age, and the diagnosis revised accordingly.

Member's Last Name: **Member's First Name:**

Prescriber Signature (Required) **Date**

By signature, the Physician confirms the above information is accurate and verifiable by member records.

Please include ALL requested information; Incomplete forms will delay the PA process.

Submission of documentation does NOT guarantee coverage.

References

[i] Neul JL, Kaufmann WE, Glaze DG, et al; RettSearch Consortium. Rett syndrome: revised diagnostic criteria and nomenclature. Ann Neurol. 2010; 68(6):944-50. DOI: 10.1002/ana.22124.

[ii] Kaur S, Christodoulou MP, Christodoulou J. MECP2 Disorders. In: GeneReviews [Internet]. Updated September 19, 2019. Accessed April 11, 2023. Available at: https://www.ncbi.nlm.nih.gov/books/NBK1497/.